# APPROVED MINUTES Institutional Biosafety Committee

July 13, 2017

Check if Attending (Members):	Check if Attending (Alternate Members):
<b>∑</b> Jessica Ayers, <b>Animal expert</b>	Lon Kendall, Director LAR
Richard Bowen, Associate Chair	
Patrick Byrne, <b>Plant expert</b>	
Chaoping Chen, <b>Chair</b>	
Claudia Gentry-Weeks, Associate BSO	Robert Ellis, <b>Director of Biosafety</b>
Sam Hendrix, <b>Unaffiliated</b>	
⊠Angelo Izzo	
Matt Kipper	
⊠Gabriela Landolt	
⊠ Nicole Marlenee, <b>Lab tech rep</b>	
June Medford, Plant/syn bio expert	
Ken Olson	
Ann Powers	
Bernard Rollin, <b>Bioethicist</b>	
Non-Voting Members:	
☐ James Graham, EHS Director	
Mike Weil, Ad-hoc, Radiation Biologist	
RICRO Staff (non-voting):	Regular Guests (non-voting):
Christine Johnson, Senior IBC Coordinator	Heather Blair, Assistant Biosafety Officer
Karen Dobos, RICRO Director	Sara Cope, Assistant Biosafety Officer
Christa Johnson, Associate Vice President for	☑Joni Van Sickle, Occupational Health
Research	Coordinator/Assistant Biosafety Officer
Other: Brad Woods, RICRO Associate Director; JJ Nelson, RICRO Administrator	

This meeting was convened at 10:35am with a quorum; quorum was maintained throughout.

#### I. Review of June 14, 2017 IBC meeting minutes.

Minutes were not available for review at this time.

- II. Review of Agent and Project Request Forms (https://protocols.research.colostate.edu/rco).
  - 1. Martin, Jennifer

Agent: methycillin resistant Staphylococcus aureus – Strain: any; BSL2 in vitro

The committee unanimously approved the above agent without additional modifications.

**Project:** Competitive Inhibition of Methicillin-resistant Staphylococcus auerus using a probiotic blend (17-052B); BSL2 in vitro. NIH Guidelines category non-exempt rDNA: NA

The committee unanimously approved the above project with the following modification: Correction of spelling in the title

#### 2. Fisk, John

**Project:** Genetic code expansion of E coli through Sense Codon Reassignment (17-047B); BSL1 in vitro. NIH Guidelines category non-exempt rDNA:?

#### The committee unanimously approved the above project without additional modifications.

Upon review of this project the IBC believes this work is exempt from the NIH Guidelines.

## 3. Antunes, Mauricio

**Project:** Engineering Synthetic Production of Durable Polymers in Plants (17-49B); plant rDNA. NIH Guidelines category non-exempt rDNA: III-E-2

The committee unanimously approved the above project without additional modifications.

### 4. Jackson, Mary

**Agent:** Mycobacterium chimaera – Strain: clinical isolates; BSL2 in vitro

The committee unanimously required the following clarifications/modifications prior to approval of the above agent:

IBC requests the use of safety goggles be added to the PPE.

#### 5. Schountz, Tony

**Agent:** Betacoronavirus SK1 – Strain: any; BSL3 in vitro and BSL3 in vivo in Artibeus jamaicensis (Jamaican fruit bat)

The committee unanimously required the following clarifications/modifications prior to approval of the above agent:

- 1. The IBC requests that all individuals listed on an IBC approval be registered with the IBC database.
- 2. This virus will likely require an import permit, thus the answer to: CDC or USDA permit required? Should be changed from NO to YES.

**Project:** Experimental infection of Jamaican fruit bats with betacoronavirus SK1 (17-050B); BSL3 in vitro and BSL3 in vivo in Artibeus jamaicensis (Jamaican fruit bat). NIH Guidelines category non-exempt rDNA: NA

The committee unanimously required the following clarifications/modifications prior to approval of the above project:

Once Agent Approval is finalized, the Project can also be approved.

### [Angelo Izzo steps out; quorum remains]

## 6. Izzo, Angelo

**Project:** Efficacy of rBCG LTA-K63 and M. tuberculosis CDC1551deltamosR in the mouse model (Aeras-3) (17-054B); BSL2 and BSL3 in vitro, BSL2 and BSL3 in vivo in mice, rDNA. NIH Guidelines category non-exempt rDNA: III-D-4.

The committee unanimously approved the above project without additional modifications

[Angelo Izzo returns; quorum remains]

## Submitted after the deadline, review if time permitting

7. Gonzalez Juarrero, Mercedes

**Agent:** Mycobacterium tuberculosis – Strain: H37Ra; BSL2 in vitro **Agent:** Mycobacterium tuberculosis – Strain: H37Rv mc(2)6206; BSL2

# The committee unanimously required the following clarifications/modifications prior to approval of the above agent:

- 1. The IBC requests that all individuals listed on an IBC approval be registered with the IBC database.
- 2. The IBC suggests combining the AARF (for Mtb-H37Ra) with the AARF for Mtb- mc(2)6206 since both strains can be handled at BSL2.

## 8. Robertson, Gregory

**Project:** Extended MIC testing of TNP-2198 against a panel of H. pylori and C. difficile isogenic strains with defined drug resistance determinants (17-056B); BSL2 in vitro. NIH Guidelines category non-exempt rDNA: NA

The committee unanimously approved the above project without additional modifications.

#### III. Unfinished business

1. Stenglein, Mark (reviewed during June 14, 2017 meeting-see additional documents attached)

Project: Experimental Infection of Ticks with an Arenavirus (Tacaribe) and a Bunyavirus (South Bay) (17-043B); BSL1 in vitro and in vivo in Ixodes scapularis, and BSL2 in vitro and BSL2 in vivo in Amblyomma americanum. NIH Guidelines category non-exempt rDNA: NA

The committee unanimously approved the above project with the changes required by the committee at the last meeting.

The PI provided additional information, including the training plan, which elevated the committee's concerns.

2. **BSL1/BSL2 lab audits – policy was approved, waiting see audit form in August**No BSL audits to report. Waiting for PI's to move into new buildings – possibly September.

## 3. Changes to AARF/PARF management – update?

Waiting for completion of shibboleth for authorization to take place. Hopes of going live on September 1.

#### IV. New Business

1. **IBC Training (after the IBC Meeting)** – ABSA Webinar – Gene Editing, CRISPR, and Gene Drives: Biosafety Considerations; July 13, 2017 at 11:30am – 1:30pm (MDT)

### V. Reports.

- 1. Coordinator's report.
  - a. Next IBC meeting: August 9, 2017
  - b. Annual Biosafety and Biosecurity Training Course Fort Collins, CO July 13-20, 2017
  - c. NIH Guidelines: Honoring the Past, Charting the Future Workshop; July 18-19, 2017

## 2. Biosafety Officer's report.

- a. Incident reports
  - i. Ram card was stolen from vehicle card was deactivated and later recovered.

- ii. Protocol breach in \_\_\_\_\_ Individual went to check on pressure testing and found door open and 2 people in area where sign indicated not to enter Case is closed: miscommunication of pressure testing schedule.
- iii. Protocol breach in \_\_\_\_\_ 2 Bags were mislabeled Supervisor talked with whole group about proper procedures, matter closed.
- iv. in Golden Needle stick injury to finger, E.coli Rosetta strain Under investigation to determine reporting requirements
- v. PPE Slippage, PAPR slid off face during observation of necropsy of sheep that had been inoculated with Francisella tularensis CDC form 3 filled out, individual monitored temperature twice daily. No fever was detected, monitoring to continue 7 days post 06/29/17.
- **b. Inspections** None to report.
- c. Laboratory audit reports None to report
- d. Misc.
  - i. Dr. Ellis coordinated a one day training for Emergency Responders on June 28<sup>th</sup>. There were a lot of people involved, it went well.
  - ii. The new CSU Medical Center is now open. They will have services for workers' comp, student health, community health, and Occupational Health. working on SOPs on how to route workers comp and Occ Health to the medical center. The hope is that people will no longer need to go to Snow Mesa. The facility will also have urgent care services, however people will still need to go the ER for exposures.

# VI. Agent and Project Approval Request Forms Reviewed at Previous IBC Meeting and Approved After Modification to be read into the minutes.

1. Rao, Sangeeta

**Agent:** Escherichia coli – Strain: any; BSL2 in vitro

2. Leach, Jan

**Agent:** Xanthomonas campestris pv. Leersiae – Strain: any; BSL2 in vitro and BSL2 in vivo in rice and cut grass

3. Stenglein, Mark

**Agent:** Tacaribe virus – Strain: any; BSL2 in vitro and BSL2 in vivo in Amblyomma americanum ticks

**Agent:** South Bay virus – Strain: any; BSL1 in vitro and BSL1 in vivo in Ixodes scapularis

4. Fisher, Ellen

Agent: Staphylococcus aureus – Strain: any; BSL2 in vitro

**Agent:** Escherichia coli – Strain: any; BSL2 in vitro

**Project:** Development of Novel High Performance Soft Materials (17-045B); BSL2 in vitro. NIH Guidelines category non-exempt rDNA: NA

# VII. New or Amended Agent Approval Request Forms Reviewed and Approved by the <u>Biosafety Officer</u> or Chair to be read into the minutes.

None

# VIII. New or Amended Project Approval Request Forms Reviewed and Approved by the <u>Biosafety Officer</u> or Chair to be read into the minutes.

- 17-031 ORDWAY, D NEW DRUGS FOR NONTUBERCULOSIS MYCOBACTERIUM (NTM) LUNG DISEASE IN PATIENTS WITH CYSTIC FIBROSIS; BSL2 IN VITRO; BSL3 IN VIVO IN MICE. NIH Guidelines category non-exempt rDNA: NA
- 17-032 ORDWAY, D PROPOSAL FOR EVALUATION OF TEST ARTICLE IN AN ACUTE NONTUBERCULOSIS INFECTION MOUSE MODEL; BSL2 IN VITRO; BSL2 AND BSL3 IN VIVO IN MICE. NIH Guidelines category non-exempt rDNA: NA

- 3. 17-034 BOWEN, R NATURAL PRODUCTS ANTIVIRAL FOR CHICKUNGUNYA VIRUS INFECTION; BSL3 IN VITRO; BSL3 IN VIVO IN HAMSTERS. NIH Guidelines category non-exempt rDNA: NA
- 4. 17-038 COX-YORK, K THE ROLE OF THE GUT MICROBIOTA IN ESTROGEN METABOLISM AND DIETARY FLAX AS A POTENTIAL MODULATOR; HUMAN SAMPLES. NIH Guidelines category non-exempt rDNA: NA
- 5. 17-041 Ferris, R Evaluation of treatments for biofilm endometritis using an equine model; BSL2 IN VITRO: BSL1 IN VIVO. NIH Guidelines category non-exempt rDNA: NA
- 6. 17-042 ORDWAY, D Novel pulmonary treatments against isolated nontuberculosis pulmonary disease; BSL2 IN VITRO: BSL2 IN VIVO. NIH Guidelines category non-exempt rDNA: NA
- 7. 17-047 BOWEN, R EVALUATION OF HUMAN MONOCLONAL ANTIBODY AGAINST A RABIES VIRUS CHALLENGE; BSL2 IN VITRO; BSL2 IN VIVO IN MICE. NIH Guidelines category non-exempt rDNA: NA
- 8. 17-053 SANTANGELO, K Exploiting Toll-like receptor antogonism to treat post-traumatic osteoarthritis; HUMAN SAMPLES. NIH Guidelines category non-exempt rDNA: NA
- 9. 17-055 ORDWAY, D NONTUBERCULOSIS MYCOBACTERIAL MIN/MBC CLINICAL SCREENING; BSL2 IN VITRO. NIH Guidelines category non-exempt rDNA: NA

Meeting adjourned at 11:10am. Minutes recorded by C. Johnson

## APPROVED MINUTES

## Institutional Biosafety Committee Special Teleconference Meeting July 26, 2017

Check if Attending (Members):	Check if Attending (Alternate Members):
Jessica Ayers, Animal expert	⊠Lon Kendall, Director LAR
Donald Bade, <b>Unaffiliated</b>	
Richard Bowen, Associate Chair	
Patrick Byrne, <b>Plant expert</b>	
Chaoping Chen, <b>Chair</b>	
☐ Claudia Gentry-Weeks, Associate BSO	Robert Ellis, <b>Director of Biosafety</b>
Sam Hendrix, <b>Unaffiliated</b>	
Gabriela Landolt	
Nicole Marlenee, Lab tech rep	
June Medford, Plant/syn bio expert	
Ken Olson	
Ann Powers	
Bernard Rollin, <b>Bioethicist</b>	
Non-Voting Members:	
James Graham, EHS Director	
Mike Weil, Ad-hoc, Radiation Biologist	
RICRO Staff (non-voting):	Regular Guests (non-voting):
Christine Johnson, Senior IBC Coordinator	Heather Blair, Assistant Biosafety Officer
Karen Dobos, RICRO Director	Sara Cope, Assistant Biosafety Officer
Christa Johnson, Associate Vice President for	Joni Van Sickle, Occupational Health
Research	Coordinator/Assistant Biosafety Officer
Other:	

This meeting was convened at 2:33pm with a quorum; quorum was maintained throughout.

I. Review of Agent and Project Request Forms (https://protocols.research.colostate.edu/rco).

#### 1. Thamm, Douglas

**Agent:** Pseudomonas aeruginosa – Strain: PAO1 / Xen 41 (Perkin-Elmer); BSL2 in vitro and BSL2 in vivo in mice

The committee unanimously required the following clarifications/modifications prior to approval of the above agent:

- 1. The IBC requests that all investigators listed on the approval provide more information regarding training. This should include a brief (2-3 sentence) summary indicating biosafety trainings completed (i.e., BSL1/2 Online Training, Biosafety Cabinet Training, etc.), types of assays experienced with, and years of experience.
- 2. The IBC requests autoclave and/or incineration be added under Methods used to inactivate for disposal.

**Project:** Bone Targeted Antibiotics (17-057B); BSL2 in vitro and BSL2 in vivo in mice, rDNA. NIH Guidelines category non-exempt rDNA: III-D-4

# The committee unanimously required the following clarifications/modifications prior to approval of the above project:

- 1. The IBC requests the name and location of the imaging machine.
- 2. The IBC requests that the disinfection protocol for the imaging machine be added to the PARF.
- 3. The IBC recommends the spelling of Psuedomonous aeruginosa and Staphylococcus aureas be corrected throughout the form.

There was a brief discussion as to why this work is considered non-exempt rDNA; it is because they are putting genetically modified bacterial strains into mice.

Meeting adjourned at 2:45pm. Minutes recorded by C. Johnson

# APPROVED MINUTES Institutional Biosafety Committee

**September 13, 2017** 

Check if Attending (Members):	Check if Attending (Alternate Members):
∑Jessica Ayers, <b>Animal expert</b>	Lon Kendall, Director LAR
⊠Donald Bade, <b>Unaffiliated</b>	
Richard Bowen, <b>Associate Chair</b>	
Patrick Byrne, <b>Plant expert</b>	
Chaoping Chen, <b>Chair</b>	
Claudia Gentry-Weeks, Associate BSO	Robert Ellis, <b>Director of Biosafety</b>
Sam Hendrix, <b>Unaffiliated</b>	
⊠Angelo Izzo	
☐ Matt Kipper	
Gabriela Landolt	
Nicole Marlenee, <b>Lab tech rep</b>	
∑June Medford, <b>Plant/syn bio expert</b>	
⊠Ken Olson	
⊠Ann Powers	
Bernard Rollin, <b>Bioethicist</b>	
Non-Voting Members:	
□ James Graham, EHS Director	
Mike Weil, Ad-hoc, Radiation Biologist	
RICRO Staff (non-voting):	Regular Guests (non-voting):
Christine Johnson, Senior IBC Coordinator	Heather Blair, Assistant Biosafety Officer
Karen Dobos, RICRO Director	Sara Cope, Assistant Biosafety Officer
Christa Johnson, Associate Vice President for	☑Joni Van Sickle, Occupational Health
Research	Coordinator/Assistant Biosafety Officer
Other: Brad Woods, RICRO Associate Director; JJ Nelson, RICRO Administrator	

The meeting was convened at 12:07pm, temporarily adjourned at 12:11pm, and reconvened at 12:14pm; quorum was maintained throughout.

I. Review of June 14, 2017, July 13, 2017 and July 26, 2017 IBC meeting minutes; August 2017 meeting was cancelled.

The committee unanimously approved all three sets of minutes with no changes.

- II. Review of Agent and Project Request Forms (https://protocols.research.colostate.edu/rco).
  - 1. Weishaar, Kristen (see additional information)

**Agent:** Listeria monocytogenes – Strain: Lm-LLO-HER2/neu; BSL2 in vivo in canine **Project:** COTC026: Evaluation of a recombinant, attenuated Listeria monocytogenes expressing a chimeric human HER2/neu protein in dogs with osteosarcoma in the adjuvant setting (17-060B); BSL2 in vivo in client owned dogs. NIH Guidelines category non-exempt rDNA: III-D-4

The committee unanimously TABLED the decision to approve the above agent and project until the following has been addressed:

The PI has indicated that the agent is intended for human use and is currently in human clinical testing. The work in this proposed study is intended to support the IND held by Advaxis and could be used to

provide additional rationale for a trial in pediatric OSA. Due to the nature of this study, the IBC has requested additional information and/or documentation, specifically:

- 1. A letter of cross reference and IND summary from the sponsor with information regarding a risk assessment and/or release conditions.
- 2. Client consent form
- 3. In the Agent/Project overview the agent is referred to as ADXS31-164c, however the in article provided for reference it is ADXS31-164 (with no C at the end). Are these the same agent?
- 4. The IBC requests any available shedding data in dogs. The data could be preliminary or from research dogs.

## 2. Kading, Rebekah

**Agent:** Zika virus – Strain: any; BSL2 in vitro

**Project:** Serologic and virologic surveillance of bat and nonhuman primate samples for Zika virus in East Africa (17-059B); BSL2 in vitro. NIH Guidelines category non-exempt rDNA: NA

#### The committee unanimously approved the above agent and project without additional modifications.

There was discussion regarding the transport of samples from one location to another; all concerns were resolved within the discussion.

**Agent:** Rift Valley Fever virus – Strain: MP-12 vaccine strain; BSL2 in vitro, BSL3 in vivo in mosquitoes

## The committee unanimously approved the above agent with the following modification:

One of the investigators listed did not indicate any BSL3 training. The IBC requests confirmation that this individual will not be working in the BSL3 lab or will complete the appropriate training prior to doing so.

## [Dr. Bowen and Dr. Marlenee recuse themselves and leave the room; a quorum remains]

#### 3. Bowen, Richard

**Project:** Keim: Evaluation of Burkholderia strains for virulence in mice (17-063B); BSL3 in vitro and BSL3 in mice. NIH Guidelines category non-exempt rDNA: NA

The committee unanimously approved the above project without additional modifications.

**Project:** <u>Inactivated Brucella abortus vaccine in elk</u> (17-070B); BSL3 in vitro and BSL3 in vivo in elk. NIH Guidelines category non-exempt rDNA: NA

## The committee unanimously approved the above agent with the following clarification:

The IBC had a question regarding how the vaccine is administered, specifically how is it blown into the nostrils and oral cavity of the elk? What type of instrument is used?

**Project:** Improved Live Attenuated Brucella Vaccines to Reduce Human Disease (17-071B); BSL1 vitro, BSL1 and BSL3 in vivo in sheep and goats. NIH Guidelines category non-exempt rDNA: NA

## The committee unanimously approved the above agent with the following clarification:

- 1. Is the test vaccine (Brucella melitensis, vjbR-QS) a live modified virus or dead?
- 2. It was unclear whether or not the animals would be challenged following vaccination. The IBC request clarification, as to whether or not they will be experimentally infected following vaccination.

## [Dr. Bowen and Dr. Marlenee return – Quorum remains]

### 4. Slayden, Richard

**Agent:** Bacillus anthracis – Strain: any; BSL3 in vitro

#### The committee unanimously approved the above agents with the following modification:

The IBC requests an appropriate sporicidal chemical disinfectant be added to the methods of inactivation for disposal.

**Agent:** Bacillus cereus – Strain: any; BSL2 in vitro

### The committee unanimously approved the above agents with the following modification:

The IBC requests an appropriate chemical disinfectant be added to the methods of inactivation for disposal.

**Project:** In Vitro Screening for Antibacterial Activity (17-068B); BSL3 in vitro. NIH Guidelines category non-exempt rDNA: NA

## The committee unanimously approved the above project without additional modifications.

Once the above agents are approved, the project approval can be processed.

#### 5. Foster, Michelle

**Agent:** adeno-associated siRNA virus – Strain: N/A; BSL1 in vivo in mice

#### The committee unanimously approved the above agent with the following modifications:

- 1. If you will be using a Biosafety Cabinet, please be sure to complete the Biosafety Cabinet Training.
- 2. The IBC requires all investigators listed on an IBC approval provide a Statement of Experience.

**Project:** Mouse Model of Lipedema (17-069B); BSL2 in vivo in mice. NIH Guidelines category non-exempt rDNA: III-D-4.

## The committee unanimously approved the above project without additional modifications.

Once the associated agent is approved, the project approval can be processed.

## 6. Zabel, Mark

**Agent:** Streptococci Pneumoniae- Strain: any non-human pathogenic lab strains; BSL1 in vivo in mice

**Agent:** Escherichia coli- Strain: any non-human pathogenic lab strains; BSL1 in vivo in mice

The committee unanimously approved the above agents without additional modifications.

Agent: Salmonella- Strain: any non-human pathogenic lab strains; BSL1 in vivo in mice

## The committee unanimously approved the above agent with the following to be addressed:

- 1. The IBC requests that the PI identify the Salmonella species intended for use.
- 2. Please confirm that the Salmonella species intended for use is a Risk Group 1 agent (as stated in the AARF).
- 3. Most Salmonella species require BSL2 handling, please confirm the species intended for use can be worked with at BSL1.

**Project:** Assessing the Role of the Cellular Prion Protein in Controlling Infection (17-069B); BSL1 in vitro and BSL1 in vivo in mice. NIH Guidelines category non-exempt rDNA: NA

#### The committee unanimously approved the above project without additional modifications.

Once the associated agents are approved, the project approval can be processed.

## [12:40pm June Medford left the meeting; a quorum remains]

#### 7. Tsunoda, Susan

**Project:** Novel MicroRNA Regulator of Neuronal Excitability (17-072B); rDNA. NIH Guidelines category non-exempt rDNA: III-D-4

## The committee unanimously TABLED the decision to approve the above project until the following has been addressed:

- 1. The IBC requests that all individuals listed on an IBC approval register with the IBC database and fill out the brief personal information page, including the text box with their statement of experience.
- 2. It is unclear what is being done with the tetrodotoxin. The IBC requests a brief explaination how the toxin is being used.
- 3. The IBC requests a brief description on how the transgenic Drosophila lines are being generated.
- 4. What kind of containment procedures are in place to contain the transgenic Drosophila?
- 5. As a new IBC PI, the IBC has requested that the Biosafety Office conduct a laboratory audit of the lab space.

The IBC was also informed that this project started prior to obtaining IBC approval and will thus require an incident report to NIH/OSP.

### III. Amendments to be reviewed by full committee

## 1. Schountz, Tony (attached)

**Project:** Experimental infection of Jamaican fruit bats with MERS-CoV coronavirus (12-104B); BSL3 in vitro and BSL3 in vivo in bats, rDNA. NIH Guidelines category non-exempt rDNA: III-D-4. Amended to add genetically modified strains of the virus (rDNA section is new)

The committee unanimously approved the above project without additional modifications.

## [1 pm Brad Woods and Ann Powers left the meeting; a quorum remains]

## IV. Unfinished business

#### 1. BSL1/BSL2 Lab Audit Form

The BSO asked the IBC to review the current lab audit form – asked to send any suggestions or revisions via e-mail to the IBC Coordinator. The BSO is looking for guidance on must haves and best lab practices, and the IBC expectations in the labs. The average time it takes to perform a lab audit is 1-1 ½ hours – depending on if the PI has any questions or concerns with their lab.

A question was also brought up about whether or not lab audits done in the teaching lab (for example, biology, animal sciences, microbiology). It was acknowledged that this is area of potential risk. Three recent Salmonella outbreaks around the country have been found to have originated from teaching labs. Several members agreed that the IBC should consider looking at teaching labs, perhaps in the form of providing biosafety education.

#### 2. Changes to AARF/PARF management – update

The launch of the revised databased has been moved to October 1st.

#### V. New Business

1. Revisit policy on diagnostic research outside of a diagnostic lab

Currently, diagnostic research performed in field studies, extension sites, or otherwise outside of falls under the same category as diagnostic work performed at the and thus does not require IBC approval, biosafety training, or documentation of SOPs for things like decontamination, therefore resulting in little to no oversite of these potential biohazards. In contrast, the while not required to have IBC approval for diagnostic work, has far more controls in place for training and standard procedures due to the nature of the facility. The IBC has been asked to give their thoughts or concerns about this current policy and whether this type of diagnostic research (performed outside of a diagnostic facility) should continue to be exempt from IBC review or if it should fall under the IBC purview in some manner.

The IBC discussed this and asked for specific examples. One example given was the , which in addition to other activity, conducts research on potato pathogens. CSU is responsible for these sites and liable if any biohazards are not disposed of correctly however the IBC currently has no oversight of this facility. Other examples include wildlife studies where researchers are collecting blood or feces and testing them in their lab for certain pathogens, if they are not storing or manipulating the agent they do not need IBC approval; however samples that test positive would presumably contain the agent, how are these being disposed of. There was concern that trying to require IBC approval for all of these activities would open a Pandora's Box of sorts, that it would be difficult to identify all of these activities and to obtain compliance from the researchers. There was a suggestion that perhaps outreach/education would be more appropriate and in the spirit of creating a culture of awareness. It was suggested that a message could be sent out to the department head (who would then identify people in their departments) notifying them of the need for SOPs for decontamination and disposal of potential biohazards, with the option to request IBC review of the SOPs. The IBC agreed that a memo to the Department Heads was a good idea; a memo will be drafted and circulated for IBC comment prior to sending.

[Patrick Byrne left the meeting; a quorum remains]

#### VI. Reports.

- 1. Coordinator's report.
  - a. Next IBC meeting: October 11, 2017

[Karen Dobos left the meeting; a quorum remains]

- 2. Biosafety Officer's report.
  - a. Incident reports
    - There were several protocol breaches in the TB suites during the past couple of months, many involving mislabeling or no labeling in autoclave staging area. Individuals and PIs have been contacted and reminded of proper procedures. No exposure risk or outside reporting required.
    - ii. The BSO had been investigating a needle stick of a CSU employee with E. coli that happened at a non-CSU facility, while the researcher was on sabbatical. As recommended by OSP/NIH, an incident report was filed on 9/12/17; awaiting their response on how to proceed.
  - b. Inspections
  - c. Laboratory audit reports
  - d. Misc. Bob Ellis will be a panelist at DURC workshop hosted by NSABB September 25-26. He will be presenting at the upcoming FRaBSA symposium on September 29th at CU-Boulder. Anyone is welcome to register to attend, this will be the first symposium.

- VII. Agent and Project Approval Request Forms Reviewed at Previous IBC Meeting and Approved After Modification to be read into the minutes.
  - 1. Martin, Jennifer

**Project:** Competitive Inhibition of Methicillin-resistant Staphylococcus auerus using a probiotic blend (17-052B); BSL2 in vitro. NIH Guidelines category non-exempt rDNA: NA

- 2. Jackson, Mary
  - **Agent:** Mycobacterium chimaera Strain: clinical isolates; BSL2 in vitro
- 3. Stenglein, Mark (reviewed during June 14, 2017 meeting-see additional documents attached)

  Project: Experimental Infection of Ticks with an Arenavirus (Tacaribe) and a Bunyavirus (South Bay) (17-043B); BSL1 in vitro and in vivo in Ixodes scapularis, and BSL2 in vitro and BSL2 in vivo in Amblyomma americanum. NIH Guidelines category non-exempt rDNA: NA
- VIII. New or Amended Agent Approval Request Forms Reviewed and Approved by the <u>Biosafety Officer</u> or Chair to be read into the minutes.

None

- IX. New or Amended Project Approval Request Forms Reviewed and Approved by the <u>Biosafety Officer</u> or Chair to be read into the minutes.
  - 1. 17-044 GONZALEZ JUARRERO, M; "Host directed therapy combined with TB chemotherapy" IN VITRO BSL3: IN VIVO BSL3. NIH Guidelines category non-exempt rDNA: NA
  - 2. 17-051 MAYO, C; Dynamics of multi-host vector-borne pathogens in ruminant communities BSL2 IN VITRO: BSL2 IN VIVO FIELD SAMPLES. NIH Guidelines category non-exempt rDNA: NA
  - 3. 17-058 BOWEN, R; FEASIBILITY STUDY TO EVALUATE CORYNEBACTERIUM PSEUDOTUBERCULOSIS VACCINES CONTAINING VARIOUS ANTIGEN INPUTS AND SUBSEQUENT CHALLENGE IN HORSES BSL2 IN VITRO; BSL2 IN VITRO IN HORSES. NIH Guidelines category non-exempt rDNA: NA
  - 4. 17-061 ORDWAY, D.; NOVEL INHALABLE MEDICATIONS FOR THE TREATMENT OF NTM LUNG INFECTIONS BSL2 IN VIVO IN MICE. NIH Guidelines category non-exempt rDNA: NA
  - 5. 17-062 HENAO-TAMAYO, M; Vaccine induced memory immunity in tuberculosis BSL3 IN VITRO. NIH Guidelines category non-exempt rDNA: NA
  - 6. 17-064 BARK, D; MECHANOBIOLOGY OF PLATELETS HUMAN SAMPLES. NIH Guidelines category non-exempt rDNA: NA
  - 7. 17-065 BOWEN, R; One year duration of immunity in dogs and cats to demonstrate the efficacy of a RNA rabies vaccine BSL2 IN VITRO: BSL2 IN VIVO DOGS &CATS. NIH Guidelines category non-exempt rDNA: NA
  - 8. 17-067 BOWEN, R; Preliminary studies on host susceptibility to Mayaro virus BSL3 IN VITRO: BSL3 IN VIVO (Cattle, alpaca, hamsters, rabbits, guinea pigs, mice, chickens, sparrows, garter snakes, frogs). NIH Guidelines category non-exempt rDNA: NA

Meeting adjured at 1:46pm Minutes recorded by C. Johnson

# APPROVED MINUTES Institutional Biosafety Committee

## October 11, 2017

Check if Attending (Members):	Check if Attending (Alternate Members):
	Lon Kendall, Director LAR
⊠Donald Bade, <b>Unaffiliated</b>	
Richard Bowen, <b>Associate Chair</b>	
Patrick Byrne, <b>Plant expert</b>	
Chaoping Chen, <b>Chair</b>	
Claudia Gentry-Weeks, Associate BSO	Robert Ellis, <b>Director of Biosafety</b>
Sam Hendrix, <b>Unaffiliated</b>	
⊠Angelo Izzo	
Matt Kipper	
Gabriela Landolt	
⊠Nicole Marlenee, <b>Lab tech rep</b>	
June Medford, Plant/syn bio expert	
⊠Ken Olson	
Ann Powers	
Bernard Rollin, <b>Bioethicist</b>	
Non-Voting Members:	
☐ James Graham, EHS Director	
Mike Weil, Ad-hoc, Radiation Biologist	
RICRO Staff (non-voting):	Regular Guests (non-voting):
Christine Johnson, Senior IBC Coordinator	Heather Blair, Assistant Biosafety Officer
Karen Dobos, RICRO Director	Sara Cope, Assistant Biosafety Officer
Christa Johnson, Associate Vice President for	☑Joni Van Sickle, Occupational Health
Research	Coordinator/Assistant Biosafety Officer
Other: Brad Woods, RICRO Associate Director; JJ Nelson, RICRO Administrator	

This meeting was convened at 12:06pm, quorum was not maintained throughout.

#### I. Review of September 13, 2017 IBC meeting minutes

The minutes were not available at this time.

#### [12:10pm – Arrival of Karen Dobos]

## II. Review of Agent and Project Request Forms (https://protocols.research.colostate.edu/rco).

1. Wilusz, Jeffrey

**Agent:** ZIka virus – Strain: Any (PRVABC59 primarily); BSL2 in vitro **Project:** Pathological Implications of Repression of Cellular RNA Decay by Zika Virus (17-074B); BSL2 in vitro, rDNA. NIH Guidelines category non-exempt rDNA: III-D-3

### The committee unanimously approved the above agent with the following condition:

The IBC requests the human risk group be changed from 1 to 2.

## The committee unanimously approved the above project without additional modifications.

Once the above agent is approved, the project approval can be processed

### 2. Hamilton, Karyn

**Project:** Cell signaling for stress resistance and slowed aging (17-077B); BSL2 in vitro, human samples; rDNA. NIH Guidelines category non-exempt rDNA: III-D-3

### The committee unanimously approved the above agent with the following clarification:

- 1. Under PPE used, Facility scrubs are indicated as being used; IBC requests confirmation that this is correct.
- 2. IBC requests PI to update investigator statement

## Submitted after the deadline; review if time permitting.

## [12:26pm Dr. Bowen stepped out of the meeting, quorum is no longer maintained]

#### 3. Bowen, Richard

**Agent:** Witwatersrand-like virus – Strain: any; HRG 2

**Project:** Preparing mouse antiserum to a bunyavirus (17-080B); BSL3 in vitro and BSL3 in vivo in mice. NIH Guidelines category non-exempt rDNA: NA

Since the above AARF/PARF do not involve rDNA, the IBC agreed that remaining voting members could review the AARF/PARF and that the IBC Coordinator could e-mail other voting members to obtain enough votes for quorum and final approval.

The committee of 7 voting members unanimously approved the above agent & project without additional modifications. The IBC Coordinator will need to obtain at least one more vote (via email) for quorum.

#### [12:30pm Dr. Bowen returned to the meeting – quorum re-established]

#### III. Amendments to be reviewed by full committee

1. Sloan, Daniel (see attached)

**Project:** Analysis of cytonuclear interactions in plants with divergent mitochondrial mutation rates (13-089B); BSL1 in vitro and BSL1 in vivo in Arabidopsis thaliana, rDNA. NIH Guidelines category non-exempt rDNA: III-E-2. PARF amended to add CRISPR-cas9 approach

The committee unanimously approved the above project amendment request without additional modifications.

### IV. Unfinished business

1. Weishaar, Kristen (Tabled from September meeting)

**Agent:** Listeria monocytogenes – Strain: Lm-LLO-HER2/neu; BSL2 in vivo in canine **Project:** COTC026: Evaluation of a recombinant, attenuated Listeria monocytogenes expressing a chimeric human HER2/neu protein in dogs with osteosarcoma in the adjuvant setting (17-060B); BSL2 in vivo in client owned dogs. NIH Guidelines category non-exempt rDNA: III-D-4

The above agent and project continue to be TABLED until more information is given, specifically the IBC is still waiting on:

- 1. A letter of cross reference and IND summary from the sponsor with information regarding a risk assessment and/or patient release conditions.
- 2. Any available shedding data from dogs or humans.

The committee reviewed the attached Client Consent Form sent by the PI and felt that the risks were adequately explained to the client.

[1pm Brad Woods exits the meeting – quorum remains.]

#### 2. Tsunoda, Susan (Tabled from September meeting)

**Project:** Novel MicroRNA Regulator of Neuronal Excitability (17-072B); rDNA. NIH Guidelines category non-exempt rDNA: III-D-4

## The committee unanimously approved the above project without additional modifications.

The IBC re-reviewed the above PARF, along the additional information provided by the PI and the lab audit report provided by the BSO. The arthropod expert on the committee agreed that the containment practices were standard and appropriate for Drosophila work. There were no additional safety concerns regarding the genes being expressed. The IBC approved the PARF at BSL1, and were reminded that an incident report would be submitted regarding this project.

#### 3. BSL1/BSL2 Lab Audit Form review/PI feedback

The committee reviewed the attached lab audit form that is given to PI's to fill out before their BSL1/BSL2 lab audits. Some members felt that the open ended questions were hard to answer and may be interpreted differently depending on the person answering.

Additionally, feedback regarding the audit process will be sought from PI's who have recently been through a BSL1/BSL2 lab audit. The IBC was asked if they had specific questions they were interested in or if they wanted to leave it open and ask for general feedback. It was suggested that the IBC Coordinator draft a list of questions; a couple of items the BSO wanted to ask feedback on was if PI's felt they had enough time/opportunity to ask questions and if all their questions were answered.

When asked how the audits were going, the BSO indicated they were going well, but that training seems to be the biggest issue in the labs. The BSO also asked if there should be a date for when corrective actions should be completed – right now there is nothing in place. The committee unanimously agreed there should be follow up on critical things such as training records, not following lab practices or protocols, and that the BSO could their judgement on a reasonable timeframe; without follow up to make sure corrective actions were taken, it is not worth the time to complete.

### 4. Changes to AARF/PARF management – update

The updates to the IBC database were implemented this week. As to be expected, there have been some issues with some areas and we are working on getting everything back to working order. Some changes that were made –

- 1. AARF's no longer have to be renewed.
- 2. AARF's now have a storage only status.
- 3. PPE is now listed on the PARF instead of the AARF.

As IBC members and PIs, the committee was asked if they come across any problems in the database to let the IBC Coordinator know.

## V. New Business

No new business to review at the time.

## VI. Reports.

## 1. Coordinator's report.

- a. **2017 Biosafety Stewardship Initiative Poster Contest winner** (Research Associate from the VandeWoude Lab in the Department of Microbiology, Immunology & Pathology)**/October is "Clean out Your Freezer" month at CSU!**
- b. **National Biosafety Month -** This year's theme is "promoting biosafety through good governance." (https://www.phe.gov/s3/Documents/FESAP-guiding-principles.pdf)
- c. Next IBC meeting: November 8, 2017

### 2. Biosafety Officer's report.

- **a. Incident reports** There was a 'near miss' regarding a potential exposure with a Brucella sp.; results later confirmed it was B. ovis which is not known to infect humans and thus not an exposure concern.
- **b.** Inspections
- **c.** Laboratory audit reports— is starting the annual Select Agent lab audits again.
- **d. Misc.** The ABSA Conference starts on October 13<sup>th</sup>, several of the BSOs will be out the following week for the conference. Both Dr. Ellis and Dr. Gentry-Weeks will be giving presentations at the conference.

# VII. Agent and Project Approval Request Forms Reviewed at Previous IBC Meeting and Approved After Modification to be read into the minutes.

1. Kading, Rebekah

**Agent:** Rift Valley Fever virus – Strain: MP-12 vaccine strain; BSL2 in vitro, BSL3 in vivo in mosquitoes

2. Bowen, Richard

**Project:** <u>Inactivated Brucella abortus vaccine in elk</u> (17-070B); BSL3 in vitro and BSL3 in vivo in elk. NIH Guidelines category non-exempt rDNA: NA

**Project:** Improved Live Attenuated Brucella Vaccines to Reduce Human Disease (17-071B); BSL1 vitro, BSL1 and BSL3 in vivo in sheep and goats. NIH Guidelines category non-exempt rDNA: NA

3. Slayden, Richard

**Agent:** Bacillus anthracis – Strain: any; BSL3 in vitro

**Agent:** Bacillus cereus – Strain: any; BSL2 in vitro

**Project:** In Vitro Screening for Antibacterial Activity (17-068B); BSL3 in vitro. NIH Guidelines category non-exempt rDNA: NA

4. Foster, Michelle

Agent: adeno-associated siRNA virus – Strain: N/A; BSL1 in vivo in mice

**Project:** Mouse Model of Lipedema (17-069B); BSL2 in vivo in mice. NIH Guidelines category non-exempt rDNA: III-D-4.

5. Zabel, Mark

Agent: Salmonella- Strain: any non-human pathogenic lab strains; BSL1 in vivo in mice

**Agent:** Streptococci Pneumoniae- Strain: any non-human pathogenic lab strains; BSL1 in vivo in mice

**Project:** Assessing the Role of the Cellular Prion Protein in Controlling Infection (17-069B); BSL1 in vitro and BSL1 in vivo in mice. NIH Guidelines category non-exempt rDNA: NA

# VIII. New or Amended Agent Approval Request Forms Reviewed and Approved by the <u>Biosafety Officer</u> or Chair to be read into the minutes.

None

# IX. New or Amended Project Approval Request Forms Reviewed and Approved by the <u>Biosafety Officer</u> or Chair to be read into the minutes.

- 1. 17-073 BOWEN, RICHARD Training domestic dogs for surveillance of avian influenza; BSL2 IN VITRO: BSL 2 IN VIVO DUCKS. NIH Guidelines category non-exempt rDNA: NA
- 2. 17-075 FAW, MEARA A Dual-Process Approach to Supportive Message Processing and Creation: Physiological Correlates and Implications; HUMAN SAMPLES. NIH Guidelines category non-exempt rDNA: NA
- 3. 17-076 FAW, MEARA Improving Couples' Conflict Resolution Strategies via Mindfulness-Based Stress Reduction: A Randomized Controlled Trial; HUMAN SAMPLES. NIH Guidelines category non-exempt rDNA: NA

Meeting adjured at 1:18pm Minutes recorded by C. Johnson

# APPROVED MINUTES Institutional Biosafety Committee

## **November 8, 2017**

Check if Attending (Members):	Check if Attending (Alternate Members):
<b>∑</b> Jessica Ayers, <b>Animal expert</b>	Lon Kendall, Director LAR
Donald Bade, <b>Unaffiliated</b>	
Richard Bowen, <b>Associate Chair</b>	
Patrick Byrne, <b>Plant expert</b>	
Chaoping Chen, <b>Chair</b>	
Claudia Gentry-Weeks, <b>Associate BSO</b>	Robert Ellis, <b>Director of Biosafety</b>
Sam Hendrix, <b>Unaffiliated</b>	
⊠Angelo Izzo	
Matt Kipper	
⊠Gabriela Landolt	
Nicole Marlenee, Lab tech rep	
☑June Medford, <b>Plant/syn bio expert</b>	
⊠Ken Olson	
Ann Powers	
Bernard Rollin, <b>Bioethicist</b>	
Non-Voting Members:	
☐ James Graham, EHS Director	
Mike Weil, Ad-hoc, Radiation Biologist	
RICRO Staff (non-voting):	Regular Guests (non-voting):
Christine Johnson, Senior IBC Coordinator	Heather Blair, Assistant Biosafety Officer
Karen Dobos, RICRO Director	Sara Cope, Assistant Biosafety Officer
Christa Johnson, Associate Vice President for	☑Joni Van Sickle, Occupational Health
Research	Coordinator
Other: JJ Nelson Assistant Admin RICRO	

The meeting was convened at 12:07pm, quorum was maintained throughout.

#### I. Review of September 13, 2017 and October 11, 2017 IBC meeting minutes

The committee unanimously approved both sets of minutes with minor grammar edits.

- II. Review of Agent and Project Request Forms (https://protocols.research.colostate.edu/rco).
  - 1. Bowen, Richard

**Agent:** Powassan virus – Strain: any; human risk group 2

The committee unanimously approved the above agent without additional modifications.

This is a tick-born virus in the northeastern US; causes encephalitis.

**Project:** Pathogenesis of Powassan virus infection in groundhogs (17-081B); BSL3 in vitro and BSL3 in vivo in groundhogs. NIH Guidelines category non-exempt rDNA: NA

## The committee unanimously approved the above agent with the following clarification:

2. Under in vitro PPE both an N95 and PAPR were indicated as being used, whereas under the in vivo PPE only a PAPR was indicated; the IBC requests clarification as to which is correct.

#### 3. Peccoud, Jean

Project: <u>iVector - biologics expression optimization</u> (17-083B); BSL1 in vitro, and rDNA. NIH Guidelines category non-exempt rDNA: III-E

### The committee unanimously approved the above project with the following conditions:

- 1. The IBC requests that all individuals listed on the PARF complete the BSL1/BSL2 Online Training.
- 2. As a relatively new IBC PI, the IBC requests the biosafety officer visit/audit the lab.

#### III. Unfinished business

#### 1. Weishaar, Kristen (see additional information attached)

**Agent:** Listeria monocytogenes – Strain: Lm-LLO-HER2/neu; BSL2 in vivo in canine **Project:** COTC026: Evaluation of a recombinant, attenuated Listeria monocytogenes expressing a chimeric human HER2/neu protein in dogs with osteosarcoma in the adjuvant setting (17-060B); BSL2 in vivo in client owned dogs. NIH Guidelines category non-exempt rDNA: III-D-4

## The committee unanimously approved the above agent and project with the following conditions:

- 1. Since the agent is a live bacterium, the IBC requests confirmation that all individuals handling and administering the agent will be informed of its potential risks.
- 2. The IBC requests that all individuals who will be handling the agent complete the BSL1/BSL2 Online Training.
- 3. The IBC agrees that it is not necessary to house the dogs in isolation following administration, however they should be housed in a manner similar to the previous study at UPenn (They were kept in the oncology ward with signage placed to indicate that the dogs were treated with live Listeria) and appropriate PPE (gloves and lab coats) should be worn when in contact with the dogs. The IBC requests that the PI specify how the dogs will be housed after receiving the agent and that this information be added to the PARF.

### 2. BSL1/BSL2 Lab Audit Form review/PI feedback

The IBC Coordinator, along with the BSO and IBC Chair have drafted a list of questions for gather feedback from PIs regarding the BSL1/BSL2 lab audits. This will be sent to PIs who have recently undergone a lab audit.

## 3. Changes to AARF/PARF management – update

With the new database changes a new help guide was drafted and will be posted on the IBC website. It was recommended to draft new AARF/PARF example forms as well with the new updates.

## IV. New Business

No new business to report.

### V. Reports.

## 1. Coordinator's report.

#### a. Pre-review training check

RICRO will be conducting a more thorough training check during the pre-review process. When a new protocol is submitted, training records of the PI and Investigators listed on the PARF will be checked in the EHS training database. The required training depends on the work described in the PARF. Only the minimum training requirements will be checked, i.e. BSL1/2 Online Training, BSL1,2,3 Training, Blood-Borne Pathogen Training, etc.

# OSP Incident Report regarding transgenic Drosophila work submitted on October 19<sup>th</sup>; OSP response received on October 27<sup>th</sup>

An incident report was filed with NIH regarding the Drosophila work being conducted without IBC approval (and discussed by the IBC during the September and October meetings). NIH reported back that the IBC's actions were appropriate and that no further action is required; this incident is now considered closed.

#### c. Next IBC meeting: December 13, 2017

The next IBC meeting is scheduled for December 13<sup>th</sup>, which is during finals week. The January meeting, currently scheduled for January 10<sup>th</sup>, may need to be rescheduled as this is during winter break and quorum may be an issue.

## [Dr. Olson leaves; a quorum remains]

- 2. Biosafety Officer's report.
  - a. Incident reports
    - An incident was reported of an individual who obtained a scalpel cut and during necropsy of a TB infected animal. Appropriate action was taken by the individual; Occupational health has been in contact with them. No external reporting required.
    - ii. An incident was reported of an individual unexpectedly getting sick and having to remove N95 mask as walking into the degowning room, appropriate action was taken. No external reporting required.
  - **b. Inspections -** None to report; the last select agent renewal inspection was May 2016, next one will be in September 2019. There will likely be an unannounced inspection between now and then.
  - c. Laboratory audit reports lab audits are moving along; there have been some challenges with the new building, BSO helping to work through issues and waiting until people get settled.
  - **d. Misc.** Several of the BSO's attended ABSA and presented; it was a very good meeting.
- VI. Agent and Project Approval Request Forms Reviewed at Previous IBC Meeting and Approved After Modification to be read into the minutes.
  - 1. Wilusz, Jeffrey

**Agent:** ZIka virus – Strain: Any (PRVABC59 primarily); BSL2 in vitro **Project:** Pathological Implications of Repression of Cellular RNA Decay by Zika Virus (17-074B); BSL2 in vitro, rDNA. NIH Guidelines category non-exempt rDNA: III-D-3

2. Hamilton, Karyn

**Project:** Cell signaling for stress resistance and slowed aging (17-077B); BSL2 in vitro, human samples; rDNA. NIH Guidelines category non-exempt rDNA: III-D-3

3. Bowen, Richard

**Agent:** Witwatersrand-like virus – Strain: any; **Project:** Preparing mouse antiserum to a bunyavirus (17-080B); BSL3 in vitro and BSL3 in vivo in mice. NIH Guidelines category non-exempt rDNA: NA

- VII. New or Amended Agent Approval Request Forms Reviewed and Approved by the <u>Biosafety Officer</u> or Chair to be read into the minutes.
- VIII. New or Amended Project Approval Request Forms Reviewed and Approved by the <u>Biosafety Officer</u> or Chair to be read into the minutes.

- 1. 17-078 GENTRY-WEEKS, CLAUDIA FUSION PROTEINS FOR ANTIBACTERIAL TREATMENT; BSL2 IN VITRO. NIH Guidelines category non-exempt rDNA: NA (reviewed by IBC Chair)
- 2. 17-079 GONZALEZ JUARRERO, MERCEDES DEMONSTRATE EFFICACY FOR REPRESENTATIVE COMPOUNDS IN A LOW-BAR IN VIVO INFECTION MODEL OF MYCOBACTERIUM ABSCESSUS TOWARD REACHING A GRANT MILESTONE; IN VIVO BSL3; IN MICE. NIH Guidelines category non-exempt rDNA: NA (reviewed by BSO)
- 3. 17-082 SCHOUNTZ, TONY Generation of T cell lines from bats; IN VITRO BSL2. NIH Guidelines category non-exempt rDNA: NA (reviewed by BSO)
- 4. 17-084 BOWEN, RICHARD EVALUATION OF RABIES-MERS VACCINE CANDIDATE IN ALPACAS; BSL2 AND BSL3 IN VITRO; BSL3 IN VIVO IN ALPACAS. NIH Guidelines category non-exempt rDNA: NA (reviewed by BSO)

Meeting adjured at 1:02pm Minutes recorded by C. Johnson

# APPROVED MINUTES Institutional Biosafety Committee

December 13, 2017

Check if Attending (Members):	Check if Attending (Alternate Members):
✓ Jessica Ayers, <b>Animal expert</b>	Lon Kendall, Director LAR
☑Donald Bade, <b>Unaffiliated</b> Arrived at 12:20pm	
Richard Bowen, <b>Associate Chair</b>	
Patrick Byrne, <b>Plant expert</b>	
Chaoping Chen, <b>Chair</b>	
Claudia Gentry-Weeks, Associate BSO	Robert Ellis, <b>Director of Biosafety</b>
Sam Hendrix, <b>Unaffiliated</b>	
⊠Angelo Izzo	
Matt Kipper	
Gabriela Landolt	
⊠Nicole Marlenee, <b>Lab tech rep</b>	
June Medford, Plant/syn bio expert	
Ken Olson	
Ann Powers	
Bernard Rollin, <b>Bioethicist</b>	
Non-Voting Members:	
☐ James Graham, EHS Director	
Mike Weil, Ad-hoc, Radiation Biologist	
RICRO Staff (non-voting):	Regular Guests (non-voting):
Christine Johnson, Senior IBC Coordinator	Heather Blair, Assistant Biosafety Officer
Karen Dobos, RICRO Director	Sara Cope, Assistant Biosafety Officer
Christa Johnson, Associate Vice President for	☑Joni Van Sickle, Occupational Health
Research	Coordinator/Assistant Biosafety Officer Arrived
	at 12:15pm
Other: Brad Woods, RICRO Associate Director; JJ Nelson, RICRO Administrator	

The meeting was convened at 12:03pm, temporarily adjourned at 12:04pm, and reconvened at 12:05pm; quorum was maintained throughout. Any member with a conflict of interest left the room during discussion and/or committee determination on the conflicted item.

## I. Review of November 8, 2017 IBC meeting minutes

The committee unanimously approved last month's minutes with no changes.

## II. Review of Agent and Project Request Forms (https://protocols.research.colostate.edu/rco).

## 1. Bowen, Richard

Agent: Rabies-MERS CoV chimeric virus – Strain: any; BSL1

The PI indicated that this is an avirulent rabies virus with a MERS glycoprotein; it does not cause disease when injected intracranially into mice.

The committee unanimously approved the above agent without additional modifications.

It was noted while reviewing the above AARF that it would be helpful to have some general information about the agent in the AARF; just 1-2 sentences describing the agent, the virulence and/or what type of disease it causes. This would be particularly helpful for new/unknown agents. Dr. Bowen indicated he could add a text box for this.

#### 2. Dow, Steven

Agent: Mannheimia hemolytica - Strain: clinical isolates from

Agent: Histophilus somnus – Strain: clinical isolates; BSL2

Agent: Pasturella multocida – Strain: clinical isolates ( ); BSL2

**Project:** Non-Antibiotic Solution to Prevention of Respiratory Tract Infections in Cattle (17-87B); BSL2 in vitro. NIH Guidelines category non-exempt rDNA: NA

#### The committee unanimously approved the above agents and project with the following:

- 1. Correct the spelling of Histophilus somnus to Histophilus somni
- 2. Ensure all investigators are registered with the IBC database
- The IBC recommends the use of safety glasses/eye protection for any work conducted outside a biosafety cabinet.

These agents are typically associated with respiratory disease in cattle.

#### 3. Dean, Gregg

Agent: human immunodeficiency virus 1 – Strain: any; BSL1

#### The committee unanimously approved the above agent with the following conditions:

- 1. Minimal biosafety level should be changed from 1 to 2.
- 2. Human risk group should be changed from 1 to 3.
- 3. Largest unconcentrated volume > 10 liters? Was marked YES; IBC requests confirmation that this is correct (as this is intended for culture volumes >10 liters in a single vessel).
- 4. The IBC requests the primary storage location for the agent.

## 4. Kading, Rebekah

Agent: Chobar Gorge virus – Strain: any; BSL2

**Project:** Reassortment potential of tick-borne orbiviruses of bats (17-091B); BSL2 in vitro. NIH Guidelines category non-exempt rDNA: NA.

#### The committee unanimously approved the above agent and project without additional modifications.

This virus is from Nepal. The PI gave a nice overview of the project.

## III. Unfinished business

#### 1. BSL1/BSL2 Lab Audit Form review/PI feedback

The initial feedback from 5 PIs has been good. It was decided that the survey should be expanded to include BSL1/2 audit at Foothills and South Campus.

#### 2. Changes to AARF/PARF management - update

Single sign-on with CSU credentials is now in place as the IBC database has been updated further and is now working in Shibboleth Authentication. The database is still undergoing minor updates and fixing bugs.

### IV. New Business

No new business to report

#### V. Reports.

- 1. Coordinator's report.
  - a. Next IBC meeting: January 10 or 17?

The IBC will keep the meeting date as January 10<sup>th</sup> – the deadline for submissions is January 3<sup>rd</sup> and they are not expecting to have protocol submissions due to the Holiday seasons. The meeting will be cancelled if there are no submissions by the deadline date.

- 2. Biosafety Officer's report.
  - a. Incident reports A dog that was brought to the VTH tested positive for Yersinia pestis, and later died. The dog had undergone surgical procedures prior to the Y. pestis diagnosis, thus there is potential for exposure of those involved with the surgery, including those caring for the animal before and after, and any animals that may have had contact with the infected dog. As soon as diagnosis was made, the RO was contacted who then submitted a report to CDC; both a Form 4 (for diagnosis of a select agent) and a Form 3 (release/potential exposure) have been/will be submitted. The VTH, along with Occ Health and Larimer County Public Health, have been working to contact all individuals who may have been exposed in order to instruct them for follow up. All proper procedures and reporting has been followed. To date, two individuals showing flu-like symptoms have been hospitalized and later released, but they did not test positive for plague.
  - **b. Inspections** no outside inspections
  - c. Laboratory audit reports
- VI. Agent and Project Approval Request Forms Reviewed at Previous IBC Meeting and Approved After Modification to be read into the minutes.
  - 1. Bowen, Richard

**Project:** Pathogenesis of Powassan virus infection in groundhogs (17-081B); BSL3 in vitro and BSL3 in vivo in groundhogs. NIH Guidelines category non-exempt rDNA: NA

2. Weishaar, Kristen (see additional information attached)

**Agent:** Listeria monocytogenes – Strain: Lm-LLO-HER2/neu; BSL2 in vivo in canine **Project:** COTC026: Evaluation of a recombinant, attenuated Listeria monocytogenes expressing a chimeric human HER2/neu protein in dogs with osteosarcoma in the adjuvant setting (17-060B); BSL2 in vivo in client owned dogs. NIH Guidelines category non-exempt rDNA: III-D-4

3. Peccoud, Jean

**Project:** <u>iVector - biologics expression optimization</u> (17-083B); BSL1 in vitro, and rDNA. NIH Guidelines category non-exempt rDNA: III-E

VII. New or Amended Agent Approval Request Forms Reviewed and Approved by the <u>Biosafety Officer</u> or Chair to be read into the minutes.

None

VIII. New or Amended Project Approval Request Forms Reviewed and Approved by the <u>Biosafety Officer</u> or Chair to be read into the minutes.

Meeting adjured at 1:09pm Minutes recorded by C. Johnson

# APPROVED MINUTES Institutional Biosafety Committee

## February 14, 2018

Check if Attending (Members):	Check if Attending (Alternate Members):
<b>∑</b> Jessica Ayers, <b>Animal expert</b>	Lon Kendall, Director LAR
Richard Bowen, Associate Chair	
Patrick Byrne, <b>Plant expert</b>	
Chaoping Chen, <b>Chair</b>	
Claudia Gentry-Weeks, Associate BSO	Robert Ellis, <b>Director of Biosafety</b>
Sam Hendrix, <b>Unaffiliated</b>	
Matt Kipper	
Gabriela Landolt	
Nicole Marlenee, Lab tech rep	
∑June Medford, <b>Plant/syn bio expert</b>	
Ken Olson, Arrived 12:23pm	
Ann Powers	
Bernard Rollin, <b>Bioethicist</b>	
Non-Voting Members:	
☐ James Graham, EHS Director	
Mike Weil, Ad-hoc, Radiation Biologist	
RICRO Staff (non-voting):	Regular Guests (non-voting):
Christine Johnson, Senior IBC Coordinator	Heather Blair, Assistant Biosafety Officer
Karen Dobos, RICRO Director	Sara Cope, Assistant Biosafety Officer
Christa Johnson, Associate Vice President for	∑Joni Van Sickle, Occupational Health
Research	Coordinator/Assistant Biosafety Officer
Other: JJ Nelson, RICRO Administrator	

The meeting was convened at 12:03pm, quorum was maintained throughout. Any member with a conflict of interest left the room during discussion and/or committee determination on the conflicted item.

## I. Review of December 13, 2017 IBC meeting minutes; no IBC meeting in January

The committee unanimously approved last month's minutes with one minor edit.

## II. Review of Agent and Project Request Forms (https://protocols.research.colostate.edu/rco).

1. MacNeill, Amy

**Project:** Evaluation of pathogenesis of MYXV OrfC in rabbits (17-094B); BSL2 in vitro and BSL2 in vivo in rabbits, rDNA. NIH Guidelines category non-exempt rDNA: III-D-3 and III-D-4

## The committee unanimously approved the above project with the following conditions:

- 1. If any other investigators/researcher will be working on this project they should be added to the PARF.
- 2. The wild-type myxoma virus requires an APHIS permit for use.

#### 2. Geiss, Brian

**Project:** Mechanism of Flavivirus RNA Capping (18-002B); BSL2 in vitro, rDNA. NIH Guidelines category non-exempt rDNA: III-D-3

#### The committee unanimously approved the above project.

3. Belisle, John

**Agent:** Borrelia burgdorferi; BSL2 **Agent:** Borrelia garinii; BSL2

## The committee unanimously approved the above agents.

Causitve agents of lymes disease; typically transmitted by ticks.

4. Clay, Colin

Agent: rAAV; BSL1

## The committee unanimously approved the above agent with the following condition:

1. The IBC requests that the agent name be spelled out as: Adeno-associated virus, recombinant

**Project:** Recombinant AAV delivery to mice (18-006B); BSL2 in vitro, BSL1 in vivo in mice, rDNA. NIH Guidelines category non-exempt rDNA: III-D-4

#### The committee unanimously approved the above project.

The IBC concurred with the PI's assessment that the in vivo work can be considered BSL1 since the virus will be produced in a helper-free system. In the event that virus production changes, the BSL containment level should be reconsidered and an amendment to the PARF should be submitted

#### 5. Goodrich, Raymond

Agent: Escherichia coli – Strain: any; BSL2

**Agent:** Mycobacterium smegmatis – Strain: any; BSL2

**Agent:** Bacillus subtilis – Strain: any; BSL2

### The committee unanimously approved the above agents with the following condition:

1. The IBC requests that a chemical disinfectant be added under: Methods used to inactivate agent for disposal.

**Project:** Bacterila sterilization with LED illlumination and Riboflavin (18-007B); BSL2 in vitro. NIH Guidelines category non-exempt rDNA: NA

## The committee unanimously approved the above project with the following:

- 1. The PARF title has some spelling errors (Bacterila sterilization with LED illlumination and Riboflavin), the IBC requests the PI correct these errors.
- 2. Bacillus subtilis is listed as BSL2 on the AARF, and BSL1 on the PARF. The PARF should be changes to list B. subtilis as BSL2.
- The IBC requests the following statement be removed from the Project Overview: We have no safety concerns.

### III. Amendments to be reviewed by full committee

1. Weishaar, Kristen (see attached)

**Project:** COTC024: Defining PK and biological activity of systemic oncolytic VSV within a dose/schedule optimization study (15-089B); BSL2 in vivo in dogs, rDNA. NIH Guidelines category non-exempt rDNA: III-D-4.

Amendment request to reduce the dog isolation time from one day to six hours, based on additional shedding data in dogs. Attachment document was given to the committee.

## The committee unanimously approved the above project amendment.

#### 2. Belisle, John

**Project:** Metabolic Biomarkers and Biosignatures for Improved Diagnosis of Lyme Disease (12-023B); BSL2 in vitro, rDNA. NIH Guidelines category non-exempt rDNA: NA.

Amendment request to add Borrelia burgdorferi and B. garinii, and to add non-exempt rDNA section III-D-2. Attachment document was given to the committee.

#### The committee unanimously approved the above project amendment.

#### IV. Unfinished business

## 1. Changes to AARF/PARF management – update

A few more changes have been made to the database, these include adding a text box on the AARF for a description of the agent and adding biosafety cabinet to the PPE list on the PARF. Additionally, a couple of bugs have also been fixed.

#### V. New Business

### 1. Eye protection recommendations

Due to recent incidents (not at CSU) of splashes in the eye while working in a biosafety cabinet, Biosafety is recommending that eye protection be worn at all times in the BSL3; the current policy states that eye protection must be worn when handling animals. However, since neither of the voting Biosafety Officers were in attendance, changes to the policy were not discussed at this time.

## 2. Spring IBC Retreat – April? Topics?

The IBC had a discussion of the next IBC retreat. A doodle poll will be sent out to the members to select the best date in April. Suggestions for topics of discussion/contuining education include updates on gene drives,

## 3. FYI - Transfer of all Dennis Pierro IBC approvals over to John Wyckoff

Dennis Pierro has left CSU, his replacement John Wyckoff completed all the necessary trainings and has taken over all of Pierro's AARFs and PARF's.

## VI. Reports.

## 1. Coordinator's report.

## a. Next IBC meeting: March 14, 2018 (during Spring Break)

The IBC was informed that the next meeting is during Spring Break, as of right now the meeting will still be held this week pending protocol submissions.

#### **2. Biosafety Officer's report** (Heather Blair gave a brief update)

**a. Incident reports** There were a couple of near misses and one protocol breach, these issues have been corrected and closed. There was one splash to the eye; the individual misunderstood the requirements and was not wearing eye protection. An incident review

- meeting was conducted and additional information given. All proper reporting procedures were followed; no outside reporting required.
- **b. Inspections** CDC/USDA conducted an unannounced inspection January 30 February 2 with 8 inspectors. The emphasis was on recent amendments. It went pretty smoothly. Will receive the final report within 30 business days of the inspection.
- c. Laboratory audit reports

# VII. Agent and Project Approval Request Forms Reviewed at Previous IBC Meeting and Approved After Modification to be read into the minutes.

1. Dow, Steven

Agent: Mannheimia hemolytica – Strain: clinical isolates from DMC; BSL2

**Agent:** Histophilus somnus – Strain: clinical isolates; BSL2

Agent: Pasturella multocida – Strain: clinical isolates (DMC); BSL2

**Project:** Non-Antibiotic Solution to Prevention of Respiratory Tract Infections in Cattle (17-87B); BSL2 in vitro. NIH Guidelines category non-exempt rDNA: NA

2. Dean, Gregg

**Agent:** human immunodeficiency virus 1 – Strain: any; BSL2

# VIII. New or Amended Agent Approval Request Forms Reviewed and Approved by the <u>Biosafety Officer</u> or Chair to be read into the minutes.

None

# IX. New or Amended Project Approval Request Forms Reviewed and Approved by the <u>Biosafety Officer</u> or <u>Chair</u> to be read into the minutes.

- 17-085 ORDWAY, DIANE Proposal for in vitro minimum inhibitory concentration testing of CPZEN-45 against recent clinical nontuberculosis mycobacterial strains; BSL2 IN VITRO. NIH Guidelines category non-exempt rDNA: NA (reviewed by BSO)
- 17-086 BOWEN, RICHARD Mouse model for binge alcohol and melioidosis; BSL3 IN VITRO; BSL3 IN VIVO MICE. NIH Guidelines category non-exempt rDNA: NA (reviewed by BSO)
- 3. 17-090 ROBERTSON, GREGORY In vivo validation of TenNor dual-acting antibiotics; BSL3 IN VITRO, BSL3 IN VIVO MICE. NIH Guidelines category non-exempt rDNA: NA (reviewed by BSO)
- 4. 17-092 ROBERTSON, GREGORY Development of Novel Proteins Synthesis Inhibitors for MDR Tuberculosis; BSL3 IN VITRO, BSL3 IN VIVO MICE. NIH Guidelines category non-exempt rDNA: NA (reviewed by BSO)
- 5. 17-093 ENGLE, TERRY Minimum bactericidal concentration of regenerated copper sulfate from the used footbath evaluated for Escherichia coli; BSL1 IN VITRO. NIH Guidelines category non-exempt rDNA: NA (reviewed by BSO)
- 17-088 MARKUS, STEVEN Molecular Pathology of Motor Neuron Disease; HUMAN SAMPLES
- 7. 17-089 LENAERTS, ANNE ChristaLena-1: In vivo exploration of regimens against novel targets for M. tuberculosis; BSL3 IN VITRO, BSL3 IN VIVO MICE
- 8. 17-095 SLAYDEN, RICHARD EFFICACY EVALUATION OF NOVEL THERAPEUTICS AGAINST BIODEFENSE PATHOGENS: BSL3 IN VITRO; BSL3 IN VIVO IN MICE
- 9. 17-096 ORDWAY, DIANE COMBATTING NATURAL RESISTANCE AND PERSISTENCE IN NON-TB MYCOBACTERIAL DISEASE; BSL2 IN VIVO IN MICE
- 10. 18-001 BOWEN, RICHARD Metabolism and Inflammation Predict Pulmonary Hypertension in Cattle; BSL1 in cattle
- 11. 18-003 DOW, STEVEN In vitro assessment of ARBs and Beta Blockers on Human Monocyte Responses; HUMAN SAMPLES.

Meeting adjured at 12:48pm Minutes recorded by C. Johnson

# Approved Minutes Institutional Biosafety Committee

## March 14, 2018

Check if Attending (Members):	Check if Attending (Alternate Members):
	Lon Kendall, Director LAR
☑Donald Bade, <b>Unaffiliated</b>	
Richard Bowen, Associate Chair	
Patrick Byrne, <b>Plant expert</b>	
Chaoping Chen, <b>Chair</b>	
Claudia Gentry-Weeks, Associate BSO	Robert Ellis, <b>Director of Biosafety</b>
Sam Hendrix, <b>Unaffiliated</b>	
⊠Angelo Izzo	
Matt Kipper	
Gabriela Landolt	
Nicole Marlenee, Lab tech rep	
June Medford, Plant/syn bio expert	
Ken Olson	
Ann Powers	
Bernard Rollin, <b>Bioethicist</b>	
Non-Voting Members:	
James Graham, EHS Director	
Mike Weil, Ad-hoc, Radiation Biologist	
RICRO Staff (non-voting):	Regular Guests (non-voting):
Christine Johnson, Senior IBC Coordinator	Heather Blair, Assistant Biosafety Officer
Karen Dobos, RICRO Director	Sara Cope, Assistant Biosafety Officer
Christa Johnson, Associate Vice President for	∑Joni Van Sickle, Occupational Health
Research	Coordinator/Assistant Biosafety Officer
Other: JJ Nelson, RICRO Administrator	

Before starting the meeting, Dr. Olson was invited to speak about his newly submitted PARF which plans to utilize CRISPR-Cas9 technology to develop a gene drive in mosquitoes that is designed to significantly reduce virus transmission. They have previously identified antiviral genes that target Zika virus and plan to insert these, using CRISPR-Cas9, into the male germ line of Aedes aegypti. They will then analyze the movement of the antiviral genes from one generation to the next during mating with non-transgenic Aedes aegypti, as well as assess the resistance in the modified mosquitoes with various species and strains of arboviruses. All mosquito work will be done at ACL2 (arthropod containment level) or in BSL3 insectaries (for infected mosquitoes). Everyone in the lab has multiple years of experience working with transgenic mosquitoes and arboviruses. They have previously made a non-drive transgenic mosquito with resistance to Dengue virus; this has been stable for 50 generations and they plan to target the same region in this new project. Initial transfers are done by micro-injection into eggs; they start with a white eyed strain of A. aegypti so that white eye can be used as marker for transformation. Dr. Olson's group is collaborating with other researchers at Univ. Missouri and Univ. of Notre Dame. Some of the micro-injections may take place elsewhere, but CSU will house most of the mosquitoes; any transfer of mosquitoes will be done at the egg stage. They are currently no plans to release these transgenic mosquitoes. A similar approach has been done by others using a different mosquito species (Gantz VM, et al. (2015) Highly efficient Cas9-mediated gene drive for population modification of the malaria vector mosquito Anopheles stephensi. Proceedings of the National Academy of Sciences of the United States of America 112(49):E6736-6743.)

The IBC thanked Dr. Olson for his summary. Since the PARF was just submitted the morning of the meeting, it will undergo full review during the next IBC meeting (April 11). In the meantime, committee members were encouraged to forward additional questions for Dr. Oslon to the IBC Coordinator to facilitate addressing them prior to the next meeting.

The meeting was convened at 12:21pm. Quorum was maintained throughout. Any member with a conflict of interest left the room during discussion and/or committee determination on the conflicted item.

## I. Review of February 14, 2018 IBC meeting minutes.

The committee unanimously approved the February meeting minutes with no changes.

## II. Review of Agent and Project Request Forms (https://protocols.research.colostate.edu/rco).

1. Kading, Rebekah

Agent: Abras virus; BSL2
Agent: Marituba virus; BSL2
Agent: Oya virus; BSL2
Agent: Oriboca virus; BSL2

The committee unanimously approved the above agents.

**Agent:** Guaratuba virus; BSL3

## The committee unanimously approved the above agent with the following to be addressed:

Under Methods of inactivation for moving agents out of containment, it states: To confirm inactivation, Trizol or lysis buffer suspensions will be filtered with Amicon filters to remove cytotoxic components. The IBC requests clarification as to what is being filtered: is Trizol being filtered.

**Project:** An integrated inter-agency approach to enhancing outbreak preparedness (18-012B); BSL2 and BSL3 in vitro. NIH Guidelines category non-exempt rDNA: NA

## The committee unanimously approved the above project with the following to be addressed:

- 1. The IBC requests that all individuals listed on the PARF register with the IBC database.
- 2. It was noted that an AARF was also requested for Oriboca virus, but that it was not included in the PARF. The IBC requests clarification as to whether it should be added to the PARF.

#### 2. Bowen, Richard

**Agent:** Leishmania infantum; BSL2

Project: <u>Hamster Model for Leishmaniasis</u> (18-011B); BSL2 in vitro, BSL2 in vivo in

hamsters. NIH Guidelines category non-exempt rDNA: NA

## The committee unanimously approved the above agent and project.

**Project:** <u>VOC Analysis in Rabbits with Tularemia</u> (18-009B); BSL3 in vitro, BSL3 in vivo in rabbits. NIH Guidelines category non-exempt rDNA: NA

#### The committee unanimously requested the following prior to approval:

The IBC requested additional information regarding aerosol exposure concerns, i.e., is there a risk of tularemia being expelled in breath of the rabbits? And if so, will the breath be filtered in some way.

**Project:** <u>Validating inactivation of tissues from animals infected with select agents</u> (18-014B); BSL3 in vitro, BSL3 in vivo in mice. NIH Guidelines category non-exempt rDNA: NA

#### The committee unanimously approved the above project.

There was discussion regarding whether or not this project was needed since there is already published data on this. It was confirmed that the CDC is requiring researchers to validate these methods at their own institutions, even if is published data is available.

#### 3. Ehrhart, Nicole

**Project:** In vivo re-animation of decellularized skeletal muscle scaffold following critical muscle tissue loss (18-015B); BSL1 in vitro, BSL1 in vivo, rDNA. NIH Guidelines category non-exempt rDNA: III-E-3

The committee unanimously approved the above project.

#### Submitted after the deadline, review if time permitting

#### 4. Tamkun, Michael

Agent: Adeno-associated virus (AAV); BSL1

## The committee unanimously approved the above agent with the following to be addressed:

- 1. The IBC requests that the PI provide a bit more detail in regards to their state of experience with biohazardous agents.
- 2. The IBC requests the PI indicate the source of the agent, i.e., will it be made in house or purchased from a vendor. Is the virus made in a helper free system?

**Project:** <u>Use of recombinant AAVs in neuron/astrocyte cocultures</u> (18-018B); BSL2 in vitro. NIH Guidelines category non-exempt rDNA: NA

The committee unanimously approved the above project, once the associated AARF is approved.

## III. Amendments to be reviewed by full committee

1. MacNeill, Amy (see attached)

**Project:** Oncolytic poxvirus therapy for soft tissue sarcoma in dogs - pilot safety study (15-025B); BSL2 in vitro and BSL1 in vivo in dogs, rDNA. NIH Guidelines category non-exempt rDNA: III-D-4

Amendment request to add treatment with oral oclacinitib (an immunomodulatory) and a booster of the MYXV-serp2 injection.

The committee unanimously approved the above amendment.

#### IV. Unfinished business

#### 1. IBC Retreat

It has been decided to wait until September for the IBC retreat. In the meantime, committee members should consider what topics they would like to learn more about during the retreat; a couple of suggestions were CRISPR technology and gene drives.

### V. New Business

No new business to report.

## VI. Reports.

- 1. Coordinator's report.
  - a. Next IBC meeting: April 11, 2018

#### 2. Biosafety Officer's report.

- **a. Incident reports** while cleaning a biosafety cabinet, the room UV light can on and the individual was momentarily exposed to UV. The light has since been disabled; no further action needed.
- b. **Inspections** In regards to the CDC/USDA inspection that occurred January 30- February 2, CSU should receive the final report within the next week or so.
- c. Laboratory audit reports No report.

# VII. Agent and Project Approval Request Forms Reviewed at Previous IBC Meeting and Approved after Modification to be read into the minutes.

1. MacNeill, Amy

**Project:** Evaluation of pathogenesis of MYXV OrfC in rabbits (17-094B); BSL2 in vitro and BSL2 in vivo in rabbits, rDNA. NIH Guidelines category non-exempt rDNA: III-D-3 and III-D-4

2. Clay, Colin

**Agent:** rAAV; BSL1

**Project:** Recombinant AAV delivery to mice (18-006B); BSL2 in vitro, BSL1 in vivo in mice, rDNA. NIH Guidelines category non-exempt rDNA: III-D-4

3. Goodrich, Raymond

**Agent:** Escherichia coli – Strain: any; BSL2

**Agent:** Mycobacterium smegmatis – Strain: any; BSL2

**Agent:** Bacillus subtilis – Strain: any; BSL2

**Project:** Bacterila sterilization with LED illlumination and Riboflavin (18-007B); BSL2 in vitro. NIH Guidelines category non-exempt rDNA: NA

4. Weishaar, Kristen (amendment)

**Project:** COTC024: Defining PK and biological activity of systemic oncolytic VSV within a dose/schedule optimization study (15-089B); BSL2 in vivo in dogs, rDNA. NIH Guidelines category non-exempt rDNA: III-D-4.

Amendment request to reduce the dog isolation time from one day to six hours, based on additional shedding data in dogs.

## VIII. New or Amended Agent Approval Request Forms Reviewed and Approved by the <u>Biosafety Officer</u> or Chair to be read into the minutes.

None

# IX. New or Amended Project Approval Request Forms Reviewed and Approved by the <u>Biosafety Officer</u> or Chair to be read into the minutes.

- 1. 18-005 BURG, ALIXANNA Fuel for Fun Follow-up; BSL1; HUMAN SAMPLES. NIH Guidelines category non-exempt rDNA: NA
- 18-010 MAYO, CHRISTIE KINETICS OF BLUETONGUE VIRUS COINFECTION AND DURATION OF VIREMIA INFECTIOUS TO CULICOIDES SONORENSIS IN VIRUS-INFECTED SHEEP; BSL2 IN VITRO; BSL2 IN VIVO IN SHEEP. NIH Guidelines category non-exempt rDNA: NA
- 3. 18-013 ROBERTSON, GREGORY Lead optimization of novel azetidine...; BSL3 IN VITRO, BSL3 IN VIVO MICE. NIH Guidelines category non-exempt rDNA: NA

Meeting adjured at 12:55pm Minutes recorded by C. Johnson

# Approved Minutes Institutional Biosafety Committee

**April 11, 2018** 

Check if Attending (Members):	Check if Attending (Alternate Members):
Jessica Ayers, <b>Animal expert</b>	Lon Kendall, Director LAR
Richard Bowen, Associate Chair	
Patrick Byrne, <b>Plant expert</b>	
Chaoping Chen, <b>Chair</b>	
Claudia Gentry-Weeks, Associate BSO	Robert Ellis, <b>Director of Biosafety</b>
Sam Hendrix, <b>Unaffiliated</b>	
⊠Angelo Izzo	
Matt Kipper	
Gabriela Landolt	
Nicole Marlenee, <b>Lab tech rep</b>	
☑June Medford, <b>Plant/syn bio expert</b>	
Ken Olson, Arrived 12:17pm	
Bernard Rollin, <b>Bioethicist</b>	
Non-Voting Members:	
☐ James Graham, EHS Director	
Mike Weil, Ad-hoc, Radiation Biologist	
RICRO Staff (non-voting):	Regular Guests (non-voting):
Christine Johnson, Senior IBC Coordinator	Heather Blair, Assistant Biosafety Officer
Karen Dobos, RICRO Director	Sara Cope, Assistant Biosafety Officer
Christa Johnson, Associate Vice President for	☑Joni Van Sickle, Occupational Health
Research	Coordinator/Assistant Biosafety Officer
Other: Brad Woods, RICRO Associate Director; JJ Nelson, RICRO Administrator; Carolyn Broccardo,	
RCR Coordinator	

The meeting was convened at 12:03pm temporarily adjured 12:26pm and resumed at 12:31pm. Quorum was maintained throughout. Any member with a conflict of interest left the room during discussion and/or committee determination on the conflicted item.

## I. Review of March 14, 2018 IBC meeting minutes.

The committee unanimously approved the March meeting minutes with no changes.

## II. Review of Agent and Project Request Forms (https://protocols.research.colostate.edu/rco).

## 1. Olson, Kenneth

**Project:** Engineering resistance to Zika virus in Aedes aegypti for Cas9 driven population modification (18-019B); BSL2 and BSL3 in vitro; BSL3 in vivo in mosquitoes; rDNA/gene drive. NIH Guidelines category non-exempt rDNA: III-D-4.

## The committee unanimously approved the above project with the following clarification:

- 1. The IBC requests the additional information provided (items 1-13 that were sent in email) be added to the form.
- 2. Within the additional comments provided, item #10 appears to have a typo and states: mosquitoes are killed by initially placing at -20C for <2hrs. Confirm that this should be changed to >2hrs.

- 3. Rooms listed for in vivo use are are indicated in the narrative. The IBC requests clarification.
- 4. DENV and CHIKV are listed for used, but use is not described. The IBC requests clarification on how these agents will be used.

The comments provided by the PI cleared up all concerns. This lab has the expertise and appropriate containment to safely do this work.

## 2. Bowen, Richard

Agent: Vaccinia rabies glycoprotein vaccine – Strain: NA; BSL2

## The committee unanimously approved the above agent with the following to be addressed:

- 1. There appears to be a typo in the Agent Description. The description states: recombinant vaccinia that expresses the glycoprotein or rabies virus. Please confirm that this should be changed to: expresses the glycoprotein OF rabies virus.
- 2. The IBC request the product name be added to the description.
- 3. Vaccine used for personnel was marked YES; the IBC requests clarification whether the vaccine used is for rabies virus or for vaccinia.

**Project:** Immunizing wild bats: Proof of concept (18-026B); BSL3 in vivo and BSL3 in vivo in bats; rDNA. NIH Guidelines category non-exempt rDNA: III-D-4.

## The committee unanimously approved the above project with the following clarification:

The IBC requests clarification on the phrase "turn them loose", so that it is clearly stated that the PI intends to turn them back into the room and not loose into the wild.

**Project:** <u>Rift Valley fever virus: Experimental infection of select North American wildlife</u> (18-025B); BSL3 in vitro and BSL3 in vivo in various birds, rabbits, wild rodents, reptiles, and amphibians. NIH Guidelines category non-exempt rDNA: NA

## The committee unanimously approved the above project with the following to be addressed:

Under the list of infectious agents, ANY strain is indicated. However in the Overview of the Project, it states that 2 RVFV viruses will be used. The IBC suggests indicating the strains to be used.

#### 3. Rose, Ruth

**Project:** <u>Influence of percutaneous electrical stimulation on revascularization and reinnervation of decellularized skeletal muscle scaffold seeded with muscle derived stem cells for the treatment of volumetric muscle loss in a rodent model (18-028B); rDNA. NIH Guidelines category non-exempt rDNA: III-E-3</u>

## The committee unanimously approved the above project.

This is very similar to a project the IBC reviewed last month.

#### 4. Anthony, Russell

**Project:** Physiological Ramifications of Chorionic Somatomammotropin Deficiency (18-029B); BSL2 in vitro and BSL2 in vivo in sheep, rDNA. NIH Guidelines category non-exempt rDNA: III-D-4.

## The committee unanimously approved the above project with the following to be addressed:

The IBC requests all investigators listed on an approval to fill out a statement of experience.

### 5. Wyckoff, John

Agent: Salmonella paratyphi – Strain: S paratyphi 9150 strain (modified); BSL2

## The committee unanimously approved the above agent with the following to be addressed:

The IBC requests a statement be added to indicate that the PI is receiving the whole bacterium and not the plasmid.

**Project:** Manufacture of Bivalent-MAPS complex (consisting of Vi-MAPS and OSP-MAPS) for GLP Studies, Assay Test Method Development

## The committee unanimously approved the above project with the following to be addressed:

- 1. The IBC requests confirmation that culture volumes will be no larger than 10L in one vessel.
- 2. The Project Overview indicates: material prepared is intended for use in pre-clinical toxicology studies. The IBC requests the PI indicate where these pre-clinical studies will be taking place.

### III. Amendments to be reviewed by full committee

1. Leach, Jan

**Project:** <u>Identification of Genes That Control Biomass Production Using Rice as a Model System (08-066B); rDNA. NIH Guidelines category non-exempt rDNA: III-E-2 **Amendment request to add CRISPR/CAS9 editing techniques.**</u>

The committee unanimously approved the above amendment request.

#### IV. Unfinished business

1. IBC Retreat - September 12, 2018

The IBC retreat is tentatively set for September 12<sup>th</sup>, a poll will be sent out to IBC members if another date in September would work better for their schedules. Topics of discussion will be updates on CRISPR/CAS9 and the overall results of the Self-Assessment tool that will be used this summer to evaluate current IBC policies and procedures.

#### V. New Business

- 1. USDA Statement on Plant Breeding Innovation (https://www.usda.gov/media/press-releases/2018/03/28/secretary-perdue-issues-usda-statement-plant-breeding-innovation)
  On March 28<sup>th</sup>, US Secretary of Agriculture issued on statement regarding USDA oversight of plants produced through "innovative new breeding techniques" which include techniques called "genome editing". The statement indicated "Under its biotechnology regulations, USDA does not currently regulate, or have any plans to regulate plants that could otherwise have been developed through traditional breeding techniques as long as they are developed without the use of a plant pest as the donor or vector and they are not themselves plant pests. This can include plant varieties with the following changes:
  - **Deletions**—the change to the plant is solely a genetic deletion of any size.
  - Single base pair substitutions—the change to the plant is a single base pair substitution.
  - **Insertions from compatible plant relatives**—the change to the plant solely introduces nucleic acid sequences from a compatible relative that could otherwise cross with the recipient organism and produce viable progeny through traditional breeding.
  - **Complete Null Segregants**—off-spring of a genetically engineered plant that does not retain the change of its parent."

While the statement never mentions CRISPR, it is clearly referring to gene editing technology, such as CRISPR. It is important to note that this only applies to plants outside the lab (i.e., field studies or crops) and that this type of work in the laboratory still requires IBC approval. There was a suggestion to develop an FAQ to address these concerns and potential confusion. The IBC Coordinator will work with the plant experts on the committee to write this FAQ.

### 2. Eye protection recommendations vs. policy

There has been some confusion regarding the IBC policy on the use eye protection in the laboratory, so it was decided to formalize the policy in a written document. The current policy is based on a recommendation (in 2015) from the BSL3 Advisory Committee and requires "appropriate eye protection to be worn in the BSL3 whenever working with animals outside of the biosafety cabinet." The IBC Coordinator presented a draft policy is based on this and other recommendations. While discussing this draft, the question came up that perhaps eye protection should be required at all times in the BSL3 labs. This was discussed but not yet voted on and IBC members were asked to discuss this with their laboratory staff for feedback. This will be discussed again at the next IBC meeting.

#### 3. IBC Program Review - NIH/OSP Self-Assessment Tool

A subcommittee has been formed to complete the NIH/OSP Self-assessment Tool, this will give the IBC guidance on weaknesses/strengths of the current policies and procedures. The goal is for the subcommittee to present the results and recommendations at the IBC retreat in September.

### VI. Reports.

- 1. Coordinator's report.
  - a. Next IBC meeting: May 9, 2018

## 2. Biosafety Officer's report.

**a. Incident reports** – There was an incident where an individual cut their finger while cutting formalin fixed tissue for histology. The tissue was infected with tuberculosis, however had been fixed in formalin for 2 weeks, and the TB was presumably dead. The individual will complete baseline and follow up PPD testing. All appropriate protocols were followed; no outside reporting required.

#### **b.** Inspections

- i. CDC inspection report from Jan 30 Feb.2 CSU received the report and has 30 days to respond. There were two moderate observations, nothing major. One issue, the IDS that had been previously okay'd to leave off during business hours, they now request it to be left on.
- **ii. USDA inspection, March 24** this was in regards to the B. abortus study in elk at no departures noted.
- **c. Laboratory audit reports** currently auditing the TB groups, as a whole keeps getting better. Mostly facilities/building issues, no issues with the groups.
- **d. Misc.** BRB renovations BRB was built in 2000 and needs repairs to the floors and HVAC systems. The money is available, but not the design. This will require BRB to be shut down for a long period of time. Researchers warned that they will need at least 1.5 years notice, as there are many long term animal studies being conducted in this facility.

# VII. Agent and Project Approval Request Forms Reviewed at Previous IBC Meeting and Approved After Modification to be read into the minutes.

1. Kading, Rebekah

**Agent:** Guaratuba virus; BSL3

**Project:** An integrated inter-agency approach to enhancing outbreak preparedness (18-012B); BSL2 and BSL3 in vitro. NIH Guidelines category non-exempt rDNA: NA

2. Bowen, Richard

**Project:** <u>VOC Analysis in Rabbits with Tularemia</u> (18-009B); BSL3 in vitro, BSL3 in vivo in rabbits. NIH Guidelines category non-exempt rDNA: NA

3. Tamkun, Michael

Agent: Adeno-associated virus (AAV); BSL1

**Project:** <u>Use of recombinant AAVs in neuron/astrocyte cocultures</u> (18-018B); BSL2 in vitro. NIH Guidelines category non-exempt rDNA: NA

# VIII. New or Amended Agent Approval Request Forms Reviewed and Approved by the <u>Biosafety Officer</u> or Chair to be read into the minutes.

- 1. HUANG, XINGFENG Clostridium butyricum Strain: ATCC 19398; BSL1
- 2. HUANG, XINGFENG Saccharomyces cerevisiae Strain: JAY270; BSL1
- 3. HUANG, XINGFENG Penicillium subrubescens Strain: P2C1; BSL1
- 4. WINKELMAN, DANA Flavobacterium psychrophilum Strain: Clear Springs Food 259-93 (CSF259-93); BSL1

# IX. New or Amended Project Approval Request Forms Reviewed and Approved by the <u>Biosafety Officer</u> or Chair to be read into the minutes.

- 1. 18-021 HUANG, XINGFENG Continuous Production of Butyric Acid Using Immobilized Clostridium butyricum; BSL1 IN VITRO. NIH Guidelines category non-exempt rDNA: NA
- 2. 18-022 HUANG, XINGFENG High Productivity Conversion of Algal Biomass Hydrolysate using Immobilized Cell Technology; BSL1 IN VITRO. NIH Guidelines category non-exempt rDNA: NA
- 3. 18-023 HUANG, XINGFENG Bio-prospecting plant biomass degradation enzymes from Penicillium subrubescens; BSL1 IN VITRO. NIH Guidelines category non-exempt rDNA: NA
- 4. 18-024 SCHISSLER, JENNIFER Efficacy of a quaternary ammonium and accelerated hydrogen peroxide disinfectants and a commercial accelerated hydrogen peroxide fogger against methicillin-resistant Staphylococcus pseudintermedius on experimentally contaminated surfaces; BSL2 IN VITRO. NIH Guidelines category non-exempt rDNA: NA
- 5. 18-027 WINKELMAN, DANA Bacterial cold water disease challenge experiment; IN VIVO BSL1 IN TROUT. NIH Guidelines category non-exempt rDNA: NA

Meeting adjured at 1:19pm Minutes recorded by J. Nelson and C. Johnson

# APPROVED Minutes Institutional Biosafety Committee

# May 9, 2018

Check if Attending (Members):	Check if Attending (Alternate Members):
<b>⊠</b> Jessica Ayers, <b>Animal expert</b>	Lon Kendall, Director LAR
Donald Bade, <b>Unaffiliated</b>	
Richard Bowen, Associate Chair	
Patrick Byrne, <b>Plant expert</b> Departed at 12:48	
Chaoping Chen, <b>Chair</b>	
Claudia Gentry-Weeks, Associate BSO	Robert Ellis, <b>Director of Biosafety</b>
Sam Hendrix, <b>Unaffiliated</b>	
⊠Angelo Izzo	
Matt Kipper	
⊠Gabriela Landolt	
⊠Nicole Marlenee, <b>Lab tech rep</b>	
☑June Medford, <b>Plant/syn bio expert</b>	
Ken Olson	
Ann Powers	
Bernard Rollin, <b>Bioethicist</b>	
Non-Voting Members:	
☐ James Graham, EHS Director	
Mike Weil, Ad-hoc, Radiation Biologist	
RICRO Staff (non-voting):	Regular Guests (non-voting):
Christine Johnson, Senior IBC Coordinator	Heather Blair, Assistant Biosafety Officer
Karen Dobos, RICRO Director	Sara Cope, Assistant Biosafety Officer
Christa Johnson, Associate Vice President for	☑Joni Van Sickle, Occupational Health
Research	Coordinator/Assistant Biosafety Officer
Other: Brad Woods, RICRO Associate Director; JJ Ne	lson, RICRO Administrator

This meeting was convened at 12:04. Quorum was maintained throughout. Any member with a conflict of interest left the room during discussion and/or committee determination on the conflicted item.

# I. Review of April 11, 2018 IBC meeting minutes.

The committee unanimously approved the March meeting minutes with no changes.

- II. Review of Agent and Project Request Forms (https://protocols.research.colostate.edu/rco).
  - 1. Bowen, Richard

Agent: Monkeypox virus – Strain: West African clade viruses; BSL3

The committee unanimously approved the above project with the following to address:

The IBC requested the storage location be indicate.

**Agent:** Brucella abortus, RB51 mutants – Strain: any; BSL1

The committee unanimously approved the above project with the following to address:

Under the Agent Description, the IBC recommends auxotropic be changed to auxotrophic.

**Project:** Goat brucellosis vaccine: Evaluation of immunogenicity and efficacy (18-033B); BSL3 in vitro and BSL3 in vivo in goats, rDNA. NIH Guidelines category non-exempt rDNA: III-D-4.

The committee unanimously approved the above project.

**Agent:** Brucella canis – Strain: any; BSL2

The committee unanimously approved the above agent.

**Project:** Canine brucellosis: Pilot immunization project (18-034B); BSL3 in vitro and BSL3 in vivo in dogs. NIH Guidelines category non-exempt rDNA: NA

The committee unanimously approved the above project.

**Project:** Swine brucellosis: Pathogenesis and Immune Responses (18-032B); BSL3 in vitro and BSL3 in vivo in swine. NIH Guidelines category non-exempt rDNA: NA

The committee unanimously approved the above project.

**Project:** <u>Adaption of avian influenza virus to peridomestic birds</u> (18-036B); BSL3 in vitro and BSL3 in vivo in various birds. NIH Guidelines category non-exempt rDNA: NA

The committee unanimously approved the above project.

# 2. Yang, Hua

**Project:** Construct a phage-mediated system to deliver CRISPR/Cas9 antimicrobials for sequence-specific elimination of foodborne pathogens in beef production (18-035B); BSL2 in vitro, rDNA. NIH Guidelines category non-exempt rDNA: III-D-2.

This project involves packaging CRISPR in phage, using the phage to infect E. coli and remove the toxin gene. The IBC discussed the how this project may be a phage version of gene drive, some members were concerned with the possibility of it getting out of the lab and spreading. It was determined M13 strain is a classic phage that doesn't integrate and is unreliable, this strain could not be used as a drive without the aid of a helper virus.

## The committee unanimously approved the above project with the following conditions:

- 1. The IBC requires individuals using biological safety cabinets to complete the Biological Safety Cabinet Training.
- 2. The IBC requests that the PI consult with the Biosafety Office to ensure all safety practices are in place. will follow up.

# Submitted after the deadline, review if time permitting

# 3. Myers, Brent

**Project:** Imaging stress and the social brain (18-037B); BSL1 in vivo in rats, rDNA. NIH Guidelines category non-exempt rDNA: III-E-1.

# The committee unanimously approved the above project with the following clarifications:

- 1. The IBC requires all individuals listed on an IBC approval be registered with the IBC database. Please confirm the eID spelling and/or instruct these individuals to register with the IBC Online Database.
- 2. The source of the recombinant material is indicated as academic/non-profit cores. The IBC requests confirmation as to whether the PI will be receiving enough rAAV for the rat injections or if they will need to grow it up in the lab.

## III. Amendments to be reviewed by full committee

#### 1. Peers, Graham

**Project:** Investigating and manipulating photosynthetic efficiency in algae and cyanobacteria (13-039B); rDNA. NIH Guidelines category non-exempt rDNA: III-D-5 **Amendment request to add CRISPR/CAS9 techniques for mutagenesis (targeted gene knockouts).** 

**Project:** Optimization of Energy Flow through Synthetic Metabolic Modules and Regulatory Networks in a Model Photosynthetic Eukaryotic Microbe (13-040B); rDNA. NIH Guidelines category non-exempt rDNA: III-D-5

Amendment request to add Additional mutagenesis techniques involving the use of CRISPR-Cas9 and transformation with synthetic episomes (shuttle vectors) that are specific for E.coli and Phaeodactylum.

The committee unanimously approved both project amendment requests with the following modifications: The IBC requests that the mode of delivery of the CRISPR construct be stated. In the original application its stated transformation via biolistics, or electroporation, or natural competency. It is unclear if the same delivery methods would be used for CRISPR.

#### IV. Unfinished business

## 1. Laboratory Eye Protection Policy draft

Members reviewed the draft reversion of the Eye Protection Policy, this draft spells out the current policy of recommending eye protection in BSL2 & 3, and under certain circumstances it is required in BSL 3. At the last discussion members were asking why it couldn't just be required to wear at all times in BSL2 & 3 labs, PI's were asked to speak with their lab staff on their thoughts of requiring eye protection, this question was also asked to the BSL 3 advisory committee. The consensus among PIs and laboratory staff was that requiring eye protection at all times would be cumbersome and could hinder certain tasks to be completed; it was suggested that highly recommending eye protection while working in the BSL2 and BSL3, and requiring eye protection under the certain circumstances as outlined in the policy document would be best. This is consistent with current policy/practice and puts it in writing. There were some committee members who still felt it should be required for all BSL 2 & 3 work. It was indicated by others that the written policy is intended to be a first step, and that the next step would involve educating people on how to conduct a risk assessment so that they know when and understand why they should be wearing eye protection. After further discussion, everyone agreed that there was a need for the policy and that it was a good first step. There was a question regarding the CSU Biosafety Policy and Manual and whether or not PPE is indicated. The policy does not address PPE, but the manual does. It was suggested that perhaps instead of a standalone eye protection policy. It was agreed that the CSU Biosafety manual should be updated to reflect the Eye Protection Policy. The IBC voted and approved the language from the eye protection policy document be put into the Biosafety Manual, thus eliminating the need for a stand-alone policy.

# 2. IBC Retreat - September 21, 2018

The IBC retreat will be on September 21, 2018, the location is still pending and will be announced when decided. The University house on Remington was suggested and will contacted to see if they are available.

## V. New Business

# 1. Gene Editing FAQ

The IBC reviewed the draft version of Gene Editing FAQ. This version didn't include any plant related information; this will be a separate document and will be reviewed by plant experts ( ) and sent out at a later date for further review by the IBC. This current document will provide further education for personnel at CSU who may not realize they require IBC approval, it will be posted on the IBC webpage and aid in additional compliance for the University.

# VI. Reports.

#### 1. Coordinator's report.

# a. Next IBC meeting: June 13, 2018

Due to the summer months members were asked if they would be able to attend the next meeting in June. A few members have already stated they will not be able to attend, the meeting will either be rescheduled or cancelled pending AARF and PARF submissions needing to be reviewed by the full committee.

# 2. Biosafety Officer's report.

# a. Incident reports

Incident report was given to the IBC for review, items listed were; there was a bad batch of autoclave tape, it was corrected and has been disposed of. An individual was poorly trained and left a BSL messy of animal feces and urine, this individual has now been trained properly. There was a protocol breach as there was gum found in the trash of the degowning room, the lab was given a training on how this is not safe. An individual accidently locked their keycard in a room and couldn't access phone or egress without a keycard. This personnel followed the fire alarm SOP and was able to exit and call a lab mate. The BSO is requesting support of adding a phone to the hallways of BSL3 buildings to prevent future occurrences, the chair will draft a letter of support for this request.

### b. Inspections

BSO sent reply to the CDC in regards to their inspection.

**c.** Laboratory audit reports – None to report this month.

# VII. Agent and Project Approval Request Forms Reviewed at Previous IBC Meeting and Approved after Modification to be read into the minutes.

1. Olson, Kenneth

**Project:** Engineering resistance to Zika virus in Aedes aegypti for Cas9 driven population modification (18-019B); BSL2 and BSL3 in vitro; BSL3 in vivo in mosquitoes; rDNA/gene drive. NIH Guidelines category non-exempt rDNA: III-D-4.

2. Bowen, Richard

Agent: Vaccinia rabies glycoprotein vaccine – Strain: NA; BSL2

**Project:** Immunizing wild bats: Proof of concept (18-026B); BSL3 in vitro and BSL3 in vivo in bats; rDNA. NIH Guidelines category non-exempt rDNA: III-D-4.

**Project:** Rift Valley fever virus: Experimental infection of select North American wildlife (18-025B); BSL3 in vitro and BSL3 in vivo in various birds, rabbits, wild rodents, reptiles, and amphibians. NIH Guidelines category non-exempt rDNA: NA

3. Anthony, Russell

**Project:** Physiological Ramifications of Chorionic Somatomammotropin Deficiency (18-029B); BSL2 in vitro and BSL2 in vivo in sheep, rDNA. NIH Guidelines category non-exempt rDNA: III-D-4

# VIII. New or Amended Agent Approval Request Forms Reviewed and Approved by the <u>Biosafety Officer</u> or Chair to be read into the minutes.

None

# IX. New or Amended Project Approval Request Forms Reviewed and Approved by the <u>Biosafety Officer</u> or <u>Chair</u> to be read into the minutes.

None

Meeting adjured at 1:19pm

# Approved Minutes Institutional Biosafety Committee

# June 6, 2018

Check if Attending (Members):	Check if Attending (Alternate Members):
<b>⊠</b> Jessica Ayers, <b>Animal expert</b>	Lon Kendall, Director LAR
Richard Bowen, <b>Associate Chair</b>	
Patrick Byrne, <b>Plant expert</b>	
Chaoping Chen, <b>Chair</b>	
Claudia Gentry-Weeks, Associate BSO	Robert Ellis, <b>Director of Biosafety</b>
Sam Hendrix, <b>Unaffiliated</b>	
Angelo Izzo	
Matt Kipper	
Gabriela Landolt	
Nicole Marlenee, Lab tech rep	
June Medford, <b>Plant/syn bio expert</b>	
Ken Olson	
Ann Powers	
Bernard Rollin, <b>Bioethicist</b>	
Non-Voting Members:	
James Graham, EHS Director	
Mike Weil, Ad-hoc, Radiation Biologist	
RICRO Staff (non-voting):	Regular Guests (non-voting):
Christine Johnson, Senior IBC Coordinator	Heather Blair, Assistant Biosafety Officer
Karen Dobos, RICRO Director	Sara Cope, Assistant Biosafety Officer
Christa Johnson, Associate Vice President for Joni Van Sickle, Occupational Health	
Research	Coordinator/Assistant Biosafety Officer
Other: Claire Calhoun, Assistant Facility Security Off	icer; JJ Nelson, RICRO Administrator

This meeting was convened at 12:02pm. Quorum was maintained throughout. Any member with a conflict of interest left the room during discussion and/or committee determination on the conflicted item.

# I. Review of May 9, 2018 IBC meeting minutes.

The committee unanimously approved the May meeting minutes with no changes.

- II. Review of Agent and Project Request Forms (https://protocols.research.colostate.edu/rco).
  - 1. Gentry-Weeks, Claudia

Agent: Staphylococcus carnosus – Strain: Any; BSL1

The committee unanimously approved of the above agent with the following clarification;

1. Please clarify the storage location of this agent.

**Project:** <u>iGEM project: A Sentinel Bacteria-Phage System for Sensing and Destruction of Target Bacteria</u> (18-039B); BSL2 in vitro, rDNA. NIH Guidelines category non-exempt rDNA: III-D-1

The committee unanimously approved of the above project with the following condition;

1. The IBC requests that the statement: there are no safety concerns, be removed from the PARF.

#### 2. Akkina, Ramesh

**Project:** Safety and efficacy evaluation of shRNAs in humanized mice (18-040B); BSL2 in vitro and BSL2 in vivo in mice, rDNA. NIH Guidelines category non-exempt rDNA: III-D-4

#### The committee unanimously approved of the above project with the following request;

1. The IBC requests information regarding shedding of the lentiviral vector. Specifically, is it known to shed and be present in the bedding of the animals? The IBC asks the PI to make a recommendation for disposal of bedding.

This PARF brought up a side conversation, regarding the disposal of bedding from animals exposed to recombinant/synthetic nucleic acid molecules (rsNA). All BSL3 bedding is autoclaved, but this is not standard practice for BSL1 or BSL2. LAR needs to be notified when animals are exposed to rsNA (same as infectious agents) and need to know if there are any special handling or disposal requires. It was suggested that a question could be added to the PARF to help identify these; LAR Associate Director and BSO will work on drafting a question and bring to IBC.

### 3. Bowen, Richard

**Project:** Emory efficacy of EEID-2801 against VEE virus infection (18-042B); BSL3 in vitro and BSL3 in vivo in mice. NIH Guidelines category non-exempt rDNA: N/A **Project:** Reptiles and Amphibians as Reservoir and Overwintering Hosts for Arboviruses (18-044B); BSL3 in vitro and BSL3 in vivo in Frog, Snake, Iguana, Toad. NIH Guidelines category non-exempt rDNA: N/A

The above projects were reviewed and approved by a Biosafety Officer after the meeting.

### 4. Hoerndli, Frederic

**Project:** <u>In Vivo investigation of AMPAR transport in synaptic plasticity and maintenance</u> (18-043B); BSL1 in Vivo C.elegans. NIH Guidelines category non-exempt rDNA: III-D-4

## The committee unanimously approved of the above project with the following conditions;

- 1. The IBC requires all individuals listed on an IBC approval be registered with the IBC database and provide a brief statement of experience.
- 2. Please ensure all personnel is up to date on their online training for the following; Risk Assessment, BSL 1 & 2 Lab Online lab training, Respiratory fit testing.
- 3. From the Methods of containment? question; Please clarify what a paper mask is.

### 5. Clay, Colin

**Project:** Delivering transgenes to sheep spermatogonial stem cells (18-045B); BSL2 in vitro and BSL2 in vivo in sheep, rDNA. NIH Guidelines category non-exempt rDNA: III-D-1

#### The committee unanimously approved of the above project with the following conditions;

- 1. There appears to be a discrepancy in the size of the rams to be used. The weight of the animal stated in the variability of PPE section as 100 kg, however it is outlined in the overview pre-pubertal rams will be injected with lentivirus. Please clarify if this was a typo.
- 2. In previous studies using ewes, it was required for all transgenic reproductive materials to be removed and incinerated prior to disposal in the landfill. Please confirm that testes that have been injected with lentivirus will be incinerated or otherwise inactivated prior to disposal, and that there will be no remaining lentivirus in the animals prior to entering the landfill.
- 3. Please ensure all personnel is up to date on their online BSL 1 & 2 Online Training.

#### 6. Dean, Gregg

**Agent:** Murine rotavirus – Strain: Any; BSL2

The committee unanimously approved the above agent as submitted.

**Project:** Novel recombinant Rotavirus vaccine utilizing the probiotic microorganism Lactobacillus acidophilus (18-046B); BSL2 in vitro and BSL2 in vivo in mice, rDNA. NIH Guidelines category non-exempt rDNA: III-D-2

## The committee unanimously approved of the above project with the following conditions;

- 1. The IBC recommends the use of Safety glasses or goggles for the PPE listed in vivo.
- 2. Booties were indicated for use for in vivo PPE, please confirm if this is correct.
- 3. Rotavirus is highly contagious in mice and will need to be in a quarantine prior to the rotavirus challenge. Please consult and coordinate with LAR Staff; lar animal care group@colostate.edu

### III. Amendments to be reviewed by full committee

None

#### IV. Unfinished business

None

#### V.New Business

#### 1. Export Control presentation

The IBC had a guest speaker from the Export Control, some key points she discussed were the following;

- What are Export Controls?
  - o They are a set of regulations that limit exporting information, technology, and physical items that might threaten the national security.
- There are different levels of control pending on the type of concern or issues these items may cause.
- There are a numerous amount of agencies that regulate different portions of export control, the main agency that has the most authority is the Department of State, and they release the Munitions List.
  - The Department of Commerce is next in line, they regulate Dual Use items that could be used for military and non-military use.
  - The Federal Select Agent Program oversees the possession, use, and transfer of biological select agents and toxins, which have the potential to pose a severe threat to public, animal, or plant health, or to animal or plant products
  - The U.S. Department of Commerce, Bureau of Industry and Security (BIS) regulates dual use articles and technology, including certain biologicals

### VI. Reports.

## 1. Coordinator's report.

## a. Next IBC meeting: July 11, 2018

The next IBC meeting will be July 11<sup>th</sup>. As a reminder the IBC coordinator will be out of the office June 15<sup>th</sup> – July 10<sup>th</sup>.

# 2. Biosafety Officer's report.

## a. Incident reports

Incident report was given to the IBC for review, items listed were;

- A cart fell into dip of the floor drain, this resulted in bruising the lab personnel's arm. Items were chemically deconned before the fall and no open wounds were present. Considered a near miss.
- LAR staff member was completing mice checks and noticed dates of inoculation were written incorrectly. This staff member showered out, just in case, upon exiting and did not open any of the cages. Researcher was applicated and will ensure they write the correct date on cages. Considered a near miss.
- Personnel did not follow BSL3 visitor policy and escorted a visitor without documentation, training, or tests prior to entering BSL3 space. Supervisor will inform Biosafety of results and actions taken with their group. Considered a protocol breach; no additional reporting required.

- Potential BBP exposure from a needle stick. Currently working with Occ. Health and will keep the Biosafety updated; no additional reporting required.
- Potential exposure after a visiting personnel was completing a necropsy accidently poked themselves
  with their knife. Occ. Health from CSU is working with individual and have notified their institution. The
  Biosafety will be kept up to date. CDC was contacted and a form three is being submitted.

#### b. Inspections

No new news to report at this time.

#### c. Laboratory audit reports

No new audit reports to review at this time. The BSO would like to report the clean-up of "unknowns" in the BSL3 labs were going well. They have been able to clean up and properly dispose of items left unlabeled. These are chemical unknowns, not biological.

# VII. Agent and Project Approval Request Forms Reviewed at Previous IBC Meeting and Approved After Modification to be read into the minutes.

1. Bowen, Richard

**Agent:** Monkeypox virus – Strain: West African clade viruses; BSL3

**Agent:** Brucella abortus, RB51 mutants – Strain: any; BSL1

2. Yang, Hua

**Project:** Construct a phage-mediated system to deliver CRISPR/Cas9 antimicrobials for sequence-specific elimination of foodborne pathogens in beef production (18-035B); BSL2 in vitro, rDNA. NIH Guidelines category non-exempt rDNA: III-D-2.

3. Myers, Brent

**Project:** Imaging stress and the social brain (18-037B); BSL1 in vivo in rats, rDNA. NIH Guidelines category non-exempt rDNA: III-E-1.

4. Peers, Graham

Project: Investigating and manipulating photosynthetic efficiency in algae and cyanobacteria (13-039B); rDNA. NIH Guidelines category non-exempt rDNA: III-D-5

Project: Optimization of Energy Flow through Synthetic Metabolic Modules and Regulatory Networks in a Model Photosynthetic Eukaryotic Microbe (13-040B); rDNA. NIH Guidelines category non-exempt rDNA: III-D-5

VIII. New or Amended Agent Approval Request Forms Reviewed and Approved by the <u>Biosafety Officer</u> or Chair to be read into the minutes.

None

- IX. New or Amended Project Approval Request Forms Reviewed and Approved by the <u>Biosafety Officer</u> or <u>Chair</u> to be read into the minutes.
  - 1. Ordway, Diane

**Project:** Aerosol Delivery of CPZEN-45 for Treatment of non-tuberculous mycobacterial (NTMs) (18-031B); BSL2 in vitro and BSL2 in vivo in mice. NIH Guidelines category non-exempt rDNA: N/A

2. Bowen, Richard

**Project:** Pandemic Influenza: Protection Studies with the GreFluSha6 (18-038B); BSL3 in vitro and BSL3 in vivo in mice. NIH Guidelines category non-exempt rDNA: N/A

3. Ordway, Diane

**Project:** Novel Mycobacterial Diagnostic Methods (18-041B); BSL3 in vitro. NIH Guidelines category non-exempt rDNA: N/A

Meeting adjured: 12:46pm

# APPROVED MINUTES Institutional Biosafety Committee

July 11, 2018

Check if Attending (Members):	Check if Attending (Alternate Members):
	Lon Kendall, Director LAR
Donald Bade, <b>Unaffiliated</b>	
Heather Blair, Assistant Biosafety Officer	Robert Ellis, <b>Director of Biosafety</b>
Richard Bowen, <b>Associate Chair</b>	
Patrick Byrne, <b>Plant expert</b>	
Chaoping Chen, <b>Chair</b>	
Sam Hendrix, <b>Unaffiliated</b>	
Angelo Izzo	
Nicole Marlenee, Lab tech rep	
☑June Medford, <b>Plant/syn bio expert,</b> Departed	
1:11pm	
Ken Olson	
Ann Powers	
Bernard Rollin, <b>Bioethicist</b>	
Non-Voting Members:	
James Graham, EHS Director	
Mike Weil, Ad-hoc, Radiation Biologist	
RICRO Staff (non-voting):	Regular Guests (non-voting):
Christine Johnson, Senior IBC Coordinator	Claudia Gentry-Weeks, Associate BSO
Karen Dobos, RICRO Director	Sara Cope, Assistant Biosafety Officer
Christa Johnson, Associate Vice President for	☑ Joni Van Sickle, Occupational Health
Research	Coordinator/Assistant Biosafety Officer
Other: Brad Woods, RICRO Associate Director	

This meeting was convened at 12:00pm, temporarily adjourned and resumed at 12:06pm. Quorum was maintained throughout. Any member with a conflict of interest left the room during discussion and/or committee determination on the conflicted item.

## I. Review of June 6, 2018 IBC meeting minutes.

The committee unanimously approved the June meeting minutes with a minor typo correction.

II. Review of Agent and Project Request Forms (https://protocols.research.colostate.edu/rco).

1. Gentry-Weeks, Claudia

Agent: Enterococcus cecorum – Strain: Any; BSL 2

The committee unanimously approved of the above agent with the following request;

1. The IBC requests that a chemical disinfectant be added to the Methods of Inactivation.

2. Borlee, Brad

Agent: Burkholderia cenocepacia – Strain: Any; BSL 2

The committee unanimously approved of the above agent with the following request;

1. The IBC requests that a chemical disinfectant be added to the Methods of Inactivation.

#### 3. Crick, Dean

Agent: Mycobacterium smegmatis - Strain: Any; BSL 2

## The committee unanimously approved of the above agent with the following requests;

- 1. Under the Agent Description the AARF states: M. smegmatis is generally considered a non-pathogenic microorganism. The IBC requests the word "generally" be removed.
- 2. Under Methods used to inactivate agent for disposal, the IBC requests clarification as to how the agent is inactivated with heat (i.e., temperature and time).
- 3. The IBC requests that the PI's statement of experience be updated. The statement currently indicates that the PI has "Worked with Mycobacterium tuberculosis for approximately 7 years." To avoid needing to update frequently, it is recommended to state "Worked with Mycobacterium tuberculosis since (year)." Also, it would be helpful for the PI to include a brief summary of the types of agents and environment (i.e. BL2, BL3) they have experience with.

**Agent:** Mycobacterium tuberculosis, avirulent – Strain: H37Ra, mc26020, mc26030, mc27000, mc26230, mc26206; BSL 2

## The committee unanimously approved of the above agent with the following request;

1. The IBC requests that the Human risk category be changed from 1 to 2.

## 4. Pearce, Stephen

Agent: Agrobacterium tumefaciens - Strains: AGL1, EHA105, GV3101; BSL1

# The committee unanimously determined that an AARF is not required for this agent:

Since these are all "disarmed" strains of A. tumefaciens, an AARF is not required and therefore these forms will be withdrawn. IF the PI should switch to using pathogenic strains of A. tumefaciens in the future, an AARF would be required at that time.

**Project:** Optimization of Winter Wheat (Triticum aestivum) Transformation (18-054B); rDNA/transgenic plants. NIH Guidelines category non-exempt rDNA: III-E-2

The committee unanimously tabled of the above project until more information is provided. Specifically, the IBC requests:

As a new PI to the IBC system, the IBC requests that the PI meet with the IBC Plant Expert ) and IBC Biosafety Officer (), to ensure all appropriate containment practices are in place.

The main concern is containment of transgenic wheat plants because wheat is a CO crop. The investigator will need to ensure that all tissue culture work is autoclaved, spills inactivated, and once in the greenhouse will need to make sure all bug screens are in good shape (and checked periodically). will discuss these things with the PI.

#### 5. Bowen, Richard

Agent: Chimpanzee adenovirus vectors, replication defective – Strain: Any; BSL 2 The committee unanimously approved of the above agent as submitted.

**Project:** <u>Transmission of LPAIV between snow geese and chickens</u> (18-053B); BSL3 in vitro and BSL3 in vivo Geese and Chickens. NIH Guidelines category non-exempt rDNA: N/A

The committee unanimously approved of the above project as submitted.

**Project:** <u>VEE virus vaccine:</u> <u>USAMRIID</u> (18-055B); BSL3 in vitro and BSL3 in vivo Mice. NIH Guidelines category non-exempt rDNA: N/A

## The committee unanimously approved of the above project with the following conditions;

1. This is a DNA vaccine which uses a plasmid; the IBC requests rDNA section of the PARF be filled out.

2. Under in vitro use, the room location is indicated as location is correct.

**Project:** Ferret Models for the Evaluation of Influenza Vaccines and Vaccination Strategies (18-056B); BSL3 in vitro and BSL3 in vivo ferrets. NIH Guidelines category nonexempt rDNA: N/A

## The committee unanimously approved of the above project with the following conditions;

- 1. The IBC requests answers to the following questions under in vivo BSL; Species exposed to the agent, Routes of exposure to the agent, Building(s) where agent will be used, Rooms where agent will be used (or TBA)
- 2. The IBC requests that the locations of work be separated for HPAIV and Influenza A non-select agent, i.e., please specify which virus will be used in which location.

## III. Amendments to be reviewed by full committee

#### 1. Borlee, Brad

**Project:** <u>Inhibition of biofilm formation by chemical and biological treatment</u> (13-101B); BSL2 in vitro. NIH Guidelines category non-exempt rDNA: N/A

## Amendment request: add Burkholderia Cenocepacia

The committee unanimously approved of the above project amendment once agent has been approved.

#### 2. Weishaar, Kristen

**Project:** COTC024: Defining PK and biological activity of systemic oncolytic VSV within a dose/schedule optimization study (15-089B); BSL2 in vivo: canines. NIH Guidelines category non-exempt rDNA: III-D-4.

# Amendment request: to reduce isolation time from 24 hours to 6 hours.

### The committee unanimously disapproved of the above project amendment request.

The IBC reviewed the above amendment request to reduce the isolation time of the dogs following administration with the human construct. The data provided indicates that infectious virus is detectable up to 6 hours post treatment, but not detected at 24 hours post treatment. But since there were no time points in between, the IBC does feel comfortable releasing the dogs at 6 hrs post treatment, and therefore the IBC requests that the dogs remain in isolation for a minimum of 24 hours post treatment. Should additional data become available, the IBC would re-review this request.

# 3. Bowen, Richard

**Project:** Development of a T Cell-Based Vaccine for Q Fever (14-069B); BSL3 in vitro and BSL3 in vivo in mice and guinea pigs. NIH Guidelines category non-exempt rDNA: III-D-2.

# Amendment request: to immunize mice using a chimpanzee adenovirus vector that expresses a concatemer of Coxiella peptides (see attached)

## The committee unanimously approved of the above project amendment.

It was discussed and confirmed the vaccine does not fall under select agent regulations because they are producing peptides.

## IV. Unfinished business

None

## V.New Business

# 1. Review of IBC policy updates

None to review at this time, will have ready at the next meeting.

## 2. PARF update: Bedding/Cage Handling

LAR staff is having concerns and questions about proper animal bedding disposal of BSL2 projects. LAR is asking for additional questions to be added to PARFs to provide guidance for animal handling and waste. It has been

requested to add a question regarding the use of the Biosafety Cabinet under the in vivo section. In addition the following questions to be added;

- 1. For ABSL1 or ABSL2 work, describe the recommended handling and disposal of animal bedding/cages/waste, based on the infectious agents' shedding pattern
- 2. How should animal bedding/caging/waste be handled for this infectious agent?

No decontamination needed (no shedding expected) No/Yes

Chemical disinfection (If yes, list type/method) No/Yes

Autoclaving/Incineration No/Yes

#### VI. Reports.

## 1. Coordinator's report.

#### a. Update to the IBC Roster

As of July 1, and as part of the BSO transition plan, Ms. Heather Blair was appointed as a full IBC member and will serve as the primary Biosafety Officer on the IBC (replacing Dr. Claudia Gentry-Weeks). Dr. Robert Ellis will continue to serve as the Alternate Biosafety Officer. Drs. Byrne and Marlenee have also been re-appointed for another three year term each. Additionally, Dr. Matt Kipper and Dr. Landolt have not renewed their membership and are no longer on the committee. Our roster now stands at 13 voting members (plus 2 alternates) and one ad-hoc consultant; with our quorum at 7 voting members.

b. Next IBC meeting: August 8, 2018

# 2. Biosafety Officer's report.

- a. Incident reports:
  - i. There were two near misses
  - **ii.** One protocol breach involving not signing in for aerosol room use; email sent to PI and researchers; no exposure concern and no outside reporting required.
  - iii. There was a needle stick while collecting blood from a mouse infected with myxoma virus (which is not known to infect humans). The biosafety report was filed one week after the incident, at that time the wound was fully healed and no medical attention was needed. The incident report indicated the agent was not recombinant, however additional questions from the IBC requested follow up to confirm this; Biosafety and Occ Health with follow up with the PI.
- **b. Inspections:** CDC inspection is closed; select agent renewal will be coming due September 2019. CSU will likely have another unannounced inspection between now and then.
- c. Laboratory audit reports

# VII. Agent and Project Approval Request Forms Reviewed at Previous IBC Meeting and Approved After Modification to be read into the minutes.

1. Gentry-Weeks, Claudia

Agent: Staphylococcus carnosus – Strain: Any; BSL1

**Project:** <u>iGEM project: A Sentinel Bacteria-Phage System for Sensing and Destruction of Target Bacteria (</u>18-039B); BSL2 in vitro, rDNA. NIH Guidelines category non-exempt rDNA: III-D-1

2. Akkina, Ramesh

**Project:** Safety and efficacy evaluation of shRNAs in humanized mice (18-040B); BSL2 in vitro and BSL2 in vivo in mice, rDNA. NIH Guidelines category non-exempt rDNA: III-D-4

3. Bowen, Richard

**Project:** Emory efficacy of EEID-2801 against VEE virus infection (18-042B); BSL3 in vitro and BSL3 in vivo in mice. NIH Guidelines category non-exempt rDNA: N/A

**Project:** Reptiles and Amphibians as Reservoir and Overwintering Hosts for Arboviruses (18-044B); BSL3 in vitro and BSL3 in vivo in Frog, Snake, Iguana, Toad. NIH Guidelines category non-exempt rDNA: N/A

4. Hoerndli, Frederic

**Project:** In Vivo investigation of AMPAR transport in synaptic plasticity and maintenance (18-043B); BSL1 in Vivo C.elegans. NIH Guidelines category non-exempt rDNA: III-D-4

5. Dean, Gregg

Agent: Murine rotavirus – Strain: Any; BSL2

**Project:** Novel recombinant Rotavirus vaccine utilizing the probiotic microorganism <u>Lactobacillus acidophilus</u> (18-046B); BSL2 in vitro and BSL2 in vivo in mice, rDNA. NIH Guidelines category non-exempt rDNA: III-D-2

- VIII. New or Amended Agent Approval Request Forms Reviewed and Approved by the <u>Biosafety Officer</u> or Chair to be read into the minutes.
  - 1. Wyckoff, John

Agent: Salmonella paratyphi: Add strain YL159

- IX. New or Amended Project Approval Request Forms Reviewed and Approved by the <u>Biosafety Officer</u> or Chair to be read into the minutes.
  - 1. Ordway, Diane

**Project**: Inhaled Delivery of Clofazimine (CFZ): An Important Anti-tuberculosis Drug (Project 18-050B); BSL3 In Vitro NIH Guidelines category non-exempt rDNA: N/A

2. Medford, June

Project: Synthetic Biological Desalination (15-035B); Room location

3. Ebel, Gregory

**Project:** Emergence of tick-borne encephalitis in North America (18-051B); BSL3 in vitro and BSL3 in vivo in mice, rDNA. NIH Guidelines category non-exempt rDNA: N/A

Meeting adjourned; 1:15pm Minutes recorded by C. Johnson

# Approved Minutes Institutional Biosafety Committee

# August 8, 2018

Check if Attending (Members):	Check if Attending (Alternate Members):
	Lon Kendall, Director LAR
⊠Donald Bade, <b>Unaffiliated</b>	
Heather Blair, Assistant Biosafety Officer	Robert Ellis, <b>Director of Biosafety</b>
Richard Bowen, <b>Associate Chair</b>	
Patrick Byrne, <b>Plant expert</b>	
Chaoping Chen, <b>Chair</b>	
Sam Hendrix, <b>Unaffiliated</b>	
Angelo Izzo	
Nicole Marlenee, Lab tech rep	
☐ June Medford, Plant/syn bio expert	
Ken Olson	
⊠Ann Powers	
Bernard Rollin, <b>Bioethicist</b>	
Non-Voting Members:	
☐ James Graham, EHS Director	
Mike Weil, Ad-hoc, Radiation Biologist	
RICRO Staff (non-voting):	Regular Guests (non-voting):
Christine Johnson, Senior IBC Coordinator	Claudia Gentry-Weeks, Associate BSO
Karen Dobos, RICRO Director	Sara Cope, Assistant Biosafety Officer
Christa Johnson, Associate Vice President for	☐ Joni Van Sickle, Occupational Health
Research	Coordinator/Assistant Biosafety Officer
Other: Brad Woods Assistant RICRO Director, JJ Nels	on, RICRO Administrator

This meeting was convened at 2:02pm. Quorum was maintained throughout. Any member with a conflict of interest left the room during discussion and/or committee determination on the conflicted item.

#### I. Review of July 11, 2018 IBC meeting minutes.

The committee unanimously approved the July meeting minutes.

II. Review of Agent and Project Request Forms (https://protocols.research.colostate.edu/rco).

# 1. Pearce, Stephen (TABLED from July Meeting-new information added)

**Agent:** Agrobacterium tumefaciens – Strains: AGL1, EHA105, GV3101; BSL1 **Project:** Optimization of Winter Wheat (Triticum aestivum) Transformation (18-054B); transgenic wheat, rDNA. NIH Guidelines category non-exempt rDNA: III-E-2

## The committee unanimously approved of the above project with the following request;

The IBC approves the work in the lab and growth chambers, however since this work will not be ready to go into the greenhouse for 7-9 months, the IBC does not approve the work in the greenhouse at this time and requests that the statements regarding greenhouse work be removed from the PARF. Once the project is to the stage where use of the greenhouse is necessary, the PI must submit an amendment request to add the greenhouse work to the approval. At that time, the greenhouse will be checked to confirm that the bug screens are in place.

## 2. Linke, Lyndsey

**Project:** A versatile transkingdom platform for therapeutic nucleic acid delivery to mucosal epithelial tissues (18-057B); BSL2 in vitro and BSL2 in vivo in mice, rDNA. NIH Guidelines category non-exempt rDNA: III-D-4

#### The committee unanimously approved of the above project with the following items to address;

- 1. Will N95/BSC be required by animal care staff for opening cages/handling mice after infection, or is this PPE only needed during the infection procedure?
- 2. LAR must be notified prior to starting an ABSL2 animal study in order to prepare the correct space and equipment. The IBC requests the PI fill out the form on the LAR webpage and email to LAR Animal Orders when the animal order is placed for this project.

**Agent:** Staphylococcus aureus – Strain: any; BSL2

#### The committee unanimously approved of the above agent with the following item to address;

The strain is indicated as any; confirm whether or not this includes MRSA.

**Project:** Development of a programmable CRISPR/Cas9 mediated strategy to resensitize Staph. aureus to antibiotics for bovine mastitis treatment (18-061B); BSL2 in vitro, rDNA. NIH Guidelines category non-exempt rDNA: III-D-1

The committee unanimously approved of the above project as submitted.

## 3. Clay, Colin

**Project:** Recombinant AAV delivery to sheep hypothalamus and pituitary (18-060B); BSL1 in vitro and BSL1 in sheep, rDNA. NIH Guidelines category non-exempt rDNA: III-D-

## The committee unanimously approved of the above project with the following item to address;

Under Infectious Agents, BSL1 is indicated for in vitro work. However, BSL2 is indicated under the detailed section for in vitro uses. Confirm which one is correct.

# 4. Wyckoff, John

**Agent:** Mycobacterium tuberculosis – Strain: Johnston strain

#### The committee unanimously approved of the above agent with the following items to address;

- 1. A specific strain (Johnston strain) is indicated. Are there any special properties about this strain (i.e., is it a lab strain, is it more virulent, less virulent than other strains, etc.)?
- 2. Pathogenic to animals should be changed from NO to YES.
- 3. Since the vaccine is not available in the US, the IBC requests that "Vaccine available for people?" be changed from YES to NO.

**Project:** TBD (18-062B); BSL3 in vitro. NIH Guidelines category non-exempt rDNA: NA The committee unanimously approved of the above project with the following items to address;

- 1. The IBC requests that a title be added to the PARF.
- 2. The IBC requests other individuals that will be working on this project be listed.
- are listed as locations of work, however these rooms are not listed under in vitro uses. IBC requests PI specify what work will be done in these rooms and what PPE will be used.

### Submitted after the deadline, review if time permitting

#### 5. McKay, John

**Project:** The Evolution of Plant Drought Tolerance and Gene Function Across Historic Frequency Gradients (18-063B); BL1-P in vitro and in vivo in Arabidopsis thaliana, rDNA. NIH Guidelines category non-exempt rDNA: III-E-2

#### The committee unanimously TABLED of the above project pending the receipt of additional information.

There was a lot of missing information. Contact for specific questions to ask Dr. McKay.

#### III. Amendments to be reviewed by full committee

1. Duval, Dawn

**Project:** Osteosarcoma: Biomarkers of Metastasis and Resistance to Therapy (11-044B); BSL2 in vitro, rDNA. NIH Guidelines category non-exempt rDNA: III-D-3 **Amendment request to add transient transfection (gene over-expression) – see attached** 

The committee unanimously approved of the above amendment request as submitted.

#### IV. Unfinished business

1. PARF update: Bedding/Cage Handling – not discussed, hold for next month

#### **V.New Business**

#### 1. RIC Tenants and IBC Approvals

Tenants at RIC are not CSU employees and do not pay F&A, therefore when the IBC reviews protocols for RIC tenants they are essentially providing a free service. Other offices charge RIC tenants for these types of services. The number of IBC protocols from RIC tenants is small. However the IBC can decide whether or not to continue to review them. If the IBC votes to continue reviewing protocols for RIC tenants, the tenants will be charged a fee. The IBC voted and agreed to continue reviewing protocols for RIC tenants.

# 2. Review of IBC policy updates

The following updated IBC policies were reviewed: Policy on redacting IBC meeting minutes and/or protocols prior to release; Policy on public comment in response to IBC actions; Policy on reporting incidents involving Recombinant and/or Synthetic Nucleic Acid Molecules to the NIH Office of Science Policy (OSP). The first two policies updated OBA to OSP. The policy on incident reporting also updated OBA to OSP, and added a timeline for reporting. All three policies were reviewed and approved by the IBC.

#### VI. Reports.

- 1. Coordinator's report.
  - a. CSU NIH/OSP Annual Report submitted August 1st
  - **b.** NIH/OSP Incident Report on 7/25/18, an incident report involving a needle stick with a recombinant agent in a BSL2 lab was submitted to NIH/OSP; no response received yet.
  - c. Next IBC meeting: IBC Retreat Friday, September 21, 2018 at Tamasag
- 2. Biosafety Officer's report.
  - a. Incident reports (see table)
  - b. Inspections
  - c. Laboratory audit reports

- **d. Misc.** will be attending an RO/ARO meeting next week and later going to DC (George Washington University) to help train fire fighters and first responders.
- VII. Agent and Project Approval Request Forms Reviewed at Previous IBC Meeting and Approved After Modification to be read into the minutes.
  - 1. Gentry-Weeks, Claudia

Agent: Enterococcus cecorum – Strain: Any; BSL 2

2. Bowen, Richard

**Project:** <u>VEE virus vaccine:</u> <u>USAMRIID</u> (18-055B); BSL3 in vitro and BSL3 in vivo Mice. NIH Guidelines category non-exempt rDNA: N/A

**Project:** Ferret Models for the Evaluation of Influenza Vaccines and Vaccination Strategies (18-056B); BSL3 in vitro and BSL3 in vivo ferrets. NIH Guidelines category nonexempt rDNA: N/A

- VIII. New or Amended Agent Approval Request Forms Reviewed and Approved by the <u>Biosafety Officer</u> or Chair to be read into the minutes.
- IX. New or Amended Project Approval Request Forms Reviewed and Approved by the <u>Biosafety Officer</u> or <u>Chair</u> to be read into the minutes.

Meeting adjourned; 3:05pm

# APPROVED Minutes Institutional Biosafety Committee

# September 21, 2018

Check if Attending (Members):	Check if Attending (Alternate Members):	
	Lon Kendall, Director LAR	
Heather Blair, Assistant Biosafety Officer	Robert Ellis, <b>Director of Biosafety</b>	
Richard Bowen, <b>Associate Chair</b>		
Patrick Byrne, <b>Plant expert</b>		
Chaoping Chen, <b>Chair</b>		
Sam Hendrix, <b>Unaffiliated</b>		
Nicole Marlenee, Lab tech rep		
June Medford, <b>Plant/syn bio expert</b>		
Ken Olson		
Ann Powers		
Bernard Rollin, <b>Bioethicist</b>		
Non-Voting Members:		
☐ James Graham, EHS Director		
Mike Weil, Ad-hoc, Radiation Biologist		
RICRO Staff (non-voting):	Regular Guests (non-voting):	
Christine Johnson, Senior IBC Coordinator	Claudia Gentry-Weeks, Associate BSO	
Karen Dobos, RICRO Director	Sara Cope, Assistant Biosafety Officer	
Christa Johnson, Associate Vice President for	☑ Joni Van Sickle, Occupational Health	
Research	Coordinator/Assistant Biosafety Officer	
Other: JJ Nelson, RICRO Administrator, Brad Woods RICRO Associate Director, Laura Hinds, IACUC		
Coordinator		

This meeting was convened at 12:20pm. Quorum was maintained throughout. Any member with a conflict of interest left the room during discussion and/or committee determination on the conflicted item.

#### I. Review of August 8, 2018 IBC meeting minutes.

The August meeting minutes were not ready to be reviewed.

II. Review of Agent and Project Request Forms (https://protocols.research.colostate.edu/rco).

## 1. McKay, John (TABLED from August Meeting-new information added)

**Project:** The Evolution of Plant Drought Tolerance and Gene Function Across Historic Frequency Gradients (18-063B); BL1-P in vitro and in vivo in Arabidopsis thaliana, rDNA. NIH Guidelines category non-exempt rDNA: III-E-2

## The committee unanimously asked for the following to be addressed:

- 1. The IBC requests that both the PI and the graduate student indicate how long they have worked in these areas. Does the graduate student have any previous transgenic plant experience?
- 2. The Project Overview indicates: The project will investigate the effects of loss of function alleles on 20 genes ...however 59 genes are listed in response to the request to specify the target genes. The IBC requests clarification as to which 20 of these be used; is there a web address where information on these code names is available.

- 3. was indicated for plant growth and phenotyping and indicated for molecular biology and bacteria culturing. The IBC requests information regarding where the plant transformation will take place. If in the transported to the double containment is advisable, e.g., in a box inside a cooler.
- 4. Under non-exempt TDNA, it states: Transgenic plants containing CRISPR-CAS9 construct will be generated using Agrobacterium tumifaciens ...The IBC requests the name of the method (such as via the floral dip method) be added to the PARF.
- 5. The IBC requests that the PI and graduate student meet with a Biosafety Officer and IBC Plant Expert to ensure all proper procedures are in place.

#### 2. Bowen, Richard

Agent: Sf rhabdovirus – Strain: any; BSL2

The committee unanimously approved the above agent as submitted.

**Project:** <u>SF-rhabdovirus safety trial</u> (18-073B); BSL2 in vivo in mice. NIH Guidelines category non-exempt rDNA: NA

The committee unanimously approved of the above project with the following to be addressed:

- 1. Please indicate whether a BSC should be used for cage changes.
- 2. Please provide a statement on how animal waste/bedding should be handled, inactivated, and/or disposed of.

**Agent:** Influenza B virus – Strain: any; BSL2

The committee unanimously approved the above agent as submitted.

**Project:** <u>Tria: Universal Influenza Vaccine</u> (18-075B); BSL2 and BSL3 in vitro; BSL2 and BSL3 in vivo in mice. NIH Guidelines category non-exempt rDNA: NA

The committee unanimously approved of the above project with the following to be addressed:

The IBC request clarification regarding the location of work, i.e., all work be done in (BSL3 space), or will BSL2 work be done elsewhere. If so, is a BSC needed for cage changes in BSL2 and what bedding disposal methods are needed?

# 3. Vivanco, Jorge

**Agent**: Pseudomonas aeruginosa – Strain: PAO1, PA14, quorum sensing mutants of PAO1 and PA14; BSL2

**Agent:** Klebsiella pneumonia – Strain: environmental; BSL2

The committee unanimously approved the above agents with the following to be addressed:

- 1. The IBC requests that a chemical disinfectant be added to the Methods of Inactivation.
- 2. The IBC requests that the PI meet with one of the Biosafety Officers to ensure all proper equipment and procedures are in place.

#### 4. Kruh-Garcia, Nicole

**Project:** Sputum-based protein markers for TB diagnostic and treatment prediction (18-076B); BSL3 in vitro. NIH Guidelines category non-exempt rDNA: NA

The committee unanimously approved the above project as submitted.

#### III. Unfinished business

No unfinished business to report.

#### IV. New Business

#### 1. Updated IBC PI Training slides

The IBC Coordinator has updated the IBC PI Training slide set to make the slides more and to add more gene editing information. The slides were emailed to the IBC for review prior to the meeting. A few members requested more time to review the slides, therefore the vote will take place next month. There were questions regarding who is required to take the training. Currently, all IBC PIs are required to taking the training every three years; this is tracked through our IBC database but will likely move to the new learning management system (Bridge) that CSU purchased. Also currently, PIs are required to train, and track training of, their laboratory staff on IBC requirements. It was suggested that perhaps the IBC should also track training for laboratory staff listed on AARFs/PARFs similar to how we currently do for BSL1/BSL2 training, etc. This was discussed and the committee agreed that all individuals listed on an IBC approval should take the IBC training. The IBC voted and approved requiring the IBC Training slides be completed by all individuals listed on an IBC approval.

2. **October National Biosafety Month -** Promoting a Culture of Biosafety and Responsibility Different ideas for recognizing biosafety month were discussed.

## 3. Poster contest – please submit your vote

Please see the eight submitted posters & submit your vote for your top three. Winners will be announced within the week.

## V.Reports.

- 1. Coordinator's report.
  - a. CSU NIH/OSP Annual Report approved 9/6/18
  - b. **NIH/OSP Incident Report** response received from NIH/OSP for potential lentivirus exposure submitted 8/16/18, no further action required.
  - c. Next IBC meeting: Wednesday, October 10, 2018
- 2. Biosafety Officer's report.
  - **a. Incident reports -** No reports were given at this time due to a lack of time. Reports will be given at the next meeting, October 10<sup>th</sup>.
  - b. Inspections
  - c. Laboratory audit reports

# VI. Agent and Project Approval Request Forms Reviewed at Previous IBC Meeting and Approved After Modification to be read into the minutes.

1. Pearce, Stephen

**Agent:** Agrobacterium tumefaciens – Strains: AGL1, EHA105, GV3101; BSL1 **Project:** Optimization of Winter Wheat (Triticum aestivum) Transformation (18-054B); transgenic wheat, rDNA. NIH Guidelines category non-exempt rDNA: III-E-2

2. Linke, Lyndsey

**Project:** A versatile transkingdom platform for therapeutic nucleic acid delivery to mucosal epithelial tissues (18-057B); BSL2 in vitro and BSL2 in vivo in mice, rDNA. NIH Guidelines category non-exempt rDNA: III-D-4

**Agent:** Staphylococcus aureus – Strain: any; BSL2

**Project:** Development of a programmable CRISPR/Cas9 mediated strategy to resensitize Staph. aureus to antibiotics for bovine mastitis treatment (18-061B); BSL2 in vitro, rDNA. NIH Guidelines category non-exempt rDNA: III-D-1

3. Clay, Colin

**Project:** Recombinant AAV delivery to sheep hypothalamus and pituitary (18-060B); BSL1 in vitro and BSL1 in sheep, rDNA. NIH Guidelines category non-exempt rDNA: III-D-1

4. Wyckoff, John

**Agent:** Mycobacterium tuberculosis – Strain: Johnston strain

Project: TBD (18-062B); BSL3 in vitro. NIH Guidelines category non-exempt rDNA: NA

VII. New or Amended Agent Approval Request Forms Reviewed and Approved by the <u>Biosafety Officer</u> or Chair to be read into the minutes.

VIII. New or Amended Project Approval Request Forms Reviewed and Approved by the <u>Biosafety Officer</u> or <u>Chair</u> to be read into the minutes.

Meeting adjourned: 1:30pm

# Approved Minutes Institutional Biosafety Committee

# October 10, 2018

Check if Attending (Members):	Check if Attending (Alternate Members):
	Lon Kendall, Director LAR
☑Donald Bade, <b>Unaffiliated</b>	
Heather Blair, Assistant Biosafety Officer	Robert Ellis, <b>Director of Biosafety</b>
Richard Bowen, <b>Associate Chair</b>	
Patrick Byrne, <b>Plant expert</b>	
Chaoping Chen, <b>Chair</b>	
Sam Hendrix, <b>Unaffiliated</b>	
⊠Angelo Izzo	
⊠Nicole Marlenee, <b>Lab tech rep</b>	
June Medford, Plant/syn bio expert	
Ken Olson, Arrived 12:07pm	
Bernard Rollin, <b>Bioethicist</b>	
Non-Voting Members:	
☐ James Graham, EHS Director	
Mike Weil, Ad-hoc, Radiation Biologist	
RICRO Staff (non-voting):	Regular Guests (non-voting):
Christine Johnson, Senior IBC Coordinator	Claudia Gentry-Weeks, Associate BSO
Karen Dobos, RICRO Director	Sara Cope, Assistant Biosafety Officer
Christa Johnson, Associate Vice President for	Joni Van Sickle, Occupational Health
Research	Coordinator/Assistant Biosafety Officer
Other: JJ Nelson, RICRO Administrator, Brad Woods RICRO Associate Director	

This meeting was convened at 12:04pm. Quorum was maintained throughout. Any member with a conflict of interest left the room during discussion and/or committee determination on the conflicted item.

I. Review of August 8, 2018 and September 21, 2018 IBC meeting minutes. The committee unanimously approved of both meeting minutes with no changes.

- II. Review of Agent and Project Request Forms (https://protocols.research.colostate.edu/rco).
  - 1. Aspelund, Amy

**Agent:** Replication Deficient H5N1 Vaccine – Strain: 6:2 IVR-116: H5N1 Reasortant virus with an NS1 Deletion; BSL2

The committee unanimously approved of the above agent with the following to be addressed:

- The IBC recommends that individuals working with this agent receive the seasonal flu
  vaccine.
- 2. Please include the building in the storage location of the agent and location of work.
- 3. The RO will consult with the PI regarding whether or not this agent is excluded from select agent regulations.

**Project:** Replication deficient H5N1 influenza vaccine (18-079B); BSL2 in vitro, rDNA. NIH Guidelines category non-exempt rDNA: III-D-7

## The committee unanimously approved of the above project with the following to be addressed:

The IBC requests that other individuals working on the project be listed on the Project Approval Request Form.

As this is a tenant, we will need to look into the process for accessing an IBC fee.

### 2. Jackson, Mary

**Project:** Mycobacterium abscessus biofilms and biofilm inhibitors (18-081B); BSL2 in vitro, rDNA. NIH Guidelines category non-exempt rDNA: III-D-1

## The committee unanimously approved of the above project with the following to be addressed:

No in vitro work was indicated on this PARF. The IBC requests confirmation that there will not be any in vitro work. If there is in vitro work, the PI should indicate the PPE to be used.

#### Submitted after the deadline, review if time permitting

## 3. Jackson, Mary

**Project:** Mycobacterium tuberculosis methylglucose lipopolysaccharides (18-082B); BSL2 and BSL3 in vitro, rDNA. NIH Guidelines category non-exempt rDNA: III-D-1

#### The committee unanimously approved of the above project with the following to be addressed:

The IBC requests clarification whether the two BSL2 agents will be handled at BSL2 or BSL3, and if they will be at BSL2, what PPE that will be used.

## III. Unfinished business

# 1. Updated IBC PI Training slide

The IBC reviewed the training slides and unanimously approved for them to be posted and used for training. The IBC Coordinator will work on getting the new training posted.

- 2. October National Biosafety Month Promoting a Culture of Biosafety and Responsibility
  - a. Poster winners Poster winners have been announced and shared with all of campus. A source article was written about the winners, RAM Safe Pledge, and October Biosafety month.
  - b. **RAM Safe Pledge** The RAM Safe Pledge has been sent out across campus to spread the awareness of biosafety. The top department with the most pledges will receive a special recognition.
  - c. IBC Meet & Greet The IBC is holding a Meet and Greet with student a faculty and students after the October meeting.

## 3. How to notify LAR of BSL2 animal work and necessary precautions

has put together a form for PIs to fill out when they are planning to do BSL2 animal work to notify LAR of any additional precautions. The forms are available online and once filled out are kept in the animal room, and contain information such as what is the agent, who is the contact person, what PPE should be used when opening cages, and how the cages should be handled. Currently, there is not a question on the PARF asking for this information, we are working on adding it; in the meantime RICRO is adding a statement regarding this form when BSL2 animal work is planned. LAR has also placed general biohazard signs on the doors of the animal room with the agents that may be present.

#### IV. New Business

No new business

#### V.Reports.

- 1. Coordinator's report.
  - a. Next IBC meeting: Wednesday, November 14, 2018
  - ABSA Annual Conference, October 12-17; several of our Biosafety Officers will be attending.
- 2. Biosafety Officer's report.
  - a. Incident reports
    - i. There were a couple of splashes to the eye; one occurred in the CDW positive animals. Individual rinsed out eye in anteroom sink (no eyewash available at that time) but did not notify Biosafety until 4 months after the incident. The individual was reminded of the importance of wearing eye protection in ABSL2 animal rooms, as well as the requirement for prompt reporting. The individual has not had any issues with their eye and was reporting to biosafety in case in future issues arise. No outside reporting required.
    - ii. Individual cut their finger on a glass red-top tube containing a sample sent for Brucella PCR testing. The sample was PCR negative for Brucella. The individual followed all appropriate clean up and reporting procedures. It has been decided to switch to plastic tubes.
    - iii. Not really an incident, but FYI...A client dog with suspected tularemia was brought to the VTH; it was put into isolation and signs were posted to indicate proper PPE to use; no exposures. The RO filed a Form 4 with CDC (clinical sample identified select agent).
  - **b. Inspections** recently had a surprise inspection of effluent decontamination systems; just received the report. One of the systems not in a select agent area but will be able to fix this. The BSOs are working on the response.
  - c. Laboratory audit reports
    did audit of select agent inventory; all was good.
- VI. Agent and Project Approval Request Forms Reviewed at Previous IBC Meeting and Approved After Modification to be read into the minutes.
  - 1. Bowen, Richard

**Project:** <u>SF-rhabdovirus safety trial</u> (18-073B); BSL2 in vivo in mice. NIH Guidelines category non-exempt rDNA: NA

**Project:** <u>Tria: Universal Influenza Vaccine</u> (18-075B); BSL2 and BSL3 in vitro; BSL2 and BSL3 in vivo in mice. NIH Guidelines category non-exempt rDNA: NA

- VII. New or Amended Agent Approval Request Forms Reviewed and Approved by the <u>Biosafety Officer</u> or Chair to be read into the minutes.
- VIII. New or Amended Project Approval Request Forms Reviewed and Approved by the <u>Biosafety Officer</u> or <u>Chair</u> to be read into the minutes.

Meeting adjourned: 12:40pm

# Approved Minutes Institutional Biosafety Committee

# November 14, 2018

Check if Attending (Members):	Check if Attending (Alternate Members):	
	Lon Kendall, Director LAR	
☑Donald Bade, <b>Unaffiliated</b>		
Heather Blair, Assistant Biosafety Officer	Robert Ellis, <b>Director of Biosafety</b>	
Richard Bowen, Associate Chair		
Patrick Byrne, <b>Plant expert</b>		
Chaoping Chen, <b>Chair</b>		
Sam Hendrix, <b>Unaffiliated</b>		
Nicole Marlenee, <b>Lab tech rep</b>		
June Medford, Plant/syn bio expert		
Ken Olson, Arrived 12:07pm		
Ann Powers		
Bernard Rollin, <b>Bioethicist</b>		
Non-Voting Members:		
James Graham, EHS Director		
Mike Weil, Ad-hoc, Radiation Biologist		
RICRO Staff (non-voting):	Regular Guests (non-voting):	
Christine Johnson, Senior IBC Coordinator	Claudia Gentry-Weeks, Associate BSO	
Karen Dobos, RICRO Director	Sara Cope, Assistant Biosafety Officer	
Christa Johnson, Associate Vice President for	a Johnson, Associate Vice President for 📗 Joni Van Sickle, Occupational Health	
Research	Coordinator/Assistant Biosafety Officer	
Other: JJ Nelson, RICRO Administrator		
This meeting was convened at 12:02pm. Quorum was maintained throughout. Any member with a conflict of		

This meeting was convened at 12:02pm. Quorum was maintained throughout. Any member with a conflict of interest left the room during discussion and/or committee determination on the conflicted item.

# I. Review of October 10, 2018 IBC meeting minutes.

The committee unanimously approved of both meeting minutes with no changes.

- II. Review of Agent and Project Request Forms (https://protocols.research.colostate.edu/rco).
  - 1. Schountz, Tony

**Agent:** Cedar virus – Strain: any; BSL2

# The committee unanimously approved of the above agent as submitted.

This is a fairly new virus; there has not been a lot of animal studies. Although considered to be BSL2, PI will work with at BSL3.

**Project:** Experimental infection of Jamaican fruit bats with Cedar virus (18-086B); BSL3 in vitro; BSL3 in vivo in bats. NIH Guidelines category non-exempt rDNA: NA

1. Under in vivo using, the room indicated is	which is an antercom.	, this should be changed
to the animal holding room).	1	, time en earla de en angea

## 2. Peebles, Christie

Agent: Staphylococcus carnosus – Strain: BSL1

## The committee unanimously approved of the above agent as submitted.

This bacteria is used in making sausage.

**Project:** Generation of a biosensor to enhance olfaction (18-087B); BSL1 in vitro, rDNA. NIH Guidelines category non-exempt rDNA: III-D-2

#### The committee unanimously approved of the above project with the following to be addressed:

- 1. What is irp9 gene from Y. enterocolitica?
- 2. A toxin is mentioned in a few different places. The IBC requests clarification as to what this toxin is and its purpose.

# 3. Goodrich, Laurie

**Agent:** IGFscAAV2 – Strain: any; BSL2 **Agent:** IL1ra-scAAV2 – Strain: any; BSL2

## The committee unanimously approved of the above agents with the following to be addressed:

1. Under Methods used to inactivate agent for disposal, the IBC request that autoclaving and the percentage of bleach be added.

**Project:** Development of diagnostic and treatment strategies for post-traumatic osteoarthritis (PTOA) (18-088B); BSL2 in vitro; BSL1 in vivo in equine, rDNA. NIH Guidelines category non-exempt rDNA: III-D-4

## The committee unanimously approved of the above project with the following to be addressed:

- 1. All individuals working in a biosafety cabinet must complete the CSU biosafety cabinet training; this can be found on the EHS training database.
- 2. There is a typo in the Project Overview, ffective should be changed to effective.
- 3. The IBC recommends wearing safety glasses, or similar type of eye protection, especially when working with animals outside a biosafety cabinet.

**Project:** Localized Gene Therapy for Prolonged Anti-Inflammatory Treatment to Prevent of Delay PTOA in an Equine Model (18-089B); BSL2 in vitro; BSL1 in vivo in equine, rDNA. NIH Guidelines category non-exempt rDNA: III-D-4

## The committee unanimously approved of the above project with the following to be addressed:

- 1. The IBC requests PTOA be defined in the Project Overview. (this was defined in the other PARF, but since these forms need to be standalone documents, it should be defined again)
- 2. All individuals working in a biosafety cabinet must complete the CSU biosafety cabinet training; this can be found on the EHS training database.
- 3. There is a typo in the Project Overview, ffective should be changed to effective.
- 4. The IBC recommends wearing safety glasses, or similar eye protection, especially when working with animals outside a biosafety cabinet.
- 5. According to the NIH Guidelines Appendix Q-I-B-1 When an animal covered by Appendix Q containing recombinant or synthetic nucleic acid molecules or a recombinant or synthetic nucleic acid molecule-derived organism is euthanized or dies, the carcass shall be disposed of to avoid its use as food for human beings or animals unless food use is specifically authorized by an appropriate Federal agency. The IBC requests a statement regarding how the carcass will disposed of.

### 4. Jackson, Mary

Agent: Mycobacterium haemophilum – Strain: DSM 44634; BSL2

## The committee unanimously approved of the above agent with the following to be addressed:

1. The IBC requests the percentage of bleach used under Methods used to inactivate agent for disposal.

## 5. Robertson, Gregory

Agent: Neisseria gonohoreae – Strain: ATCC #49226; BSL2

#### The committee unanimously approved of the above agent with the following to be addressed:

1. The IBC requests that a chemical disinfectant be added to the Methods used to inactivate agent for disposal.

**Project:** Gerica Helton Ph.D project (18-090B); BSL2 in vitro and human samples; NIH Guidelines category non-exempt rDNA: NA

## The committee unanimously approved of the above project with the following to be addressed:

- 1. The IBC requests all individuals listed on an IBC approval be registered with the IBC Online Database.
- 2. All individuals listed need to complete the BSL1/BSL2 Online Training and the Biosafety Cabinet Training.
- 3. All individuals listed need to enroll in the Occupational Health Program by completing the online risk assessment.

#### III. Unfinished business

1. October National Biosafety Month – "RAM Safe Pledge" was a big success!

There was a total of 200 RAM pledges, it included everyone from undergrads to faculty staff. The winning department has not yet been announced and the trophy is currently in production.

## IV. New Business

1. BSL3 Advisory Committee and BRB Shutdown/Renovation update

The BSL3 Advisory Committee recently met to discuss issues related to the upcoming BRB shutdown/renovation. BRB was the first BSL3 space built at the Foothills campus, it is approx. 9000 sq ft and is occupied by the group. The floors need to be replaced and HVAC system needs some modifications. All research in this area will either be temporarily halted or moved to another location. Some researchers will have to move into select agent areas; the RO is working on getting these individuals select agent approved. Work is also being done so that the Imaging and Mass Spec Suites can be commissioned to become BSL3, and some work will move here. Once the research has moved out, BRB will be deconed (surface decon followed by VHP), and renovation/maintenance will commence. BRB will be down for approx. 9 months. This is a huge undertaking with many logistical issues, and impacting many of our researchers. The BSL3 Advisory Committee met to discuss some of these issues. Below is the tentative timeline for the renovation.

# **BRB Renovation – Timeline**

Date	Activity
Nov 30, 2018	BSL-3 commissioning of imaging and mass spec labs
1 <sup>st</sup> week of Dec 2018	Move over to mass spec/imaging starts

Dec 10, 2018	One day regular shutdown of BRB (any other regular maintenance delayed until March shutdown)
Jan 2019	Cleanout and final decon of BRB
March 4, 2019	Start mechanical renovation/flooring projects*
August 30, 2019	Complete mechanical renovation/flooring projects

<sup>\*</sup>Once the final bids have been received from contractors and firms are selected (sometime in early January), a more detailed timeline during those dates (March-August) will be available.

## V.Reports.

#### 1. Coordinator's report.

a. Next IBC meeting: Wednesday, December 12, 2018 – special guest Dr. Zach Adelman; meeting will be held in at 9am.

## b. January meeting

The January meeting will be moved to the 16<sup>th</sup>, this will allow additional time after the Holiday break for researchers to submit new protocols.

## 2. Biosafety Officer's report.

## a. Incident reports

- i. Accident/exposure while microinjecting mosquitoes with chikungunya virus in the BSL3, the nanoject chord slipped and the individual made a quick movement with hand and accidentally hit finger with the injection needle. The individual later developed symptoms and sought medical treatment. There is no specific treatment for this virus, thus supportive care was given and the individual is doing better. During a follow up incident review meeting, researchers determined a different way of moving mosquitoes to prevent something like this from happening again. The individual followed all appropriate clean up and reporting procedures; no outside reporting required.
- Protocol breach use of earbuds with cell phones in the BSL3. A supervisor observed this happening and confirmed with biosafety that it was not approved. Supervisor informed all personnel that earbuds and cell phones are not allowed in the BSL3.

### b. Inspections

i. CSU has submitted the response to the CDC inspection of the EDS system.

### c. Laboratory audit reports

i. Select agent labs are currently being audited; everything is looking very good.

## d. Mics.

i. Heather Blair was recently elected as a Council Member to ABSA International

# VI. Agent and Project Approval Request Forms Reviewed at Previous IBC Meeting and Approved After Modification to be read into the minutes.

### 1. Jackson, Mary

**Project:** Mycobacterium abscessus biofilms and biofilm inhibitors (18-081B); BSL2 in vitro, rDNA. NIH Guidelines category non-exempt rDNA: III-D-1

**Project:** Mycobacterium tuberculosis methylglucose lipopolysaccharides (18-082B); BSL2 and BSL3 in vitro, rDNA. NIH Guidelines category non-exempt rDNA: III-D-1

## 2. Vivanco, Jorge

**Agent**: Pseudomonas aeruginosa – Strain: PAO1, PA14, quorum sensing mutants of PAO1 and PA14; BSL2

**Agent:** Klebsiella pneumonia – Strain: environmental; BSL2

**Project:** Exploring alternatives to the chemical control of nematodes in potato in the San Luis Valley (15-015B); BSL2 in vitro. NIH Guidelines category non-exempt rDNA: NA. Amended to add agents.

3. McKay, John (TABLED from August Meeting; new information added and lab visit)

**Project:** The Evolution of Plant Drought Tolerance and Gene Function Across Historic Frequency Gradients (18-063B); BL1-P in vitro and in vivo in Arabidopsis thaliana, rDNA. NIH Guidelines category non-exempt rDNA: III-E-2

VII. New or Amended Agent Approval Request Forms Reviewed and Approved by the <u>Biosafety Officer</u> or Chair to be read into the minutes.

none

- VIII. New or Amended Project Approval Request Forms Reviewed and Approved by the <u>Biosafety Officer</u> or Chair to be read into the minutes.
  - 1. 18-052 WEIL, MICHAEL Effects of long-term, low-dose-rate irradiation exposure in a humanized liver mouse model IN VIVO; Mice
  - 18-058 De LONG, SUSAN Developing Drinking Water Disinfection Technologies for Small Systems BSL2 IN VITRO
  - 3. 18-065 ROBERTSON, GREGORY REPLICATION RATIOS AS A MEASURE OF M. TUBERCULOSIS VIABILITY IN MICE BSL3 IN VITRO; BSL3 IN VIVO IN MICE
  - 4. 18-066 DEAN, GREGG EFFECTS OF VACCINATION AND RICE BRAN ON FECAL IgA HUMAN SAMPLES
  - 5. 18-067 BOWEN, RICHARD MUCOSAL IMMUNIZATION OF ELK AGAINST BRUCELLA ABORTUS BSL3 IN VITRO AND BSL3 IN VIVO IN ELK
  - 18-069 CHICCO, ADAM Integrative metabolism of oocyte development and its modulation by maternal diet HUMAN SAMPLES
  - 7. 18-070 BOWEN, RICHARD Pathogen Inactivation Studies for "Reduction of FLUAV, WNV, and MERS using the Mirasol System for Whole Blood BSL2 IN VITRO
  - 8. 18-071 BROUSSARD, JOSIANE Constant routine to assess circadian rhythms HUMAN SAMPLES
  - 18-072 BOWEN, RICHARD Pasquel Brucella melitensis vaccine BSL3 IN VITRO AND BSL3 IN VIVO IN GOATS
  - 10. 18-074 BROUSSARD, JOSIANE Impact of sleep and circadian disruption on insulin sensitivity HUMAN SAMPLES
  - 11. 18-077 NETT, TERRY Determination of estradiol concentration in human plasma HUMAN SAMPLES
  - 12. 18-078 BROUSSARD, JOSIANE Tissue-specific effects of insufficient sleep HUMAN SAMPLES
  - 13. 18-080 ORDWAY, DIANE Experimental Testing of Oxazolidinones against Mycobacterium abscessus BSL2 IN VIVO IN MICE
  - 14. 18-084 MARKUS, STEVEN Molecular Pathology of Motor Neuron Disease HUMAN SAMPLES
  - 15. 18-085 FAW, MEARA Evaluating the BSharp Program using Salivary Telomere Assays HUMAN SAMPLES

Meeting adjourned: 12:45pm

# Approved Minutes Institutional Biosafety Committee

# December 12, 2018

Check if Attending (Members):	Check if Attending (Alternate Members):
	Lon Kendall, Director LAR
Donald Bade, <b>Unaffiliated</b>	
Heather Blair, Assistant Biosafety Officer	Robert Ellis, <b>Director of Biosafety</b>
Richard Bowen, Associate Chair	
Patrick Byrne, <b>Plant expert</b>	
Chaoping Chen, <b>Chair</b>	
Sam Hendrix, <b>Unaffiliated</b>	
⊠Angelo Izzo	
Nicole Marlenee, <b>Lab tech rep</b>	
☑June Medford, <b>Plant/syn bio expert</b>	
⊠Ken Olson	
⊠Ann Powers	
Bernard Rollin, <b>Bioethicist</b>	
Non-Voting Members:	
☐ James Graham, EHS Director	
Mike Weil, Ad-hoc, Radiation Biologist	
RICRO Staff (non-voting):	Regular Guests (non-voting):
Christine Johnson, Senior IBC Coordinator	Claudia Gentry-Weeks, Associate BSO
Karen Dobos, RICRO Director	Sara Cope, Assistant Biosafety Officer
Christa Johnson, Associate Vice President for	☐ Joni Van Sickle, Occupational Health
Research	Coordinator/Assistant Biosafety Officer
Other: JJ Nelson, RICRO Administrator; Zach Adelma	ın, Guest Speaker

This meeting was convened at 1:05pm. Quorum was maintained throughout. Any member with a conflict of interest left the room during discussion and/or committee determination on the conflicted item.

I. Guest speaker Dr. Zach Adelman, Professor, Department of Entomology, Texas A&M Dr. Adelman gave a talk/training titled "Emerging Biotechnologies: Challenges Raised for Our Current System of Biosafety Oversight by Gene Drive". The slides will be sent to the committee members for reference.

## II. Review of November 14, 2018 IBC meeting minutes.

The committee unanimously approved of both meeting minutes with no changes.

- III. Review of Agent and Project Request Forms (https://protocols.research.colostate.edu/rco).
  - 1. Henao-Tamayo, Marcela

**Agent:** Mycobacterium haemophilum – Stain: any; BSL2

The committee unanimously approved of the above agent with the following to be addressed:

- 1. Which room is this stored in
- 2. The IBC requests the PI specify the chemical and dilution used under Methods to inactive the agent for disposal.

**Agent:** Mycobacterium smegmatis expressing mc2 155 Rv1411c – Strain: Mycobacterium smegmatis; BSL2

## The committee unanimously approved of the above agent with the following to be addressed:

The IBC requests the PI specify the chemical and dilution used under Methods to inactive the agent for disposal.

## 2. Nelson, Brad

Agent: Staphylococcus aureus – Strain: any; BSL2

### The committee unanimously approved of the above agent with the following to be addressed:

- 1. Under Strain, the IBC requests NA to be changed to ANY EXCEPT MRSA.
- 2. The IBC requests the PI provide the dilution of bleach used for Methods to inactivate the agent for disposal.
- 3. The IBC requests autoclave be added as a Method of inactivation.

**Project:** Forcast Ortho - Investigation of an Antibiotic Dispensing Spacer for eradication of arthroplasty infection using an ovine model (18-094B); BSL2 in vitro and BSL2 in vivo in sheep. NIH Guidelines category non-exempt rDNA: NA

## The committee unanimously approved of the above project with the following to be addressed:

- 1. The IBC requests a brief description of how will the animal carcass and PPE be contained/ disposed.
- 2. All individuals working with a BSL2 agent must complete the Online BSL1/BSL2 Training; those working in a biosafety cabinet must also complete the CSU Biosafety Cabinet Training.

## 3. Peebles, Christie

**Project:** Olfaction Enhancement Sensor Testing (18-095B); BSL1 in vitro and BSL1 in vivo in rats, rDNA. NIH Guidelines category non-exempt rDNA: III-D-4

#### The committee unanimously approved of the above project with the following to be addressed:

- 1. In reference to Mechanisms in place for containment and disposition of infected animals or plants, bleach is not used by LAR to clean cages, they are washed in a mechanical cage wash system with detergent at 180 degrees. If something additional decontamination of cages is recommended, the IBC recommends they be autoclaved.
- 2. The IBC requests clarification as to whether the functioning toggle switch be demonstrated in vitro (in S. carnosus) prior to use in rats?

# 4. Gentry-Weeks, Claudia

Agent: Bacillus cereus NOT biovar anthracis – Strain: any; BSL2

Agent: Bacillus subtilis – Strain: any; BSL2

**Agent:** Aeromonas hydrophila – Strain: any; BSL2

**Agent:** Pasteurella multocida – Strain: any; BSL2

**Agent:** Acinetobacter haemolyticus – Strain: any; BSL2

**Agent:** Pseudomonas fluorescens – Strain: any; BSL2

**Agent:** Pseudomonas putida – Strain: any; BSL2

**Agent:** Staphylococcus xylosus – Strain: any; BSL2

Agent: Vibrio parahaemolyticus – Strain: any; BSL2

# The committee unanimously approved of the above agents with the following to be addressed:

- 1. Please provide the Building name of storage location for each agent.
- 2. Is this ready to use cavicide or is there a dilution with it? If yes, what is the percentage?

#### IV. Unfinished business

1. BRB Shutdown/Renovation update

and provided an update on the shutdown progress. The commissioning of the Imaging Suite has been delayed until February so that equipment can be moved prior to going hot; they were having a hard time finding movers that would go into the "hot" lab space. Construction is scheduled to begin March 3, 2019.

#### 2. October National Biosafety Month

Dr. Ellen Fisher presented the top RAM Safe Pledge department the Golden Googles trophy at the department chair breakfast on December 12<sup>th</sup>, the second and third place certificates were also presented at this time.

#### **V.New Business**

No new business to report.

#### VI. Reports.

- 1. Coordinator's report.
  - a. Next IBC meeting: Wednesday, January 16, 2019 Happy New Year!
- 2. Biosafety Officer's report.
  - a. Incident reports there were a couple of needle sticks, both are following up with Occupational Health; one involved a recombinant agent and will require an incident report to NIH. No other outside reporting required.
  - **b. Inspections** CSU submitted its response to the ED inspection by the CDC; now waiting for reply
  - Laboratory audit reports wrapping up South Campus audits, IDRC (
     ), select agent inventory audits, all look good.
- VII. Agent and Project Approval Request Forms Reviewed at Previous IBC Meeting and Approved After Modification to be read into the minutes.
  - 1. Schountz, Tony

**Agent:** Cedar virus – Strain: any; BSL2

**Project:** Experimental infection of Jamaican fruit bats with Cedar virus (18-086B); BSL3 in vitro; BSL3 in vivo in bats. NIH Guidelines category non-exempt rDNA: NA

2. Peebles, Christie

**Agent:** Staphylococcus carnosus – Strain: BSL1

**Project:** Generation of a biosensor to enhance olfaction (18-087B); BSL1 in vitro, rDNA. NIH Guidelines category non-exempt rDNA: III-D-2

3. Jackson, Mary

Agent: Mycobacterium haemophilum – Strain: DSM 44634; BSL2

4. Robertson, Gregory

**Agent:** Neisseria gonohoreae – Strain: ATCC #49226; BSL2

- VIII. New or Amended Agent Approval Request Forms Reviewed and Approved by the <u>Biosafety Officer</u> or Chair to be read into the minutes.
- IX. New or Amended Project Approval Request Forms Reviewed and Approved by the <u>Biosafety Officer</u> or <u>Chair</u> to be read into the minutes.
  - 18-091 BOWEN, RICHARD Passive protection of mice from MERS CoV infection; BSL3 IN VITRO; BSL3 IN VIVO IN MICE. NIH Guidelines category non-exempt rDNA: NA

Meeting adjourned: 1:39pm

# Approved Minutes Institutional Biosafety Committee

# January 16, 2019

Check if Attending (Members):	Check if Attending (Alternate Members):
	Lon Kendall, Director LAR
Heather Blair, Assistant Biosafety Officer	Robert Ellis, <b>Director of Biosafety</b>
Richard Bowen, Associate Chair	
Patrick Byrne, <b>Plant expert</b> Departed at	
<u>12</u> :46pm	
Chaoping Chen, <b>Chair</b>	
Sam Hendrix, <b>Unaffiliated</b>	
⊠Angelo Izzo, Arrived 12:08pm	
Nicole Marlenee, <b>Lab tech rep</b>	
June Medford, Plant/syn bio expert	
Ken Olson	
Ann Powers	
Bernard Rollin, <b>Bioethicist</b>	
Non-Voting Members:	
☐ James Graham, EHS Director	
Mike Weil, Ad-hoc, Radiation Biologist	
RICRO Staff (non-voting):	Regular Guests (non-voting):
Christine Johnson, Senior IBC Coordinator	Claudia Gentry-Weeks, Associate BSO
Karen Dobos, RICRO Director	Sara Cope, Assistant Biosafety Officer
Christa Johnson, Associate Vice President for	☐ Joni Van Sickle, Occupational Health
Research	Coordinator/Assistant Biosafety Officer
Other: JJ Nelson, RICRO Administrator; Anthony Appleton, Research Safety Culture Coordinator;	
Joanie Ryan, IBC Intern	

This meeting was convened at 12:03pm and temporarily adjourned at 12:04pm and reconvened at 12:08pm. Quorum was maintained throughout. Any member with a conflict of interest left the room during discussion and/or committee determination on the conflicted item.

## I. Review of December 12, 2018 IBC meeting minutes.

The committee unanimously approved of December meeting minutes with no changes.

II. Review of Agent and Project Request Forms (https://protocols.research.colostate.edu/rco).

1. Geornaras, Ifigenia

**Agent:** Listeria spp. – Strain: Any; BSL2

The committee unanimously approved of the above agent with the following to be addressed:

1. The IBC requests chemical disinfectant be added to the method of inactivation for disposal.

**Project:** Microbial ecology of Listeria spp. in a newly constructed meat processing plant (19-001B); BSL2 in vitro. NIH Guidelines category non-exempt rDNA: N/A

## The committee unanimously approved of the above project with the following to be addressed:

- 1. Addition of a statement to the Project Overview as to what will happen to the Listeria cultures after storage at -80; for example, will they be used for later experiments for which will later approval will be requested or will they simply be held in storage.
- 2. The IBC recommends the use of eye protection

#### 2. Bowen, Richard

**Project:** Burkholderia pseudomallei: Evaluation of PEP regimens for laboratory exposure (19-003B); BSL3 in vitro and BSL3 in vivo in Goats. NIH Guidelines category non-exempt rDNA: N/A

#### The committee unanimously approved of the above project with the following to be addressed:

The Select Agent requirements are becoming more stringent; an amendment will be required for this project.

There was a discussion as to why they are using goats for this work; goats are susceptible to the agent and are a manageable size.

## 3. Kendall, Lon

**Agent:** Adeno-associated virus – Strain: Any; BSL1

#### The committee unanimously approved of the above agent with the following to be addressed:

- 1. Dr. Kendall's IBC training has expired and needs to be completed.
- 2. The IBC requests confirmation that the agent is or is not pathogenic to animals.
- 3. The IBC requests confirmation that the agent is or is not the wild type virus.
- 4. The IBC requests the PI indicate where the virus is being received from.
- 5. The IBC requests a room for the storage location be provided.

**Project:** AAV gene therapy to enhance endurance (19-004B); BSL2 in vivo in Mice. NIH Guidelines category non-exempt rDNA: III-D-4

# The committee unanimously approved of the above project with the following to be addressed:

- 1. Will the vector integrate into the mouse genome?
- 2. The IBC request the PI update his statement of experience.
- 3. The IBC recommends the use of eye protection.

## 4. Garrity, Deborah

**Project:** The cardiac jelly plays a role in supplying mechanical cues for heart valve development (19-005B); rDNA. NIH Guidelines category non-exempt rDNA: III-D-4

#### The committee unanimously approved of the above project with the following to be addressed:

- 1. A statement needs to be added to the Project Overview indicating that 'zebrafish' embryos will be used.
- 2. The NIH Guidelines requires all liquid and solid waste containing recombinant or synthetic nucleic acid molecules (including animals) be appropriately decontaminated prior to disposal. If the lab does not have access to an autoclave, the euthanized zebrafish can be bagged and LAR contacted for autoclaving.

#### 5. Borlee, Brad

**Agent:** Zika virus – Strain: any; BSL2

The committee unanimously approved of the above agent as submitted.

#### 6. Spencer, John

Agent: Mycobacterium leprae – Strain: any; BSL2

# The committee unanimously approved of the above agent with the following to be addressed:

- 1. The IBC requests the building be added to the storage location.
- 2. The IBC requests confirmation that the usage status is remaining as STORED or changing to ACTIVE.
- 3. Antibiotic resistance was marked YES. The IBC request clarification to whether this is naturally occurring resistance.
- 4. Indication of whether a chemical disinfectant is to be used in addition to autoclaving.

Agent: Mycobacterium haemophilum – Strain: any; BSL2

### The committee unanimously approved of the above agent with the following to be addressed:

- 1. The building needs to be added to the storage location.
- 2. Indication of whether a chemical disinfectant is to be used in addition to autoclaving.
- 3. Clarification of the necessity of a CDC or USDA permit.

# III. Unfinished business

### 1. BRB shutdown/renovation – update

provided an update on the shutdown progress. The large decon recently passed with a few hiccups such as not taking into consideration that would not have an autoclave. The move is on schedule with freezers being relocated today. There will be a second decon at the end of January, with the rest of the massive clean up before the final decon.

### IV. New Business

## 1. Updated Biosafety Manual

Ms. Blair described key changes to the manual. The last update was in 2016. Currently, the manual is 67 pages. Some key changes include addition of recombinant synthesis of DNA, decontamination method for kill tanks, a section regarding eye protection, updates to occupational health, reduction in redundancies of PI responsibilities, and a section regarding leur-loc syringes which is also recommended for BSL2. The updated manual along with a document notating the key changes will be sent out for IBC review.

## 2. IBC Membership - suggestion to add IBC Coordinator as alternate member

Addition of the IBC Coordinator as an alternate member would help the committee achieve quorum when needed. Other institutions include the IBC Coordinator as a member; setting precedent for this addition. Also at CSU both the IACUC and IRB have their coordinators as members. The committee did not voice any concerns to making this change.

The committee unanimously approved the addition of the IBC Coordinator as an alternate member.

# V.Reports.

# 1. Coordinator's report.

- a. An incident report was submitted to NIH/OSP on 1/15/18 regarding the incident with recombinant M. smeg that was talked about last meeting.
- b. Next IBC meeting: Wednesday, February 13, 2019

## 2. Biosafety Officer's report.

- a. Incident reports- one incident involved a cut from the door to the men's shower in the men's degowning room. The individual was asked to file an incident report and a workman's compensation report which have not been received yet. This situation has occurred before in the woman's locker room of the suites. To help prevent recurrence, a sign will be added to the door for both locker rooms. The second incident happened in the dirty cage wash of the A STERIS employee was putting in a new part and nearly sliced off their finger; they are following up with their occ health. It was treated as a BBP spill. No outside reporting required for either incident.
- **b. Inspections** a renewal inspection for Select Agents through the CDC is tentatively scheduled the week of May 6<sup>th</sup>-10<sup>th</sup>. The unannounced CDC inspection resulted in a request for more information regarding the effluent decontamination system. Dr. Bob Ellis is responding to that request.
- c. Laboratory audit reports- overall going well.

# VI. Agent and Project Approval Request Forms Reviewed at Previous IBC Meeting and Approved After Modification to be read into the minutes.

1. Nelson, Brad

**Agent:** Staphylococcus aureus – Strain: any; BSL2

**Project:** Forcast Ortho - Investigation of an Antibiotic Dispensing Spacer for eradication of arthroplasty infection using an ovine model (18-094B); BSL2 in vitro and BSL2 in vivo in sheep. NIH Guidelines category non-exempt rDNA: NA

2. Peebles, Christie

**Project:** Olfaction Enhancement Sensor Testing (18-095B); BSL1 in vitro and BSL1 in vivo in rats, rDNA. NIH Guidelines category non-exempt rDNA: III-D-4

3. Gentry-Weeks, Claudia

Agent: Bacillus cereus NOT biovar anthracis – Strain: any; BSL2

Agent: Bacillus subtilis – Strain: any; BSL2

**Agent:** Aeromonas hydrophila – Strain: any; BSL2

Agent: Pasteurella multocida – Strain: any; BSL2

Agent: Acinetobacter haemolyticus – Strain: any; BSL2

Agent: Pseudomonas fluorescens – Strain: any; BSL2

Agent: Pseudomonas putida – Strain: any; BSL2

Agent: Staphylococcus xylosus – Strain: any; BSL2

Agent: Vibrio parahaemolyticus – Strain: any; BSL2

4. Goodrich, Laurie

**Agent:** IGFscAAV2 – Strain: any; BSL2

**Agent:** IL1ra-scAAV2 – Strain: any; BSL2

**Project:** Development of diagnostic and treatment strategies for post-traumatic osteoarthritis (PTOA) (18-088B); BSL2 in vitro; BSL1 in vivo in equine, rDNA. NIH

Guidelines category non-exempt rDNA: III-D-4

**Project:** Localized Gene Therapy for Prolonged Anti-Inflammatory Treatment to Prevent of Delay PTOA in an Equine Model (18-089B); BSL2 in vitro; BSL1 in vivo in equine, rDNA. NIH Guidelines category non-exempt rDNA: III-D-4

VII. New or Amended Agent Approval Request Forms Reviewed and Approved by the <u>Biosafety Officer</u> or Chair to be read into the minutes.

VIII. New or Amended Project Approval Request Forms Reviewed and Approved by the <u>Biosafety Officer</u> or <u>Chair</u> to be read into the minutes.

Meeting adjourned: 1:00pm

# Approved Minutes Institutional Biosafety Committee

February 13, 2019

Check if Attending (Members):	Check if Attending (Alternate Members):
	Lon Kendall, <b>Director LAR</b>
Donald Bade, <b>Unaffiliated</b>	
Heather Blair, Assistant Biosafety Officer	Robert Ellis, <b>Director of Biosafety</b>
Richard Bowen, <b>Associate Chair</b> – leaves at	
12:37pm	
Patrick Byrne, <b>Plant expert</b> -leaves at 12:46pm	
Chaoping Chen, <b>Chair</b>	
Sam Hendrix, <b>Unaffiliated</b>	
Angelo Izzo, Arrived 12:08pm	
$\square$ Nicole Marlenee, <b>Lab tech rep</b> – leaves at	
12:37pm	
∑June Medford, <b>Plant/syn bio expert</b>	
Ken Olson	
Ann Powers	
Bernard Rollin, <b>Bioethicist</b>	
Non-Voting Members:	
☐ James Graham, EHS Director	
Mike Weil, Ad-hoc, Radiation Biologist	
RICRO Staff (non-voting):	Regular Guests (non-voting):
Christine Johnson, Senior IBC Coordinator	Claudia Gentry-Weeks, Associate BSO
Karen Dobos, RICRO Director	Sara Cope, Assistant Biosafety Officer
Christa Johnson, Associate Vice President for	☐ Joni Van Sickle, Occupational Health
Research	Coordinator/Assistant Biosafety Officer
Other: JJ Nelson, RICRO Administrator, Joanie Ryan,	IBC Intern

This meeting was convened at 12:02pm and temporarily adjourned at 12:35pm and reconvened at 12:37pm. Quorum was maintained throughout. Any member with a conflict of interest left the room during discussion and/or committee determination on the conflicted item.

## I. Review of January 16, 2018 IBC meeting minutes.

The committee unanimously approved of January meeting minutes with no changes.

# II. Review of Agent and Project Request Forms (https://protocols.research.colostate.edu/rco).

1. Spencer, John

**Project:** <u>Use of Immunological and Genetic Markers to Understand Infection and Transmission of Mycobacterium leprae in Brazil (19-006B); BSL2 in vitro. NIH Guidelines category non-exempt rDNA: N/A</u>

# The committee unanimously approved of the above project with the following to be addressed:

- 1. Dr. Spencer's Statement of Experience explains how the agents will be handled, but does not actually describe his training. The IBC requests of Dr. Spencer provide a brief description of his training and experience with biohazardous agents.
- 2. Under the Human-origin materials section, it states "Human skin tissue biopsy material fixed in 70% ethanol." Will 70% Ethanol fix the tissue? The requests confirmation that this is the fixative being use.

- 3. The IBC recommends the use of safety glasses for BSL2 procedures.
- 4. needs to be added when arrives

## 2. Belisle, John

Agent: Mycobacterium kansasii

The committee unanimously approved of the above agent with the following to be addressed:

The IBC requests the human risk group be changed from 1 to 2.

**Project:** Analyses of non-tuberculosis Mycobacterium (19-013B); BSL2 in vitro, rDNA. NIH Guidelines category non-exempt rDNA: III-D-2

The committee unanimously approved of the above project as submitted, once the associated agent has been approved.

# 3. Vigh, Joseph

Agent: Adeno-Associated Virus (AAV)—Strain: Any; BSL1

The committee unanimously approved of the above agent with the following to be addressed:

- 1. The agent description indicates that the vectors will be received as plasmid. The IBC requests clarification of who is making the actual virus; it is recommended to perform this at BSL2
- 2. Confirm access to a biosafety cabinet
- 3. The IBC suggest autoclaving be added as a method of inactivation.

**Project:** Use of Adeno Associated Virus (AAV) vectors to transfect retinal neurons in vivo (19-009); BSL1 in vitro and in vivo. NIH Guidelines category non-exempt rDNA: III-D-4

The committee unanimously approved of the above project with the following to be addressed:

- 1. The IBC recommends the intraocular injections be conducted in a biosafety cabinet. If this is not feasible, the PI should describe the procedures that are done in place of using a cabinet.
- 2. The IBC recommends that the in vivo work be conducted at BSL2 and to consult with LAR regarding the appropriate animal rooms.
- 3. LAR must be notified when the PI is ready to start an ABSL2 or Recombinant DNA molecule animal study in order to prepare the correct space and equipment. The PI should fill out the LAR ABSL2 Animal Housing Form when ordering animals for this project. The form can also be found on LAR's website under the eAnimal Ordering Info tab.

# 4. Gentry-Weeks, Claudia

**Agent:** Bacillus mojavensis—Strain: Any, BSL1

The committee unanimously approved of the above agent as submitted.

#### 5. Kruh-Garcia, Nicole

**Agent:** Mycobacterium tuberculosis—Strain: H37Rv leucine/pantothenate auxotroph, BSL2

The committee unanimously approved of the above agent with the following to be addressed:

- 1. The agent name should be Mycobacterium tuberculosis with the strain being H37Rv leucine/pantothenate auxotroph
- 2. The human risk group should be 2
- 3. A chemical disinfectant should be added the Methods used to inactivate agent for disposal.

**Project:** Secretion analysis of Mycobacterium tuberculosis avirulent auxotroph (19-011B); BSL2 in vitro. NIH Guidelines category non-exempt rDNA: N/A

The committee unanimously approved of the above project with the following to be addressed:

- 1. The IBC requests clarification as to what is meant by "the same fraction produced by virulent M. tuberuclosis H37Rv". Where/how are the fractions from virulent M. tuberculosis being produced?
- 2. The IBC requests that statement "there are no safety concerns" be removed.

#### 6. Crans, Debbie

Agent: Chlorobaculum tepidum – Strain: any; BSL1

## The committee unanimously approved of the above agent with the following to be addressed:

- 1. Dr. Crans' experience states experience for experience with biohazardous agents for Dr. Crans.
- 2. For the storage location, please indicate the building and room.
- 3. Under methods of inactivation for disposal, the IBC requests the percent for the bleach used be added.

**Project:** Impact of Rhenium on Green Sulfur Bacteria (19-014B); BSL1 in vitro. NIH Guidelines category non-exempt rDNA: N/A

# The committee unanimously approved of the above project as submitted, once the associated agent has been approved.

There was a discussion as to why they are using a fume hood instead of a biosafety cabinet; this is because of the potential for sulfur to be released from the media that the bacteria grow in.

# 7. Bowen, Richard

**Project:** Evaluation of a Coxiella vaccine in mice (19-015B); BSL3 in vitro and BSL3 in vivo in mice, rDNA. NIH Guidelines category non-exempt rDNA: III-D-2, III-D-4

#### The committee unanimously approved of the above project with the following to be addressed:

Clarification of whether a biosafety cabinet is being used for in vivo work

**Project:** Anthrax Vaccine Efficacy Against Diverse Strains of Bacteria (19-016B); BSL3 in vitro and BSL3 in vivo in rabbits, DURC agent. NIH Guidelines category non-exempt rDNA: N/A

# The committee unanimously approved of the above project with the following to be addressed:

Clarification of whether a biosafety cabinet is being used for in vivo work

**Project:** <u>DeltaFLU interference study in ferrets</u> (19-017B); BSL2 in vitro and BSL3 in vivo in ferrets. NIH Guidelines category non-exempt rDNA: III-D-4

## The committee unanimously approved of the above project with the following to be addressed:

- 1. Clarification of whether a biosafety cabinet is being used for in vivo work
- 2. Only the PI is listed on the PARF; the IBC requests any additional personnel be added to the PARF.

**Project:** <u>Virulence of Environmental Isolates of Burkholderia pseudomallei</u> (19-018B); BSL3 in vitro and BSL3 in vivo in mice. NIH Guidelines category non-exempt rDNA: N/A

#### The committee unanimously approved of the above project with the following to be addressed:

- 1. In the Project Overview, it is unclear what the first sentence (A new influenza virus potently induces interferon) has to do with the rest of the overview. The IBC requests a bit more information to clarify.
- 2. The IBC requests confirmation that the in vivo work will be done at BSL3.

## III. Unfinished business

1. BRB shutdown/renovation – update

provided an update on the shutdown progress. All suites are in the seven day waiting period to ensure they pass decon. There have been some good lessons learned in the process but overall it is going better than expected.

#### 2. Updated Biosafety Manual

The updated biosafety manual has been reviewed by the IBC, and one item remains. The BSO suggested that the use of leur-lock syringes used at BSL2 be changed from a recommended practice to a required practice. The IBC discussed this and unanimously approved the recommended change.

#### IV. New Business

None

#### V.Reports.

#### 1. Coordinator's report.

- **a.** NIH/OSP incident report submitted 1/15/18 received a response 2/1/19 with no further action requested; this incident is considered closed.
- b. The IBC Membership now includes the Sr. IBC Coordinator as an alternate member; she will only act as a voting member when needed for quorum.
- c. The next IBC meeting is Wednesday, March 13, 2019
- d. The is holding their IBC conference June 11-13, 2019

# 2. Biosafety Officer's report.

#### a. Incident reports-

- i. An individual stuck themselves with a needle while working with a dog that had been inoculated with Coccidioides posadasii. The individual has consulted with Occ Health; treatment is not recommended as the risk of infection is low. No outside reporting required.
- **ii.** There was a protocol breach in the BSL3 staging area; PI contacted biosafety and personnel have been notified. No outside reporting required.
- iii. There were several incidents (cut to the hand, splash to the eye, and scratch to the hand) surrounding the same group of dogs that are part of a rabies study. PPE changes have been suggested and additional eyewashes have been placed at the kennels. No outside reporting required.
- b. Inspections- The renewal inspection for Select Agents through the CDC has been scheduled for May 6<sup>th</sup>-10<sup>th</sup>. Dr. Ellis sent in a response for monitoring the effluent decontamination system.
- c. Laboratory audit reports- going well.
- **d. Near misses-** There has been very good reporting of near misses recently.

# VI. Agent and Project Approval Request Forms Reviewed at Previous IBC Meeting and Approved After Modification to be read into the minutes.

## 1. Geornaras, Ifigenia

Agent: Listeria spp. – Strain: Any; BSL2

**Project:** Microbial ecology of Listeria spp. in a newly constructed meat processing plant (19-001B); BSL2 in vitro. NIH Guidelines category non-exempt rDNA: N/A

#### 2. Bowen, Richard

**Project:** Burkholderia pseudomallei: Evaluation of PEP regimens for laboratory exposure (19-003B); BSL3 in vitro and BSL3 in vivo in Goats. NIH Guidelines category non-exempt rDNA: N/A

## 3. Kendall, Lon

Agent: Adeno-associated virus – Strain: Any; BSL1

**Project:** AAV gene therapy to enhance endurance (19-004B); BSL2 in vivo in Mice. NIH Guidelines category non-exempt rDNA: III-D-4

## 4. Garrity, Deborah

**Project:** The cardiac jelly plays a role in supplying mechanical cues for heart valve development (19-005B); rDNA. NIH Guidelines category non-exempt rDNA: III-D-4

5. Spencer, John

Agent: Mycobacterium leprae – Strain: any; BSL2

Agent: Mycobacterium haemophilum – Strain: any; BSL2

VII. New or Amended Agent Approval Request Forms Reviewed and Approved by the <u>Biosafety Officer</u> or Chair to be read into the minutes.

VIII. New or Amended Project Approval Request Forms Reviewed and Approved by the <u>Biosafety Officer</u> or Chair to be read into the minutes.

- 1. 18-093 FOY, BRIAN TRACKING ANTIMALARIAL RESISTANCE IN MOSQUITO POPULATIONS; BSL2 IN VITRO; BSL3 IN VIVO IN MOSQUITOES
- 2. 19-002 Brown, Samantha The Role of Sleep in the Health and Well-Being of Children and Families; Human Samples
- 3. 19-007 Foster, Michelle Protein Analysis of Hormone Factors Associated with Stage 1-3 Lipedema Adipose Tissue; Human Samples
- 4. 19-008 Kruh-Garcia, Nicole High-purity extracellular vesicle isolation from blood and sorting by MS-defined surface epitopes; Human Samples

Meeting adjourned: 12:58pm

# Approved Minutes Institutional Biosafety Committee

# March 20, 2019

Check if Attending (Members):	Check if Attending (Alternate Members):	
☑Jessica Ayers, <b>Animal expert</b> left 4:11pm	Lon Kendall, <b>Director LAR</b>	
Donald Bade, <b>Unaffiliated</b>		
Heather Blair, Assistant Biosafety Officer	Robert Ellis, <b>Director of Biosafety*</b>	
Richard Bowen, Associate Chair		
Patrick Byrne, <b>Plant expert</b>	Christine Johnson, <b>Senior IBC Coordinator</b> ,	
	Alternate-at-Large	
Chaoping Chen, <b>Chair</b>		
Sam Hendrix, <b>Unaffiliated</b>	*non-voting at this meeting	
⊠Angelo Izzo, Arrived 12:08pm		
Nicole Marlenee, Lab tech rep		
June Medford, Plant/syn bio expert		
Ken Olson		
Ann Powers		
Bernard Rollin, <b>Bioethicist</b>		
Non-Voting Members:		
☐ James Graham, EHS Director		
Mike Weil, Ad-hoc, <b>Radiation Biologist</b>		
	Regular Guests (non-voting):	
RICRO Staff (non-voting):	Claudia Gentry-Weeks, Associate BSO	
Karen Dobos, <b>RICRO Director</b>	Sara Cope, Assistant Biosafety Officer	
Christa Johnson, Associate Vice President for		
Research Coordinator/Assistant Biosafety Officer		
Other: Angie Chromiak, RICRO Administrator, Joanie Ryan, IBC Intern, Anthony Appleton, Research		
Safety Culture Coordinator		

This meeting was convened at 3:04pm. Quorum was maintained throughout. Any member with a conflict of interest left the room during discussion and/or committee determination on the conflicted item.

# I. Review of February 13, 2019 IBC meeting minutes.

The meeting minutes for February are not available at this time.

II. Review of Agent and Project Request Forms (<a href="https://protocols.research.colostate.edu/rco">https://protocols.research.colostate.edu/rco</a>).

## 1. Dow, Steven

**Agent:** Klebsiella pneumonia—Strain: Any; BSL2

The committee unanimously approved of the above agent with the following to be addressed:

- 1. The IBC requests more information in the agent description.
- 2. The IBC requests that the building location be spelled out for clarity and the room number added.
- 3. The Human Risk category and Biosafety Level should be changed from 1 to 2.
- 4. Pathogenic for animals should be change from NO to YES.
- 5. The IBC requests that Dr. Dow update his Statement of experience to include information about the types of agents and assays he has worked with, how long he has worked with the agents, and the types of trainings he has completed.

**Project:** Antimicrobial Cellular Therapy for Treatment of Bacterial Pneumonia (19-020B); BSL2 in vitro and in vivo in mice. NIH Guidelines category non-exempt rDNA: N/A

#### The committee unanimously approved of the above project with the following to be addressed:

- 1. The source of mesenchymal stem cells needs to be clarified (human, mouse, other).
- 2. If a biosafety cabinet is not used during mouse work, the IBC recommends the use of safety glasses when conducting work with mice.
- 3. Personnel listed on this project are due for updating their BSL1/BSL2 Online Training.

## 2. Moreno, Julie

**Agent**: Prion – Strain: mouse, cervid, and sheep; BSL2

#### The committee unanimously approved of the above agent with the following to be addressed:

- 1. The IBC requests that the specific Prions be identified under the strain; for example, Scrapie, CWD, etc., instead of mouse, cervid, and sheep.
- 2. The Human Risk category should be changed from 1 to 2.
- 3. Pathogenic for animals should be changed from NO to YES.
- 4. The IBC requests more information in the agent description.

**Project:** Cell therapeutics for prion diseases (19-023B); BSL2 in vitro BSL1 in vivo, rDNA. NIH Guidelines category non-exempt rDNA: N/A

## The committee unanimously tabled the above project with the following to be addressed:

- 1. The IBC requests clarification of the genetic editing mechanism by which the olfactory neuronal precursors (ONPs) are rendered prion resistant.
- 2. Aim 2 states: "we will determine if we are able to revert a genetic prion disease through genetically editing transgenic ONPs expressing a mutation for a genetic human prion disease Gerstmann-Straussler-Scheinker syndrome (GSS)." The IBC requests more information for how the transgenic ONPs are going to be genetically edited to expresses the human mutation for GSS.
- 3. The IBC requests description of how genetically edited AdMSCs that produce a secreted dominant negative prion protein will be made
- 4. The IBC requests identification of the specific prions used in the project (Scrapie, CWD, etc) and how each of them will be used.
- 5. The IBC requests that the statement regarding "no safety concerns" be removed.
- 6. The IBC requests the following updates to the in-vivo use section:
  - a. The BSL should be changed from 1 to 2
  - b. The IBC recommends safety glasses for in vivo work
  - c. Clarification regarding the use of a biosafety cabinet
  - d. The room in which the in-vivo work will be performed should be added once it is available

## 3. Bowen, Richard

**Project:** <u>Vaccine efficacy for biodefense pathogens</u> (19-025); BSL3 in vitro and in vivo. NIH Guidelines category non-exempt rDNA: III-D-2, DURC

The committee unanimously approved of the above project as submitted.

**Project:** <u>Indications Against Highly Pathogenic Agents for a Transportable Pathogen</u> <u>Reduction and Blood Safety System for Whole Blood (</u>19-027); BSL3 in vitro. NIH Guidelines category non-exempt rDNA: N/A, DURC

## The committee unanimously approved of the above project with the following to be addressed:

1. Personnel listed on this project must complete the Blood-borne Pathogen training

## 4. Hansen, Thomas

**Agent:** Mannheimia hemolytica—Strain: Any; BSL2

#### The committee unanimously approved of the above agent with the following to be addressed:

- 1. The IBC requests that a room number be added to the storage location.
- 2. The Human Risk category should be changed from 1 to 2.
- 3. Personnel listed on this Agent application must complete the CSU IBC online training.

#### 5. MacNeill, Amy

**Project:** Post-operative Administration of Myxoma Virus to Reduce Recurrence of Soft <u>Tissue Sarcomas in Dogs</u> (19-026); BSL2 in vitro and in vivo in dogs. NIH Guidelines category non-exempt rDNA: III-D-1 and III-D-4

## The committee unanimously tabled the above project with the following to be addressed:

- 1. The IBC requests clarification regarding the timeline and virus shedding testing in a chronological list format including the following information:
  - a. At what point will the patients be released and what is the criteria regarding viral shedding prior to release?
    - i. Is there data to support the aforementioned release criteria that confirms that there is no viral shedding?
  - b. When will the patients be tested for viral shedding post-surgery?
  - c. What will happen if a patient tests positive for viral shedding at each timepoint?
- 2. The IBC requests that information regarding surgical procedures and items not related to the Biosafety aspect of the project be removed to reduce confusion. Any information concerning individuals who may contact the virus (the laboratorian making the virus, the clinicians administering the virus, and the owners of the patients) and containment of the virus in areas where the virus will be present (the laboratory in which it is made, the clinic where it is administered, the home where the patients recover, etc.) should be stated. Details regarding surgery and care for the patient will be reviewed by the IACUC.
- 3. The IBC highly recommends the use of permanent needle syringe or leur-lock syringe needle combination as well as the use of safety glasses when injecting animals.
- 4. The IBC states that confirmation of USDA permit is required for approval.

## 6. Kading, Rebekah

**Agent:** West Nile Virus—Strain: Any, BSL2

# The committee unanimously approved of the above agent with the following to be addressed:

1. The IBC requests that a room number for the storage location be added.

Agent: Entebbe bat virus—Strain: Any, BSL2

#### The committee unanimously approved of the above agent with the following to be addressed:

1. The IBC requests that a room number for the storage location be added.

**Project:** Surveillance of mosquito and arbovirus dispersal using smart microcrystals (19-032B); BSL3 in vitro and in vivo mosquitoes. NIH Guidelines category non-exempt rDNA: N/A

#### The committee unanimously approved of the above project with the following to be addressed:

- The IBC requests confirmation that infected mosquitoes are not being released into the environment
  at any point and a that statement be added to the Project Overview indicating that infected
  mosquitoes are only being used as positive controls to test the beacon-laden crystals and there will
  be no release of infected mosquitoes.
- 2. The IBC requests that the detailed information regarding field work for aim #3 which is not necessary for assessing the biosafety risks associated with the project be removed to reduce confusion.
- 3. The IBC requests clarification as to whether lab coats are being used in the BSL3 or not.

#### 7. Schountz, Tony

Agent: Nipah virus VLP —Strain: Any, BSL1

#### The committee unanimously approved of the above agent with the following to be addressed:

1. The IBC requests that information regarding the specific composition of the VLP communicated through email be added to the application.

**Project:** Bat immune responses to Nipah virus VLPs (19-031); BSL1 in vitro and BSL2 in vivo bats. NIH Guidelines category non-exempt rDNA: N/A

## The committee unanimously approved of the above project with the following to be addressed:

- 2. The IBC requests that information regarding the specific composition of the VLP communicated through email be added to the application.
- 3. In-vitro work should be conducted at BSL 2.
- 4. The IBC recommends eye protection for BSL 2 in vivo work particularly during transfer to and from the biosafety cabinet.
- The IBC requests clarification regarding bat serum handling and location of testing for seroconversion.

## 8. Ellis, Robert

**Agent:** Clostridium perfringens—Strain: Any, BSL2 – storage only

## The committee unanimously approved of the above agent with the following to be addressed:

- 1. The IBC requests that the PI add a Statement of Experience regarding his work with biohazardous materials to the IBC database.
- 2. The PI needs to update his IBC Training through the online database.

## III. Amendments to be reviewed by full committee

#### 1. Pearce, Stephen

**Project:** Optimization of Winter Wheat (Triticum aestivum) Transformation (18-054B); P-BL1 in vitro and P-BL1 in vivo in Triticum aestivum. NIH Guidelines category non-exempt rDNA: III-E-2

# Amended to add transgenic plant growth in greenhouse

# The committee unanimously approved of the above project amendment with the following to be addressed:

- 1. The IBC requests that greenhouse bay be inspected by the BSO and/or IBC plant expert.
- 2. The IBC had no additional comments/concerns, and deferred to the IBC plant experts for review and recommendations of the amendment.

#### IV. Unfinished business

#### 1. BRB shutdown/renovation - update

Dr. Ellis reported that the renovation has begun. The prediction is six months until completion. Updates include floor replacement, HVAC system maintenance, emergency lighting installation, and baulin-tube additions. Addressing the bowing walls is going to be re-communicated to the contractors. On a side note, construction for the Center for Vector Borne Diseases (CVBD) will begin in May. The expected timeline is 9 months. This 42,000 square foot addition will include a modern insectary BSL2 and Arthropod BSL2 space.

## **V.New Business**

None

# VI. Reports.

## 1. Coordinator's report.

a. Next IBC meeting: Wednesday, April 10, 2019

## 2. Biosafety Officer's report.

- a. Incident reports- Two reported incidents were presented. One incident is a reoccurring protocol breach that involved to PI's. The BSO communicated with both and is awaiting a response from one of the groups regarding preventative action. The second incident involved a select agent infected animal bite. The BSO has reported to CDC and is filing a form 3. The individual is doing well after treatment and the last serology will be performed on March 25<sup>th</sup>.
- **b. Inspections-** Select agent renewal inspection by the CDC is scheduled for May 6<sup>th</sup>-10<sup>th</sup>. The BSO is waiting for information requests to prepare for this ahead of time.
- c. Laboratory audit reports- TB lab audits are beginning shortly
- **d. Personnel-** The BSO is working on getting approval for additional personnel as Dr. Ellis is set to retire in July 2020.

# VII. Agent and Project Approval Request Forms Reviewed at Previous IBC Meeting and Approved After Modification to be read into the minutes.

1. Spencer, John

Project: <u>Use of Immunological and Genetic Markers to Understand Infection and Transmission of Mycobacterium leprae in Brazil (</u>19-006B); BSL2 in vitro. NIH Guidelines category non-exempt rDNA: N/A

2. Belsile, John

Agent: Mycobacterium kansasii—Strain: Any; BSL2

3. Vigh, Joseph

Agent: Adeno-Associated Virus (AAV)—Strain: Any; BSL1

**Project:** <u>Use of Adeno Associated Virus (AAV) vectors to transfect retinal neurons in vivo (19-009); BSL1 in vitro and in vivo. NIH Guidelines category non-exempt rDNA: III-D-4</u>

4. Kruh-Garcia, Nicole

**Agent:** Mycobacterium tuberculosis—Strain: H37Rv leucine/pantothenate auxotroph, RSI 2

**Project:** Secretion analysis of Mycobacterium tuberculosis avirulent auxotroph (19-011B); BSL2 in vitro. NIH Guidelines category non-exempt rDNA: N/A

5. Crans, Debbie

Agent: Chlorobaculum tepidum – Strain: any; BSL1

6. Bowen, Richard

**Project:** Evaluation of a Coxiella vaccine in mice (19-015B); BSL3 in vitro and BSL3 in vivo in mice, rDNA. NIH Guidelines category non-exempt rDNA: III-D-2, III-D-4

**Project:** Anthrax Vaccine Efficacy Against Diverse Strains of Bacteria (19-016B); BSL3 in vitro and BSL3 in vivo in rabbits, DURC agent. NIH Guidelines category non-exempt rDNA: N/A

**Project:** DeltaFLU interference study in ferrets (19-017B); BSL2 in vitro and BSL3 in vivo in ferrets. NIH Guidelines category non-exempt rDNA: III-D-4

**Project:** <u>Virulence of Environmental Isolates of Burkholderia pseudomallei</u> (19-018B); BSL3 in vitro and BSL3 in vivo in mice. NIH Guidelines category non-exempt rDNA: N/A

# VIII. New or Amended Agent Approval Request Forms Reviewed and Approved by the <u>Biosafety Officer</u> or Chair to be read into the minutes.

1. Gentry Weeks, Claudia

Agent: Xantamonas campestris—Strain: any; BSL1 Agent: Brevundimonas species—Strain: any, BSL1

Agent: Bacillus safensis—Strain: any, BSL1

2. Winkelman, Dana

Agent: Myxobolus cerebralis—Strain: any, BSL1

3. Charkowski, Amy

Agent: Pseudomonas syringae—Strain: any, BSL1

Agent: Erwinia species—Strain: any, BSL1 Agent: Brennaria—Strain: any, BSL1

# IX. New or Amended Project Approval Request Forms Reviewed and Approved by the <u>Biosafety Officer</u> or Chair to be read into the minutes.

- 1. 19-010B Winkelman, Dana; Bacterial Coldwater Disease and Whirling Disease duel exposures; BSL1 in vivo and in vitro. NIH Guidelines category non-exempt rDNA: N/A
- 2. 19-014 Crans, Debbie; Impact of Rhenium on Green Sulfer Bacteria; BSL1 in vitro. NIH Guidelines category non-exempt rDNA: N/A
- 3. 19-024 Lark, Daniel; Examining the impact of exercise and body composition on plasma exosomes; Human Samples. NIH Guidelines category non-exempt rDNA: N/A
- 4. 19-033 Kading, Rebekah; Vector competence of Colorado Mosquitoes for Rift Valley fever virus; BSL3 in vivo and in vitro. NIH Guidelines category non-exempt rDNA: N/A

Meeting adjourned: 4:28pm

# Approved Minutes Institutional Biosafety Committee

# April 10, 2019

Check if Attending (Members):	Check if Attending (Alternate Members):	
<b>⊠</b> Jessica Ayers, <b>Animal expert</b>	Lon Kendall, <b>Director LAR</b>	
Donald Bade, <b>Unaffiliated</b>		
Heather Blair, Assistant Biosafety Officer	Robert Ellis, <b>Director of Biosafety*</b>	
Richard Bowen, <b>Associate Chair</b>		
Patrick Byrne, <b>Plant expert</b> left at 12:47PM	Christine Johnson, <b>Senior IBC Coordinator</b> ,	
	Alternate-at-Large*	
Chaoping Chen, <b>Chair</b>		
Sam Hendrix, <b>Unaffiliated</b>	*non-voting at this meeting	
Angelo Izzo, Arrived 12:08pm		
⊠Nicole Marlenee, <b>Lab tech rep</b>		
☑June Medford, <b>Plant/syn bio expert</b>		
Ken Olson		
Ann Powers		
Bernard Rollin, <b>Bioethicist</b>		
Non-Voting Members:		
☐ James Graham, EHS Director		
Mike Weil, Ad-hoc, Radiation Biologist		
	Regular Guests (non-voting):	
RICRO Staff (non-voting):	Claudia Gentry-Weeks, Associate BSO	
Karen Dobos, RICRO Director	Sara Cope, Assistant Biosafety Officer	
Christa Johnson, Associate Vice President for		
Research	Coordinator/Assistant Biosafety Officer	
Other: Angie Chromiak, RICRO Administrator, Joanie Ryan, IBC Intern		

This meeting was convened at 12:08. Quorum was maintained throughout. Any member with a conflict of interest left the room during discussion and/or committee determination on the conflicted item.

# I. Review of February 13, 2019 IBC meeting minutes.

The committee unanimously approved the February minutes with no changes.

II. Review of Agent and Project Request Forms (https://protocols.research.colostate.edu/rco).

#### 1. Bowen, Richard

**Project:** Burkholderia vaccine (McMillian) (19-035B); BSL3 in vitro and in vivo in mice. NIH Guidelines category non-exempt rDNA: N/A, DURC Agents

The committee unanimously approved of the above agent with the following to be addressed:

The IBC requests that the room number for in vitro work be confirmed.

# 2. Hansen, Thomas

**Project:** BVDV Compromises Fetal Immune Organ Development Leading to Post-Natal Predisposition to Secondary Infections (19-037); BSL2 in vitro and in vivo in cows. NIH Guidelines category non-exempt rDNA: N/A

The committee unanimously approved of the above agent with the following to be addressed:

- 1. IBC records indicate that the last biosafety audit for this lab was completed in May 2015; the committee requests that an audit be scheduled with the Biosafety Office.
- 2. When using trizol in a biosafety cabinet, the IBC recommends that the cabinet be Class IIB2 or one with a Thimble connection.

#### 3. Thamm, Douglas

**Project:** Cellular Immunotherapy for Canine Cancers (19-038B); BSL1 in vitro; BSL2 in vivo in mice, rDNA. NIH Guidelines category non-exempt rDNA: III-D-4

## The committee unanimously tabled the above project with the following to be addressed:

- 1. The IBC requests that an AARF be submitted for the lentiviral vector indicated in this project.
- 2. Lentiviral work should be performed at BSL2, thus the IBC requests that the in vitro BSL be changed from 1 to 2.
- 3. Information provided in the Project Overview indicated in vivo work with mice, however this is not indicated in the in vivo section which is marked no. The IBC requests clarification of any in vivo work planned for this study and that information regarding this work be included.
- 4. The IBC requests that the methods of containment for the non-exempt rDNA section be updated to include containment and inactivation methods.

## 4. Borlee, Brad

Agent: Enterobacter bugandensis – Strain: any; BSL2

# The committee unanimously approved of the above agent with the following to be addressed:

- 1. The IBC requests that more information regarding the agent be added to the description.
- 2. The IBC requests that the answer for "Pathogenic for animals including humans?" be changed from NO to YES.

**Project:** Enterobacter virulence in mice (19-039B); BSL2 in vitro and BSL2 in vivo in mice. NIH Guidelines category non-exempt rDNA: N/A

## The committee unanimously approved of the above project with the following to be addressed:

- 1. The IBC asks that in vivo work be performed in a biosafety cabinet and if this is not possible, information regarding containment is requested.
- 2. The IBC requests that be removed from the in vitro work section as this is an animal room.

# III. Amendments to be reviewed by full committee

## 1. Aspelund, Amy

**Project:** Replication deficient H5N1 influenza vaccine (18-079B); BSL2 in vitro, rDNA. NIH Guidelines category non-exempt rDNA: III-D-7.

Amendment request to add: H7N9 influenza vaccine strains to this project.

## The committee unanimously approved of the above project amendment with the following to be addressed:

- 1. The IBC requests that all personnel listed on the project register with the IBC database, fill out a statement of experience, and complete the online IBC training.
- 2. The IBC discussed that the investigator and Biosafety Office are working with the USDA to re-confirm that these agents are exempt from the Federal Select Agent Program.

## 2. Schountz, Tony

**Agent: Cedar virus** 

**Project:** Experimental infection of Jamaican fruit bats with Cedar virus (18-086B); BSL3 in vitro and BSL3 in vivo in bats. NIH Guidelines category non-exempt rDNA: N/A

Amendment request to lower the in vivo containment level from BSL3 to BSL2.

The committee unanimously denied the above amendment request for the following reasons:

- 1. Currently there is not enough safety data regarding this agent, particularly in bats, to support a reduction in containment.
  - a. The IBC discussed that while this agent does not appear to cause disease in bats, there are several other examples where similar viruses do not cause disease in bats but have the capacity to cause significant disease in other species. An example is Hendra virus, which is genetically similar to Cedar virus.
  - b. The IBC found the detection of virus in bat urine (in the original publication) to be of concern and felt that the mechanisms of transmission need to be evaluated further, prior to lowing the level.
- 2. The IBC requests that all work remain at BSL3, including in vitro work, as described in the approved project. Should more safety data become available, the committee will consider additional amendment requests regarding this agent and project.

#### IV. Unfinished business

1. MacNeill, Amy – TABLED from March meeting

**Project:** Post-operative Administration of Myxoma Virus to Reduce Recurrence of Soft <u>Tissue Sarcomas in Dogs</u> (19-026); BSL2 in vitro and in vivo in dogs. NIH Guidelines category non-exempt rDNA: III-D-1 and III-D-4

The committee unanimously approved the above project with the following to be addressed:

Documentation from the USDA granting approval to conduct this work in client animals is required for final approval.

#### 2. Pearce, Stephen - TABLED from March meeting

PARF: Optimization of Winter Wheat (Triticum aestivum) Transformation (18-054B); P-BL1 in vitro and P-BL1 in vivo in Triticum aestivum. NIH Guidelines category non-exempt rDNA: III-E-2

Amended to add transgenic plant growth in greenhouse

The committee unanimously approved the above project with the following to be addressed:

The IBC requests confirmation that there is an SOP in place to check the integrity of the insect screens on a regular basis.

visited the greenhouse. Everything was in good order, with controlled entry, water decontamination methods, and aphid screens. The investigator is very consciences and experienced. The work being done is not hazardous, but could be bad if it got out.

#### 3. Moreno, Julie - TABLED from March meeting

**Project:** Cell therapeutics for prion diseases (19-023B); BSL2 in vitro BSL1 in vivo, rDNA. NIH Guidelines category non-exempt rDNA: N/A

The committee unanimously tabled the above project pending information requested at the March 20<sup>th</sup> 2019 meeting.

#### 4. BRB shutdown/renovation--update

provided information that the renovation is going well. The movers for moving items back in are looking at the space and forming a plan. Concerns regarding the bowing walls in the dirty hallway have been recommunicated to the planning committee and a quote for replacement has been requested. Emergency lighting is being added to prevent complete black out in the event of a power outage.

#### **V.New Business**

#### 1. IBC Membership Update

A new community member needs to be recruited because commitment is complete on June 30<sup>th</sup> 2019. The commitment has requested that suggestions be submitted to her by the end of the month. She will send a description of the role and time expectations so that information is available when discussing the opportunity. The committee discussed the qualifications for one individual who has been contacted and felt they were very similar to the BSO. The committee also spoke about the necessity for the individual to be a Fort Collins community member and the possibility of a new perspective from a medical doctor as previous members of the medical community brought interesting perspectives to the IBC.

#### 2. October Biosafety Month—Biosafety Fair

To build on the momentum and success of the previous Biosafety Month, we planning to host a Biosafety Fair, which would be a fun and educational event. A subcommittee was formed for planning the first Biosafety Fair. Members on the subcommittee include, Christine Johnson, Heather Blair, Joanie Ryan, Chaoping Chen, and Jessica Ayers. The subcommittee will identify a mission, audience, and scope for the event to be presented to the full committee. Members are requested to think about any sponsors or connections that might be interested in helping with this event.

# VI. Reports.

#### 1. Coordinator's report.

a. Next IBC meeting: Wednesday, May 8th, 2019

#### 2. Biosafety Officer's report.

- a. Incident reports- Two incidents and one near miss were reported.
  - i. There was a potential exposure to Q fever due to a goat abortion at the Veterinary Teaching Hospital. Biosafety and Occupational Health were immediately notified. The BSO filed Form 3 and Form 4 with the Select Agent Program. Occupational health has contacted all individuals who were potentially exposed. No one has sought medical consultation, but they are aware that they can.
  - **ii.** An individual was putting an Eppendorf tube into liquid nitrogen for storage and the tube exploded. The BSO is working with the lab to determine if the agrobacterium in the tube was disarmed or not to verify the rDNA status.
  - **iii.** An individual was removing a cow brain for rabies testing and some drops of blood got on their arm. This cow was confirmed positive for rabies. The individual is vaccinated and confirmed to have acceptable titer in February of this year. A near miss safety concern was filed with the BSO and Occupational Health.
- **b. Inspections-** Information regarding the Select Agent Program renewal inspection, scheduled for May 6-10, is being gathered.
- c. Laboratory audit reports- TB lab audits are happening soon.

# VII. Agent and Project Approval Request Forms Reviewed at Previous IBC Meeting and Approved After Modification to be read into the minutes.

1. Bowen, Richard

**Project:** Indications Against Highly Pathogenic Agents for a Transportable Pathogen Reduction and Blood Safety System for Whole Blood (19-027); BSL3 in vitro. NIH Guidelines category non-exempt rDNA: N/A, DURC

2. Hansen, Thomas

Agent: Mannheimia hemolytica—Strain: Any; BSL2

3. Kading, Rebekah

**Agent:** West Nile Virus—Strain: Any, BSL2 **Agent**: Entebbe bat virus—Strain: Any, BSL2

**Project:** <u>Surveillance of mosquito and arbovirus dispersal using smart microcrystals</u> (19-032B); BSL3 in vitro and in vivo mosquitoes. NIH Guidelines category non-exempt rDNA: N/A

4. Schountz, Tony

Agent: Nipah virus VLP —Strain: Any, BSL1

**Project:** Bat immune responses to Nipah virus VLPs (19-031); BSL1 in vitro and BSL2 in vivo bats. NIH Guidelines category non-exempt rDNA: N/A

5. Ellis, Robert

**Agent:** Clostridium perfringens—Strain: Any, BSL2 – storage only

- VIII. New or Amended Agent Approval Request Forms Reviewed and Approved by the <u>Biosafety Officer</u> or Chair to be read into the minutes.
- IX. New or Amended Project Approval Request Forms Reviewed and Approved by the <u>Biosafety Officer</u> or Chair to be read into the minutes.
  - 1. Easley, Jeremiah

**Project:** Angiocrine-Evaluation of engineered endotheial cells for the treatment of intervertebral disc degeneration (19-028); BSL1 in vitro. NIH Guidelines category non-exempt rDNA: N/A

2. Boss, Mary-Keara

**Project:** <u>Human lung cancer xenograft pilot study in mice</u> (19-030); BSL2 in mice. NIH Guidelines category non-exempt rDNA: N/A

3. Kato, Takamitsu

**Project:** Radiation biology project with human cell lines (19-022); BSL2 in vitro. NIH Guidelines category non-exempt rDNA: N/A

4. Quakenbush, Sandra

**Project:** CDK8 regulation of immune response and metabolic gene expression during Zika virus infection (19-029(; BSL2 in vitro. NIH Guidelines category non-exempt rDNA: N/A

Meeting adjourned: 1:31pm

# Approved Minutes Institutional Biosafety Committee

# May 8, 2019

Check if Attending (Members):	Check if Attending (Alternate Members):
Jessica Ayers, Animal expert	Lon Kendall, <b>Director LAR</b>
☑Donald Bade, <b>Unaffiliated</b>	
Heather Blair, Assistant Biosafety Officer	Robert Ellis, <b>Director of Biosafety</b>
Richard Bowen, Associate Chair	
Patrick Byrne, <b>Plant expert</b> left at 12:44PM	Christine Johnson, <b>Senior IBC Coordinator</b> ,
	Alternate-at-Large*
Chaoping Chen, <b>Chair</b>	
Sam Hendrix, <b>Unaffiliated</b>	*non-voting at this meeting
⊠Angelo Izzo,	
Nicole Marlenee, <b>Lab tech rep</b>	
June Medford, Plant/syn bio expert	
Ken Olson	
Bernard Rollin, <b>Bioethicist</b>	
Non-Voting Members:	
Mike Weil, Ad-hoc, <b>Radiation Biologist</b>	
	Regular Guests (non-voting):
RICRO Staff (non-voting):	Claudia Gentry-Weeks, Associate BSO
Karen Dobos, <b>RICRO Director</b>	Sara Cope, Assistant Biosafety Officer
Christa Johnson, <b>Associate Vice President for</b>	
Research	Coordinator/Assistant Biosafety Officer
Other: Joanie Ryan, IBC Intern, Anthony Appleton, S	afety Culture Coordinator

This meeting was convened at 12:04. Quorum was maintained throughout. Any member with a conflict of interest left the room during discussion and/or committee determination on the conflicted item.

# I. Review of March 20, 2019 and April 10, 2019 IBC meeting minutes.

The committee unanimously approved the March and April minutes with no changes.

II. Review of Agent and Project Request Forms (https://protocols.research.colostate.edu/rco).

1. Borlee, Brad

**Agent:** Dengue viruses—Strain: any; BSL2

The committee unanimously approved of the above agent with the following to be addressed:

The IBC requests that the percentage and type of Clorox be added to the methods used to inactivate the agent for disposal.

# 2. Goodrich, Laurie

Agent: Staphylococcus aureus—Strain: equine clinical isolate; BSL2

The committee unanimously approved of the above agent with the following to be addressed:

1. The IBC requests additional information regarding the agent itself and the type of infection/disease it causes.

2. The IBC discussed that double-bagging prior to autoclaving is no longer recommended and requests that the PI contact the Biosafety Office for more information.

**Project:** Antimicrobial properties of equine mesenchymal stem cells (19-041B); BSL2 in vitro and in vivo in horses. NIH Guidelines category non-exempt rDNA: N/A

#### The committee unanimously approved of the above project with the following to be addressed:

- 1. The IBC requests clarification for the type of hood described as "bacteriology hood" to confirm that it is a biological safety cabinet (BSC).
- 2. The IBC requests information regarding the disposal of the animals after the study.
- 3. The IBC would like to confirm that the lab space has been audited by a biosafety officer. If an audit has not been performed, one will need to be scheduled.

#### 3. Bosco-Lauth, Angela

Agent: West Nile Virus—Strain: any; BSL3

#### The committee unanimously approved of the above agent with the following to be addressed:

- 1. The IBC requests that the agent description include more information about the virus and the type of infection/disease it causes.
- 2. The IBC asks that the spelling of Arbovirus in the agent description be corrected.
- 3. The IBC requests a room number be added for the storage location.
- 4. The IBC requests the addition of a chemical disinfectant to the Methods for inactivation.

**Project:** West Nile virus interspecies and environmental transmission (19-043B); BSL3 in vitro and in vivo in birds, alligators, and hamsters. NIH Guidelines category non-exempt rDNA: N/A

#### The committee unanimously approved of the above project with the following to be addressed:

- 1. The IBC requests confirmation that a PAPR will be used for in vitro work as indicated on the form.
- 2. Both face shield and PAPR were indicated for in vivo work. The IBC requests confirmation as to when these will be used.
- 3. The IBC requests more information regarding the terrarium in order to confirm the mechanism for secondary containment.
- 4. The IBC requests more details regarding the containment of the mosquitoes during terrarium use.

#### 4. Handa, Robert

Agent: Recombinant AdenoAssociated Viral particles—Strain: any; BSL1

## The committee unanimously approved of the above agent with the following to be addressed:

- 1. The agent description mentions Adenovirus helper virus. The IBC requests the following information regarding the material being received:
  - a. Is the material being received already inactivated? If so, what is the mechanism for inactivation?
  - b. How are the rAAV particles isolated?
  - c. How is the helper virus inactivation verified?
- 2. The IBC requests a brief description of the recombinant protein that is being expressed.

**Project:** Estrogen Regulation of the hypothalamus-pituitary-adrenal axis (19-044B); BSL1 in vivo in mice. NIH Guidelines category non-exempt rDNA: III-D-4

## The committee unanimously approved of the above project with the following to be addressed:

- 1. The Project Overview references a novel transgenic mice. The IBC requests information regarding the source of these mice.
- 2. Following infection of the mice, it is recommended that cages are labeled with a biohazard sticker for the first 72 hours and that no cages are open during this time unless absolutely necessary. If a cage must be opened, it should be done in a BSC.

- 3. The IBC requests that the cage bedding and animals be autoclaved prior to disposal.
- 4. The IBC asks that the acronym DREDD be described out and the statement "no safety concerns" be removed.
- 5. All investigators need to be registered with the IBC database and complete a statement of experience. Additionally, all individuals using a biosafety cabinet must complete the Biosafety Cabinet Training.

## 5. Reynolds, Stephen

Agent: Staphylococcus aureus (MRSA)—Strain: any; BSL2

#### The committee unanimously approved of the above agent with the following to be addressed:

1. The IBC requests that the agent name be changed to Staphylococcus aureus and the strain changed to "any, including MRSA".

## 6. Ebel, Gregory

**Project:** Emergence of Tick Borne Encephalitis North America (19-045B); BSL3 in vitro and in vivo in ticks, guinea pigs, and mice. NIH Guidelines category non-exempt rDNA: III-D-1

#### The committee unanimously approved of the above project with the following to be addressed:

- 1. Because reverse genetics with POWV is not part of the current project, the IBC requests that the information be removed and a future amendment be submitted when/if necessary.
- 2. The IBC requests that mice and guinea pigs be added to the species exposed to the agent under the in vivo uses section.
- 3. The IBC requests clarification as to whether a biosafety cabinet will be used when handling animals.
- 4. The IBC recommends that all investigators listed on a project complete the IBC at CSU online training.

#### 7. Thamm, Douglas

**Agent:** <u>3<sup>rd</sup> generation SIN (self-inactivating) lentiviral vector</u>—Strain: any; BSL2

# The committee unanimously approved of the above agent with the following to be addressed:

1. The IBC requests that human risk group be changed from 1 to 2.

#### III. Unfinished business

1. Moreno, Julie – TABLED from March meeting

**Project:** Cell therapeutics for prion diseases (19-023B); BSL2 in vitro BSL1 in vivo, rDNA. NIH Guidelines category non-exempt rDNA: N/A

The committee unanimously tabled the above project pending information requested at the March 20<sup>th</sup> 2019 meeting.

# 2. Thamm, Douglas-TABLED from April meeting

**Project:** Cellular Immunotherapy for Canine Cancers (19-038B); BSL1 in vitro; BSL2 in vivo in mice, rDNA. NIH Guidelines category non-exempt rDNA: III-D-4

## The committee unanimously tabled the above project with the following to be addressed:

1. The IBC requests that the in vivo biosafety level be changed from 1 to 2.

# 3. BRB shutdown/renovation--update

No update was provided as the Biosafety Officers were absent for the ongoing Select Agent Program Renewal audit.

#### 4. IBC Membership Update

The committee received the CV for an additional candidate to serve as an unaffiliated member beginning July 1<sup>st</sup> 2019. In order to give sufficient time for reviewing the CVs of the two potential members, the committee will vote by email to finalize the new member so that the candidate can be presented to the Vice President for Research and receive onboarding training before the July meeting.

## 5. October Biosafety Month—Biosafety Fair

Four dates were proposed: October 9<sup>th</sup>, 10<sup>th</sup>, 16<sup>th</sup> or 17<sup>th</sup> based on space availability at . The IBC decided to request October 9<sup>th</sup> pending final availability. The event will be held in half of a ballroom with a six hour window, allotting approximately two hours for set up and clean up. The IBC members are asked to email or bring any activity ideas to the Senior Coordinator.

## IV. New Business

#### 1. Polio virus survey

The IBC reviewed a request sent to the chair by the CDC requesting assistance disseminating a survey to PIs about potential possession of poliovirus containing samples. It was discussed that the IBC chair, IBC Senior Coordinator, RICRO Director, EHS Director, and Vice President for Research have begun the initial steps for sending the information out. An email has been sent to the deans, department heads, and directors. An email to PIs registered with the IBC is forthcoming.

#### 2. Changes to the NIH Guidelines

The IBC Senior Coordinator will present the recent changes to the NIH Guidelines at the June meeting. The main changes are related to human gene transfer trials. Of note, the appendices have changed and the online CSU IBC training will be updated to reflect the changes.

## V.Reports.

#### 1. Coordinator's report.

a. Next IBC meeting: Wednesday, June 12th, 2019

b. RICRO has had some staffing changes.

is on

leave until the first week of June.

# 2. Biosafety Officer's report.

- **a. Incident reports-** One incident originally reported at the April meeting was followed up on. Three incidents and one near miss were reported.
  - i. Follow up: An individual was putting an Eppendorf tube into liquid nitrogen for storage and the tube exploded. It was determined that the tube contained Agrobacterium tumefaciens carrying rice DNA. Because this agent is BSL1, it was determined that a report with the NIH is not required.
  - ii. An individual was leaving through and waiting for the gate to close behind them when a white dodge ram skirted the waiting individual and entered the gated area without swiping their access card. The individual reentered the area to record a photo of the vehicle and reported the incident to the BSO and RBL BSL3 manager. The police were called, the owner of the vehicle was identified and their supervisor notified.
  - iii. An individual was drawing blood from a Mycobacterium tuberculosis infected mouse when they passively capped the needle. It bent and punctured through the plastic cap and into the individual's left middle finger. The individual washed the wound with soap and water, then contacted the BSO and Occupation Health. They have an appointment scheduled for medical follow up. No outside reporting required.

- iv. An individual was vaccinating a heifer restrained in a headlock with RB51 brucellosis vaccine and poked their left index finger after injecting the vaccine. The individual cleaned the wound with alcohol and betadine scrub. Occupational Health was contacted and a worker's compensation incident report was filed. No outside reporting required.
- v. Near miss: During BSL3 training the trainer was showing the unisex shower and degowing area as the emergency evacuation location. When they tried to re-enter into the BSL3 dirty corridor the door would not open. The trainer used the fire alarm procedure to enter back into the pod 3 area to open the unisex door for the others being trained. The BSO was informed and it was determined that the door must be pulled and then pushed open after a successful access card scan. The BSO is posting a sign for that door to alert other users.
- **b. Inspections-** The Select Agent Program renewal inspection is ongoing and expected to be completed by Friday, May 10<sup>th</sup> 2019.
- c. Laboratory audit reports- None to report at this time.
- VI. Agent and Project Approval Request Forms Reviewed at Previous IBC Meeting and Approved After Modification to be read into the minutes.
  - 1. Bowen, Richard

**Project:** Burkholderia vaccine (McMillian) (19-035B); BSL3 in vitro and in vivo in mice. NIH Guidelines category non-exempt rDNA: N/A, DURC Agents

2. Hansen, Thomas

**Project:** BVDV Compromises Fetal Immune Organ Development Leading to Post-Natal Predisposition to Secondary Infections (19-037B); BSL2 in vitro and in vivo in cows. NIH Guidelines category non-exempt rDNA: N/A

3. Borlee, Brad

**Agent:** Enterobacter bugandensis – Strain: any; BSL2

**Project:** Enterobacter virulence in mice (19-039B); BSL2 in vitro and BSL2 in vivo in mice. NIH Guidelines category non-exempt rDNA: N/A

4. Dow, Steven

Agent: Klebsiella pneumoniae – Strain: any, BSL2

**Project:** Antimicrobial Cellular Therapy for Treatment of Bacterial Pneumonia (19-020B); BSL3 in vitro and BSL2 in vivo mice. NIH Guidelines category non-exempt rDNA: N/A

- VII. Amended Project or Agent approval Request Forms Reviewed at Previous IBC Meeting and Approved After Modification to be read into the minutes.
  - 1. Aspelund, Amy

**Project:** Replication deficient H5N1 influenza vaccine (18-079B); BSL2 in vitro, rDNA. NIH Guidelines category non-exempt rDNA: III-D-7.

Amendment request to add: H7N9 influenza vaccine strains to this project.

2. Pearce, Stephen – TABLED from March meeting

**Project:** Optimization of Winter Wheat (Triticum aestivum) Transformation (18-054B); P-BL1 in vitro and P-BL1 in vivo in Triticum aestivum. NIH Guidelines category non-exempt rDNA: III-E-2

Amended to add transgenic plant growth in greenhouse

- VIII. New or Amended Agent Approval Request Forms Reviewed and Approved by the <u>Biosafety Officer</u> or Chair to be read into the minutes.
  - 1. Winkelman, Dana

Agent: Renibacterium salmoninarum (Rsal)—Strain: any; BSL1

2. Bowen, Richard

Agent: Coccidioides immitis/posadasii—Strain: any; BSL3

Amended to add posadasii designation

3. Thamm, Douglas

Agent: E. coli—Strain: DH5a, Top10; BSL1

4. Wyckoff, John

**Agent:** WEVEE Viral Replicon Particle (VRP)—Strain: VEEV V3014VRP; BSL3 Amended to change Neutral Q concentration from 2% to 7% as method for inactivation.

**Agent:** Venezuelan Equine Encephalitis virus (vaccine strain)—Strain: Vaccine strain TC-83; BSL 2

Amended to change Neutral Q concentration from 2% to 7% as method for inactivation.

- IX. New or Amended Project Approval Request Forms Reviewed and Approved by the <u>Biosafety Officer</u> or <u>Chair</u> to be read into the minutes.
  - 1. Ordway, Diane

**Project:** Experimental Testing of Novel Therapeutic (19-021B); BSL2 in vitro and in vivo in mice. NIH Guidelines category non-exempt rDNA: N/A

2. Bowen, Richard

**Project:** <u>Innate Immunity: Antimicrobial Pepties and Sepsis</u> (19-036B); BSL2 in vitro and in vivo in mice. NIH Guidelines category non-exempt rDNA: N/A

3. Winkelman, Dana

**Project:** <u>Transmission of Renibacterium salmoninarum in Colorado Native Greenback</u> <u>Trout</u> (19-040B); BSL1 in vitro and in vivo in trout. NIH Guidelines category non-exempt rDNA: N/A

4. Ordway, Diane

**Project:** <u>Pathogenesis of Mycobacterium abscessus Reinfection</u> (19-042B); BSL2 in vitro and in vivo in mice. NIH Guidelines category non-exempt rDNA: N/A

Meeting adjourned: 1:07pm Minutes recorded by C. Johnson

# Approved Minutes Institutional Biosafety Committee

June 12, 2019

Check if Attending (Members):	Check if Attending (Alternate Members):	
	Lon Kendall, <b>Director LAR</b>	
Donald Bade, <b>Unaffiliated</b>		
Heather Blair, Assistant Biosafety Officer	Robert Ellis, <b>Director of Biosafety</b>	
Richard Bowen, <b>Associate Chair</b>		
Patrick Byrne, <b>Plant expert</b> left at 12:44PM	Christine Johnson, <b>Senior IBC Coordinator</b> ,	
	Alternate-at-Large*	
Chaoping Chen, <b>Chair</b>		
Sam Hendrix, <b>Unaffiliated</b>	*non-voting at this meeting	
⊠Angelo Izzo,		
Nicole Marlenee, Lab tech rep		
June Medford, <b>Plant/syn bio expert</b>		
Ken Olson		
⊠Ann Powers		
Bernard Rollin, <b>Bioethicist</b>		
Non-Voting Members:		
Mike Weil, Ad-hoc, Radiation Biologist		
	Regular Guests (non-voting):	
RICRO Staff (non-voting):	Claudia Gentry-Weeks, <b>Associate BSO</b>	
Karen Dobos, <b>RICRO Director</b>	Sara Cope, Assistant Biosafety Officer	
Christa Johnson, Associate Vice President for		
Research	Coordinator	
Other: Ryan Clark, RICRO Business and Operations Manager		

This meeting was convened at 12:00. Quorum was maintained throughout. Any member with a conflict of interest left the room during discussion and/or committee determination on the conflicted item.

## I. Introduction of Ryan T. Clark

The new Business and Operations Manager for RICRO was introduced to the committee.

## II. Review of May 8, 2019 IBC meeting minutes.

The committee unanimously approved the March and April minutes with no changes.

- III. Review of Agent and Project Request Forms (https://protocols.research.colostate.edu/rco).
  - 1. Ehrhart, Nicole

**Project:** Muscle Stem Cells Reprogrammed Through Genome Engineering for Autonomously Regulated Anti-Fibrotic Therapy (19-049); BSL1 in vitro and in vivo in mice. NIH Guidelines category non-exempt rDNA: III-E-1

# The committee unanimously approved of the above project with the following to be addressed:

1. The committee requests clarification regarding animal disposal and whether they will be submitted to the tissue digester or if LAR will dispose of them under their procedures.

#### Regan, Daniel

Agent: Infectious bursal disease virus—Strain: any, BSL2

#### The committee unanimously approved of the above agent with the following to be addressed:

- 1. The IBC requests that autoclave be added to the methods used to inactivate the agent for disposal.
- 2. The IBC requests a reference for the specific concentrations of chemical disinfectant listed, and confirmation that they inactivate this virus.

**Project** Infectious bursal disease virus as a novel oncolytic agent for B cell lymphoma (19-050); BSL2 in vitro and in vivo in mice. NIH Guidelines category non-exempt rDNA: N/A

## The committee unanimously approved of the above project with the following to be addressed:

- 1. The IBC requests clarification regarding animal disposal and whether they will be submitted to the tissue digestor or if LAR will dispose of them under their procedures.
- 2. The IBC requests that autoclave and 10% bleach be included in the AARF since they are part of this project application.
- 3. The IBC requests all individuals listed on the project be registered with the Online IBC Database. Any unregistered investigators log in to the database complete a Statement of Experience, and complete the IBC at CSU online training.

## 3. Kruh-Garcia, Nicole

Agent: Mycobacterium africanum—Strain: any; BSL3

# The committee unanimously approved of the above agent with the following to be addressed:

- 1. The IBC requests that a storage location be listed for the agent.
- 2. The IBC requests confirmation that 5% Vesphene solution is to be used for agent inactivation prior to disposal as 2.5% is the typical concentration.

#### 4. Stewart, Jane

**Project:** <u>Understanding the impacts of forest pathogens in western forests in the presence of increased drought and warming climates (19-053); BSL1 in vivo. NIH Guidelines category non-exempt rDNA: N/A</u>

## The committee unanimously TABLED the above project with the following to be addressed:

- 1. The following agents require submission of an Agent Approval Request Form (AARF): Cytospora canker, Thousand Cankers, White Pine blister rust, and Lophodermella needle cast disease.
- 2. The IBC requests information regarding the PPE and methods of inactivation used for in vitro work.
- 3. The IBC requests identification of the host tree species to be inoculated.
- 4. The IBC requests information regarding the PPE and methods of inactivation for in vivo plant work.
- 5. The IBC requests that as well as the room numbers in the included.
- 6. The IBC requests a statement of experience from the investigator regarding previous work with biohazardous agents.

## 5. Kading, Rebekah

**Agent:** Asaia bogorensis—Strain: any; BSL1

## The committee unanimously approved of the above agent with the following to be addressed:

1. The IBC requests the concentration of Microchem plus be included in the methods used to inactivate agent for disposal.

**Project:** <u>Vaccination on the Fly: The Use of Mosquitoes to Vaccinate Bat Populations that Harbor Human Pathogens (19-054); BSL2 in vitro and in vivo in mosquitoes. NIH Guidelines category non-exempt rDNA: III-D-2</u>

#### The committee unanimously approved of the above agent with the following to be addressed:

1. There was some confusion regarding the biosafety levels as BSL1, 2, and 3 are all indicated in various places. The IBC requests clarification of what work will be done at each particular biosafety level.

#### 6. Bowen, Richard

**Agent:** Camelpox virus—Strain: any; BSL3

## The committee unanimously approved of the above agent.

This virus causes a mild disease in humans. It was confirmed that human risk group 2 is correct.

**Agent:** <u>Vaccinia-Coxiella vector</u>—Strain: any; BSL2

## The committee unanimously approved of the above agent with the following to be addressed:

1. The IBC requests that a chemical disinfectant be added to the methods of inactivation.

This agent is exempt from select agent regulations.

**Project:** <u>Susceptibility of Alpacas to Camelpox Virus</u> (19-055); BSL2 in vitro and in vivo in alpacas; NIH Guidelines category non-exempt rDNA: N/A

- 1. For added protection during animal work, the IBC recommends that investigators wear a cape hood piece if an N95 is not being worn under headpiece.
- 2. The IBC requests that a statement be added to indicate that access to animal rooms is restricted to vaccinated personnel.

#### 7. Rose, Ruth J

Agent: Staphylococcus aureus—Strain: any, BSL2

## The committee unanimously approved of the above agent with the following to be addressed:

- 1. The IBC requests more information about the properties of the agent for the Agent description section including where it is typically isolated and what kind of infection or disease it causes.
- 2. If MRSA is not to be used, the IBC requests that the agent strain be changed to "any, except MRSA".
- 3. The IBC requests that the type of Chlorox and concentration be added to the methods used to inactivate the agent for disposal.

**Project:** A novel acellular treatment for implant-associated osteomyelitis (19-056); BSL2 in vitro and in vivo in mice; NIH Guidelines category non-exempt rDNA: N/A

# The committee unanimously approved of the above project with the following to be addressed:

- 1. The IBC requests clarification regarding animal disposal and whether they will be submitted to the VDL tissue digestor or if LAR will dispose of them under their procedures.
- The IBC recommends that safety glasses be work when working with animals outside of the biosafety cabinet.

#### 8. Ehrhart, Nicole

**Project**: Effects of Circulating Factors and Progenitors on Wound healing during <u>Pregnancy</u> (19-057); BSL1 in vivo in mice; NIH Guidelines category non-exempt rDNA: III-E-3

## The committee unanimously approved of the above project with the following to be addressed:

- 1. The committee requests clarification regarding animal disposal and whether they will be submitted to the tissue digester or if LAR will dispose of them under their procedures.
- 2. The IBC recommends safety glasses be work when working with animals outside the biosafety cabinet.

#### 9. Chanda, Soham

Agent: Lentivirus (Recombinant)—Strain: any, BSL2

#### The committee unanimously approved of the above agent with the following to be addressed:

- Regarding the Agent description, the IBC requests that the information not specific to the agent be removed.
- 2. The IBC requests specification of which generation of lentiviral vectors will be used.
- 3. The IBC does not recommend disposing of disinfectant down the drain and instead recommends autoclaving all liquid and solid waste.
- 4. The IBC requests that the human risk group be changed from 3 to 2.

Agent: Adeno-Associated virus (recombinant)—Strain: any, BSL2

## The committee unanimously approved of the above agent with the following to be addressed:

- 1. Regarding the Agent description, the IBC requests that the information not specific to the agent be removed.
- 2. The IBC requests specification of which generation of Adeno-Assisted vectors will be used.
- 3. The IBC does not recommend disposing of disinfectant down the drain and instead recommends autoclaving all liquid and solid waste.
- 4. The IBC requests that autoclave be added under the Methods used to inactivate agent for disposal.

**Project:** Pathophysiology of Autism-Associated Neuroligin-4 Mutations in Human Neurons (19-059); BSL2 in vitro and human cell lines; NIH Guidelines category nonexempt rDNA: III-D-3

## The committee unanimously approved of the above project with the following to be addressed:

The IBC requests all individuals listed on the project be registered with the Online IBC Database. Any
unregistered investigators should log in to the database complete a Statement of Experience and
complete the IBC at CSU online training.

#### 10. Geornaras, Ifigenia

**Agent:** Campylobacter spp. – Strain: any; BSL2 (storage)

# The committee unanimously approved of the above agent with the following to be addressed:

1. The IBC requests that a storage location be listed for the agent.

#### 11. Bowen, Richard

**Project:** <u>Building Laboratory Diagnostic Capacity for Zoonotic Disease Risk Mitigation In Underserved Arid and Semi-Arid Areas of Kenya</u> (19-061B); BSL2 in vitro. NIH Guidelines category non-exempt rDNA: NA

#### The committee unanimously approved of the above project with the following to be addressed:

1. The IBC requests that a statement be added indicating the potential to collect and ship to entities in the US, and if this does happen an AARF would be submitted at that time.

#### 12. VandeWoude, Sue

**Agent:** <u>Microsporum spp, Trichophyton spp</u>.—Strain: M. Canis CBS113480 and field, M. gypseum, T. mentagrophytes; BSL2

## The committee unanimously approved of the above agent with the following to be addressed:

1. The IBC requests that autoclave be added to the Methods used to inactivate the agent for disposal.

**Project:** Pathogenesis and Development of a Rapid Diagnostic Test for Superficial Fungal Infections (Project 19-063B); BSL2 in vitro. NIH Guidelines category non-exempt rDNA: N/A

The committee unanimously approved of the above project with the following to be addressed:

The IBC requests all individuals listed on the project be registered with the Online IBC Database. Any
unregistered investigators should log in to the database complete a Statement of Experience and
complete the IBC at CSU online training.

#### IV. Amendments to be reviewed by full committee:

1. Bowen, Richard

**Project:** <u>Development of a T Cell-Based Vaccine for Q Fever (</u>14-069B); BSL 3 in vitro and in vivo in mice and guinea pigs; NIH Guidelines category non-exempt rDNA: III-D-2 **Amendment request to add Vaccinia-Coxiella vector for immunization.** 

#### The committee unanimously approved of the above amendment with the following to be addressed:

1. The IBC requests clarification as to the BSL at which the vaccine will be used.

#### V.Unfinished business

1.	<b>IBC</b>	Mem	bersh	ip U	pdate
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Beginning July 1, will be the Biosafety Officer member on the IBC and be the new unaffiliated member.

2. BRB shutdown/renovation—update

Currently the construction is on schedule and we are getting all the updates Biosafety requested.

3. October Biosafety Month—Biosafety Fair

A planning subcommittee has been formed and planning is underway. The event will be held on Wednesday, October 16, 2019.

4. Moreno, Julie--TABLED from March meeting – waiting for information from PI

**Project:** <u>Cell therapeutics for prion diseases</u> (19-023B); BSL2 in vitro BSL1 in vivo, rDNA. NIH Guidelines category non-exempt rDNA: N/A

#### VI. New Business

1. Request from Dr. Schountz to use KingFisher automated sample processor in BSL2 lab to process samples from BSL3 lab that have Cedar virus in them.

The plan would be to add the lysis buffer to the samples in the BSL3 and allow them to incubate the recommended time and then bring them out to the BSL2 where the KingFisher instrument it located. The IBC discussed this request and had the following questions/concerns: Does the lysis buffer inactivate the virus without putting in the machine; is there an instrument in BSL3 that could be used; concerned about vigorous shaking and aerosol generation; not too worried about Cedar virus, what are the possibilities of cross-contamination with other viruses. The IBC Coordinator will contact the PI regarding these questions and the request will be re-reviewed.

#### VII. Reports.

- 1. Coordinator's report.
  - a. Next IBC meeting: Wednesday, July 17th, 2019
  - b. Gene-editing in the news several recent articles were shared with the IBC:

## 2. Biosafety Officer's report.

- a. Incident reports
  - i. Needlestick The individual passively capped a needle after drawing blood from TB infected mouse heart. The needle bent and went through the cap, and stuck the individual in the finger. The individual contacted Biosafety and Occ Health. During the incident review meeting, suggestions for improving the process were identified. No additional reporting required

- ii. Mouse bite the individual was holding a mouse while it was coming out of anesthesia, as they were putting the mouse in the recovery area, it bit the individual's finger. The individual followed up with the Occ Health provider; provider feels it is low risk. There was discussion regarding re-training for mice handling. No additional reporting required.
- iii. Two near misses 1) Needles found in a pipet boat. Lab group informed and reminded of correct procedures. 2) During construction, one of the HEPA filter housing units was handled and removed. This was above a hallway and considered low risk. The individual was concerned about exposure and followed up with Occ Health.
- **b. Inspections** The Select Agent Program renewal inspection final report has not been received yet.
- c. Laboratory audit reports- BRB audits are finishing up. The next set of audits will be for the ARBL.

# VIII. Agent and Project Approval Request Forms Reviewed at Previous IBC Meeting and Approved After Modification to be read into the minutes.

1. Borlee, Brad

Agent: Dengue viruses—Strain: any; BSL2

2. Goodrich, Laurie

Agent: Staphylococcus aureus—Strain: equine clinical isolate; BSL2

Project: Antimicrobial properties of equine mesenchymal stem cells (19-041); BSL2 in

vitro and in vivo in horses. NIH Guidelines category non-exempt rDNA: N/A

3. Bosco-Lauth, Angela

Agent: West Nile Virus—Strain: any; BSL3

**Project:** West Nile virus interspecies and environmental transmission (19-043); BSL3 in vitro and in vivo in birds, alligators, and hamsters. NIH Guidelines category non-exempt rDNA: N/A

4. Reynolds, Stephen

Agent: Staphylococcus aureus (MRSA)—Strain: any; BSL2

5. Ebel, Gregory

**Project**: Emergence of Tick Borne Encephalitis North America (19-045); BSL3 in vitro and in vivo in ticks, guinea pigs, and mice. NIH Guidelines category non-exempt rDNA: III-D-1

6. Thamm, Douglas

**Agent:** <u>3<sup>rd</sup> generation SIN (self-inactivating) lentiviral vector</u>—Strain: any; BSL2 **Project:** <u>Cellular Immunotherapy for Canine Cancers</u> (19-038B); BSL1 in vitro; BSL2 in vivo in mice, rDNA. NIH Guidelines category non-exempt rDNA: III-D-4

- IX. Amended Project or Agent approval Request Forms Reviewed at Previous IBC Meeting and Approved After Modification to be read into the minutes.
- X. New or Amended Agent Approval Request Forms Reviewed and Approved by the <u>Biosafety Officer</u> or Chair to be read into the minutes.
- XI. New or Amended Project Approval Request Forms Reviewed and Approved by the <u>Biosafety Officer</u> or <u>Chair</u> to be read into the minutes.
  - 1. Akkina Ramesh

**Project:** Modeling Zika Viral Pathenogenesis in Humanized Mice (19-048B); BSL2 in vitro and BSL1 in vivo in mice. NIH Guidelines category non-exempt rDNA: N/A

2. Bowen, Richard

Project: Transmission of Monkeypox Virus in an Artificial Ecosystem (19-051B); BSL3 in vitro and in vivo in rodents. NIH Guidelines category non-exempt rDNA: N/A

# 3. Mattupalli, Chakradhar

Project: Management of foliar and soil-borne potato diseases in the San Luis Valley (19-052B); BSL1 in vitro. NIH Guidelines category non-exempt rDNA: N/A

Meeting adjourned: 1:34pm

# Approved Minutes Institutional Biosafety Committee

July 17, 2019

Check if Attending (Members):	Check if Attending (Alternate Members):
	Lon Kendall, <b>Director LAR</b>
Donald Bade, <b>Unaffiliated</b>	Robert Ellis, <b>Director of Biosafety*</b>
Richard Bowen, <b>Associate Chair</b>	Christine Johnson, <b>Senior IBC Coordinator</b> ,
	Alternate-at-Large*
Patrick Byrne, <b>Plant expert</b>	
Chaoping Chen, <b>Chair</b>	*non-voting at this meeting
Sara Cope, Assistant Biosafety Officer	
Angelo Izzo, <b>Mycobacteria Immunology</b>	
⊠Nicole Marlenee, <b>Lab tech rep</b>	
June Medford, <b>Plant/syn bio expert</b>	
Edwin Neas, <b>Unaffiliated</b>	
Ken Olson, <b>Virology</b>	
Bernard Rollin, <b>Bioethicist</b>	
Non-Voting Members:	
James Graham, EHS Director	
RICRO Staff (non-voting):	Regular Guests (non-voting):
Karen Dobos, <b>RICRO Director</b>	Claudia Gentry-Weeks, Associate BSO
Christa Johnson, Associate VP for Research	Heather Blair, Associate Biosafety Officer
	☐ Joni Van Sickle, Occupational Health Coord.
Other:	

This meeting was convened at 12:01. Quorum was maintained throughout. Any member with a conflict of interest left the room during discussion and/or committee determination on the conflicted item.

#### I. Introduction of new IBC members

The new community member, Edwin Neas, was introduced to the committee and the transition of Sara Cope onto the committee as the new voting Biosafety Officer was announce. The committee introduced themselves and welcomed the new members.

# II. Review of June 12, 2019 IBC meeting minutes.

The minutes were not available for review at this time.

# III. Review of Agent and Project Request Forms (https://protocols.research.colostate.edu/rco).

## 1. Winger, Quinton

**Project:** <u>Trophoblast Gene Regulation by the ARID3B complex</u> (19-064B); BSL2 in vitro and in vivo in sheep, human samples. NIH Guidelines category non-exempt rDNA: III-D-4

# The committee unanimously approved of the above project with the following to be addressed:

- 1. The committee requests that the specific human cell lines for this project be listed out.
- 2. The committee requests that all individuals listed on the project review their Occupational Health Risk Assessment and ensure it matches the work included in this project.

3. The committee requests that all individuals working in a biosafety cabinet complete the Biosafety Cabinet training through the Biosafety Office.

The procedure is done group. ; this is similar to previous work by this group.

#### 2. Geiss, Brian

Agent: Influenza A virus—Strain: H1N1; A/Swine/1976/31, BSL2

The committee unanimously approved of the above agent with the following to be addressed:

1. The IBC requests that the human risk group be changed from 1 to 2.

**Project:** <u>Detection of Influenza A virus on thermoplastic electrodes (</u>19-066B); BSL2 in vitro. NIH Guidelines category non-exempt rDNA: N/A

## The committee unanimously approved of the above project with the following to be addressed:

- 1. The IBC requests that if any individuals other than the PI are working on this project they be added to the personnel section.
- 2. The IBC requests clarification regarding the use of 70% ethanol to decontaminate gloves; is it a process intended for just prior to glove disposal or in between uses. The committee recommends that gloves should be changed rather than disinfected between use.
- 3. The IBC requests that the individuals on the project review their Occupational Health Risk Assessment to ensure it includes work with Influenza A virus.

#### 3. Bowen, Richard

Agent: Equine herpesvirus—Strain: any; BSL2

The committee unanimously approved of the above agent.

#### 4. Izzo, Angelo

**Project:** <u>Advanced Small Animal Models for the Testing of Candidate Preventative</u> <u>Intervention Against Mycobacterium tuberculosis (19-070B); BSL3 in vitro and in vivo in mice and guinea pig. NIH Guidelines category non-exempt rDNA: III-D-1</u>

# The committee unanimously tabled the above project with the following to be addressed:

- 1. The IBC requests additional information regarding he types of immunological assays that will be performed.
- 2. The IBC requests clarification for the statement: AARF will be submitted when required.
- 3. The IBC requests that the PPE appropriate for animal care staff handling and disposing of animals during ABSL2 work be described. Specifically, should the cages and bedding be autoclaved or are they appropriate for the regular trash and cage wash procedures.
- 4. The IBC requests that an ABSL2 form be filled out for LAR prior to starting animal work.

#### 5. Kading, Rebekah

Agent: Rift Valley fever virus—Strain: DDVax; BSL2

The committee unanimously approved of the above agent.

**Project:** Rift Valley fever virus vaccine safety studies in mosquito vectors (19-073B); BSL3 in vitro and BSL3 in vivo in mosquitoes. NIH Guidelines category non-exempt rDNA: III-D-4

The committee unanimously approved of the above agent with the following to be addressed:

- 1. Under the list of Infectious Agents, it is recommended to list the vaccine strains of RVFV, which are worked with at BSL2, separately from the virulent strains of RVFV, which are handled at BSL3.
- 2. Goats are mentioned in the overview but not indicated as a species used for in vivo work. The IBC requests clarification and that goats be added to in vivo species.

## 6. Easley, Jeremiah

**Agent:** Lentivirus— Strain: lentiCRISPRv2 plasmid; BSL2

## The committee unanimously approved of the above agent with the following to be addressed:

- 1. The IBC requests clarification as to if this is a third generation virus.
- 2. The IBC requests that the human risk group be changed from 3 to 2.
- 3. Under Methods to inactive agent for disposal, it is unclear what is meant by: Autoclave (stocks) or bleach (cultures). The IBC recommends that all material containing the agent, whether stock or culture, be autoclaved prior to disposal.
- **4.** The IBC requests the % of bleach be included.
- 5. The IBC requests that a specific room number for storage be included

**Project**: Cytex Therapeutics – Caprine Hip Cartilage Regeneration with Tunable Inflammation Resistance (19-071B); BSL2 in vivo in sheep. NIH Guidelines category nonexempt rDNA: N/A

# The committee unanimously approved of the above project with the following to be addressed:

- The IBC requests that information not specific to the biohazardous risks be removed from the project overview.
- 2. The IBC requests clarification regarding the mechanism of modification for groups 4 and 5 in the project overview, specifically if they are altered using lentivirus.
- 3. The IBC asks for information regarding the validation that cells are free from the lentivirus, specifically will the source provide some type of documentation verifying that the cells are virus free.
- 4. Due to the implants, are there any special animal handling and/or carcass disposal requirements for LAR?
- 5. The IBC requires all individuals listed on an IBC approval to be registered with the Online IBC Database.

**Project**: Using lentivirus to modify genes in the sheep genome (19-072B); BSL2 in vitro. NIH Guidelines category non-exempt rDNA: III-D-1

# The committee TABLED the above project with the following to be addressed:

- 1. It was unclear from the Project Overview what the intent of this project is. The Overview mentions transgenic large animal model of osteoporosis, however no in vivo work is described. The IBC requests more information about what is being done in this project and how it ties in with transgenic animal models.
- 2. More information is also needed under the Non-exempt recombinant DNA. Where is the CRISPR-cas9 and gRNA coming from? Are they on the same vector? What genes are being edited? How are they being edited (knocking out genes, adding genes, increasing expression of genes, etc.)? What is the predicted outcome of these edits?

## IV. Amendments to be reviewed by full committee:

1. Kim, Seonil

**Project:** <u>Investigation of calcium</u> (17-030B); BSL1 in vitro and BSL1 in vivo in mice. NIH Guidelines category non-exempt rDNA: III-D-4

Amendment request to use adenovirus.

The committee unanimously approved of the above amendment.

#### V.Unfinished business

#### 1. BRB shutdown/renovation—update

The Biosafety Office reported that the timeline has been pushed back two weeks. It was unclear when this was announced whether the mid-September timeline given was for the beginning or completion of the commissioning process. Clarification will be requested.

- October Biosafety Month—Biosafety Fair October 16<sup>th</sup>
   Draft letters of requests for support will be forthcoming to recruit sponsors for the event.
- 3. Moreno, Julie--TABLED from March meeting waiting for more information from the PI Project: Cell therapeutics for prion diseases (19-023B); BSL2 in vitro BSL1 in vivo, rDNA. NIH Guidelines category non-exempt rDNA: N/A

#### VI. New Business

None

#### VII. Reports.

- 1. Coordinator's report.
  - a. Next IBC meeting: Wednesday, August 14th, 2019
- 2. Biosafety Officer's report.
  - a. Incident reports
    - i. Protocol breach When the facility shoe rack fell, an individual was observed coming out of the shower room with a ladder and wearing normal clothes and shoes. It was discovered that the person had not changed out and entered a dirty area then walked through the shower and locker room. The area is considered a "warm" area with low risk of exposure. Occupational health was notified and the incident is under review. No outside reporting required.
    - **ii.** Needlestick Occurred when an individual was drawing blood from an uninfected mouse and poked their finger when recapping the needle because it went through the cap. Occupational health was notified. The individual was reminded to avoid recapping needles.
    - iii. Near miss report An individual was working in an ABSL3 location when their PAPR air flow seemed low so they left the room to address the equipment failure. The cards were not labeled with what pathogen the animals were infected with, causing significant concern to the individual. The PI was immediately reachable to explain that it was not a high risk pathogen requiring ABSL3. Occupational health was notified and involved with the incident review. As a result of this, LAR is considering replacing PAPRs with units that have an alarm sound when the battery or air flow is low. The IBC coordinator, LAR manager, and BSO will be meeting to discuss how to address inconsistent communication between researchers and LAR when animals are infected with an agent.
  - b. Inspections- the Select Agent Program renewal inspection report was received by Dr. Ellis. He noted that none of the action items were classified of high importance or immediate concern; there were a few moderates. Overall it went very well and there were no surprises in the report. The Biosafety Office has already begun responding to many of the 25 items, many of which were questions about details that had been included in the pre-inspection documentation but were missed by the inspectors. The Biosafety Office has 30 business days to reply to the report (due by August 8<sup>th</sup>).
  - c. Laboratory audit reports- ARBL audits are ongoing.
- VIII. Agent and Project Approval Request Forms Reviewed at Previous IBC Meeting and Approved After Modification to be read into the minutes.

#### 1. Ehrhart, Nicole

**Project:** Muscle Stem Cells Reprogrammed Through Genome Engineering for Autonomously Regulated Anti-Fibrotic Therapy (19-049); BSL1 in vitro and in vivo in mice. NIH Guidelines category non-exempt rDNA: III-E-1

**Project:** Effects of Circulating Fators and Progenitors on Wound healing during Pregnancy (19-057); BSL1 in vivo in mice. NIH Guidelines category non-exempt rDNA: III-E-3

#### 2. Kruh-Garcia, Nicole

Agent: Mycobacterium africanum—Strain: any; BSL3

# 3. Kading, Rebekah

**Agent:** Asaia borogrensis—Strain: any; BSL1

Project: <u>Vaccination on the Fly: The Use of Mosquitoes to Vaccinate Bat Populations</u>
<u>that Harbor Human Pathogens (19-054)</u>; BSL2 in vitro and in vivo in mosquitoes. NIH
Guidelines category non-exempt rDNA: III-D-2

#### 4. Bowen, Richard

**Project:** Susceptibility of Alpacas to Camelpox Virus (19-055); BSL2 in vitro and in vivo in alpacas. NIH Guidelines category non-exempt rDNA: N/A

Agent: Vaccinia-Coxiella vector—Strain: any; BSL2

**Project:** Building Laboratory Diagnostic Capacity for Zoonotic Disease Risk Mitigation In Underserved Arid and Semi-Arid Areas of Kenya (19-061B); BSL2 in vitro. NIH Guidelines category non-exempt rDNA: NA

#### 5. Rose, Ruth J

Agent: Staphylococcus aureus—Strain: any, BSL2

**Project:** A novel acellular treatment for implant-associated osteomyelitis (19-056); BSL2 in vitro and in vivo in mice. NIH Guidelines category non-exempt rDNA: N/A

#### 6. Chanda, Soham

Agent: Lentivirus (Recombinant)—Strain: any, BSL2

Agent: Adeno-Associated virus (recombinant)—Strain: any, BSL2

**Project:** Pathophysiology of Autism-Associated Neuroligin-4 Mutations in Human Neurons (19-059); BSL2 in vitro and human cell lines. NIH Guidelines category nonexempt rDNA: III-D-3

# 7. Geornaras, Ifigenia

**Agent:** Campylobacter spp. – Strain: any; BSL2 (storage)

## 8. MacNeill, Amy L

**Project**: Post-operative Administration of Myxoma Virus to Reduce Recurrence of Soft <u>Tissue Sarcomas in Dogs</u> (19-026B); BSL2 in vitro and in vivo in canines. NIH Guidelines category non-exempt rDNA: III-D-1

- IX. Amended Project or Agent approval Request Forms Reviewed at Previous IBC Meeting and Approved After Modification to be read into the minutes.
- X. New or Amended Agent Approval Request Forms Reviewed and Approved by the <u>Biosafety Officer</u> or Chair to be read into the minutes.
- XI. New or Amended Project Approval Request Forms Reviewed and Approved by the <u>Biosafety Officer</u> or <u>Chair</u> to be read into the minutes.

#### 1. Kruh-Garcia, Nicole

**Project:** Characterization of mycobacterial vesicles (19-046B); BSL3 in vitro. NIH Guidelines category non-exempt rDNA: N/A

## 2. Izzo, Angelo

**Project**: Examining the Importance of the Microbiota in Mycobacterial Growth (19-058B); BSL3 in vitro and in vivo in mice. NIH guidelines category non-exempt rDNA: N/A

# 3. Robertson, Gregory

**Project**: Impact of Sterilizing and Non-sterilizing Antibiotics on M. Tuberculosis rRNA Synthesis (19-060B); BSL2 in vitro. NIH Guidelines category non-exempt rDNA: N/A

4. Ordway, Diane

**Project**: Impact of reinfection on Mycobacterium abscessus in a cystic fibrosis mouse model (19-062B); BSL2 in vitro and in vivo in mice. NIH Guidelines category non-exempt rDNA: N/A

## 5. VandeWoude, Sue

**Project:** <u>Pathogenesis and Development of a Rapid Diagnostic Test for Superficial Fungal Infections (</u>19-063B); BSL2 in vitro. NIH Guidelines category non-exempt rDNA: N/A

# 6. Mathiason, Candace

**Project:** Characterization of immune profile at the maternal-fetal interface during subclinical ZIKV infection (19-065B); BSL2 in vitro. NIH Guidelines category non-exempt rDNA: N/A

Meeting adjourned: 1:12pm

# Approved Minutes Institutional Biosafety Committee

# August 14, 2019

Check if Attending (Alternate Members):	
Lon Kendall, <b>Director LAR</b>	
Robert Ellis, <b>Director of Biosafety</b>	
Christine Johnson, <b>Senior IBC Coordinator</b> ,	
Alternate-at-Large*	
*non-voting at this meeting	
Regular Guests (non-voting):	
Claudia Gentry-Weeks, Associate BSO	
Heather Blair, Associate Biosafety Officer	
☐ Joni Van Sickle, Occupational Health Coord.	
Other: Anthony Appleton, Research Safety Culture Coordinator arrived at 12:50PM	

This meeting was convened at 12:04. Quorum was maintained throughout. Any member with a conflict of interest left the room during discussion and/or committee determination on the conflicted item.

# I. Review of June 12, 2019 and July 14, 2019 IBC meeting minutes.

The committee unanimously approved the June and July minutes with no changes

II. Review of Agent and Project Request Forms (https://protocols.research.colostate.edu/rco).

1. Dean, Gregg

Agent: Lactobacillus acidophilus—Strain: any; BSL2

The committee unanimously approved of the above agent with the following to be addressed:

1. The committee requests that the minimum biosafety level be changed from 2 to 1

**Agent:** Feline coronavirus – Strain: any; BSL2

The committee unanimously approved of the above agent with the following to be addressed:

1. The committee requests that the minimum biosafety level be changed from 2 to 1

**Project:** Recombinant Lactobacillus as an Oral Mucosal Vaccine Against Feline Enteric Coronavirus (19-080B); BSL2 in vitro and in vivo in cats. NIH Guidelines category non-exempt rDNA: III-D-2

The committee unanimously approved of the above project with the following recommendation:

- 1. Tyvek's are typically not used in the IBC recommends room specific lab coats and a change of clothes prior to contacting other cat areas in place of tyveks.
- 2. The use of booties, hair net, and surgical mask are not required for this agent, the IBC suggests removing them from list of PPE to be used.
- 3. The IBC requests all individuals listed on an IBC approval to register with the IBC Online Database, fill out a statement of experience, and complete the IBC at CSU online training.

## 2. Stenglein, Mark

Agent: Galbut virus—Strain: any; BSL1

## The committee unanimously approved of the above agent with the following to be addressed:

1. The IBC requests a room number for the agent storage location.

**Agent:** Drosophila C virus—Strain: any; BSL1

The committee unanimously approved of the above agent without changes.

**Project:** The impact of the virome on animal health and fitness (19-086B); BSL1 in vivo. NIH Guidelines category non-exempt rDNA: N/A

## The committee unanimously approved of the above project with the following to be addressed:

1. The IBC requests that all personnel using a biological safety cabinet complete the BSC training through the Biosafety Office.

**Project:** <u>Analysis of bunyavirus reassortment (</u>19-085B); BSL2 in vitro. NIH Guidelines category non-exempt rDNA: III-D-2

## The committee unanimously approved of the above project without changes.

There was discussion regarding whether or not the plasmids could pick up the UTR and produce infectious virus. The virologist in the room did not feel that this was a concern. This work is being done in cell culture.

### 3. Bosco-Lauth, Angela

Agent: Coccidioides immitis/posadasii—Strain: any; BSL3

# The committee unanimously approved of the above agent with the following to be addressed:

1. The IBC requests a room number for the agent storage location.

**Project:** Coccidioides pathogenicity and environmental transmission (19-088B); BSL3 in vitro and in vivo in rodents, armadillos, and bats. NIH Guidelines category non-exempt rDNA: N/A

The committee unanimously approved of the above project.

#### 4. Kading, Rebekah

**Project:** <u>Transstadial inhibition of Rift Valley Fever virus infection in mosquitoes (</u>19-089B); BSL3 in vitro and in vivo in mosquitoes. NIH Guidelines category non-exempt rDNA: N/A

# The committee unanimously approved of the above project with the following to be addressed:

 The IBC requests that the select agent question be changed from no to yes to reflect the overview and agents being used.

# 5. Jackson, Mary

**Project:** Adjunct therapeutic potential of biofilm inhibitors in the treatment of nontuberculosis mycobacterial infections (19-090B); BSL2 in vitro. NIH Guidelines category non-exempt rDNA: III-D-1

## The committee unanimously approved of the above project with the following to be addressed:

- 1. The IBC recommends the use of eye protection.
- 2. The IBC requests that all personnel using a biosafety cabinet complete the BSC training through the Biosafety Office.
- 3. The IBC requests that all individuals register with the IBC databased, fill out a statement of experience, and complete the IBC at CSU training.

**Project:** <u>Tailoring modifications of polysaccharides in Mycobacterium tuberculosis</u> (19-091B); BSL3 in vitro. NIH Guidelines category non-exempt rDNA: III-D-2

## The committee unanimously approved of the above project with the following to be addressed:

- 1. The IBC requests that BRB be added to the locations of work.
- 2. If an avirulent mycobacteria is to be used as a shuttle vector, that agent should be added to this project.
- 3. The IBC requests that all individuals register with the IBC databased, fill out a statement of experience, and complete the IBC at CSU training.

## 6. Gonzalez-Juarrero, Mercedes

**Project:** "Tailoring modifications of polysaccharides in Mycobacterium tuberculosis" (19-092B); BSL3 in vitro and in vivo in mice. NIH Guidelines category non-exempt rDNA: III-D-4

## The committee unanimously approved of the above project with the following to be addressed:

- 1. The IBC requests that "cages within thorns" be changed to "IVC caging".
- **2.** The IBC requests that a SteriGage strip be used to indicate sterility rather than autoclave tape.

## 7. Bowen, Richard

**Project:** <u>Indications Against Highly Pathogenic Agents for a Transportable Pathogen</u>
<u>Reduction and Blood Safety System for Whole Blood (</u>19-093B); BSL3 in vitro and human samples. NIH Guidelines category non-exempt rDNA: N/A

# The committee unanimously approved of the above project with additional information.

The "the pathogen reduction system" was discussed as several members were unfamiliar with it. This is a commercial system/device called Mirasol (Terumo BCT) marketed in several non-US countries for reducing pathogens in blood/plasma by illuminating the blood product with UV light in the presence of riboflavin as a photosensitizer. The principle is that all pathogens have a nucleic acid genome that can be disrupted by UV light and that such exposure does not affect the red cells in the blood or plasma proteins. The blood is treated while in bags and never comes in contact with the device and the device is used in a biosafety cabinet, in a BSL3 lab.

1. The IBC requested the PI add a brief description of the pathogen reduction system to the PARF.

#### 8. Stewart, Jane

Agent: Cytospora leucostoma – Strain: Colorado collected strains; BSL1

The committee unanimously approved of the above agent.

**Agent:** Geosmithia morbid (Thousand Cankers Disease) – Strain: Colorado collected strains; BSL1

The committee unanimously approved of the above agent.

Agent: Cronarium ribicola (white pine blister rust) – Strain: Colorado Collected strains; BSL1 The committee unanimously approved of the above agent.

**Agent:** Lophodermella needle cast disease (Lophodermella species) – Strain: Any Colorado Collected Strains; BSL1

## The committee unanimously approved of the above agent

All of the above agents were collected in CO. This lab was recently inspected by APHIS.

#### III. Unfinished business

1. Stewart, Jane – TABLED from June meeting – AARFs and additional information submitted

**Project:** Understanding the impacts of forest pathogens in western forests in the presence of increased drought and warming climates (19-053); BSL1 in vitro and BSL1 in vivo. NIH Guidelines category non-exempt rDNA: N/A

The committee unanimously approved of the above project.

## 2. Easley, Jeremiah

**Project**: <u>Using lentivirus to modify genes in the sheep genome (19-072B)</u>; BSL2 in vitro. NIH Guidelines category non-exempt rDNA: III-D-1 – **TABLED from July meeting** – **additional information added** 

## The committee unanimously approved of the above project without changes.

This current PARF is for cell culture work, with the eventual plan to move in vivo (at which time a new PARF will be submitted). There was a discussion as to whether or not there is a requirement to show that the experiment works before moving into the in vivo model. While it is not specifically a requirement, this is something the IACUC would address at the time the in vivo protocol was submitted.

**Project**: Cytex Therapeutics – Caprine Hip Cartilage Regeneration with Tunable Inflammation Resistance (19-071B); BSL2 in vivo in sheep. NIH Guidelines category non-exempt rDNA: III-D-4 – **PENDING from July meeting** – additional information added

#### The committee unanimously approved of the above project with the following to be addressed:

1. The IBC requests that specific deposition of animal tissue with recombinant nucleic acids be described as it cannot go in the regular waste stream without inactivation.

# 3. Moreno, Julie – TABLED from March meeting – application WITHDRAWN from review due to inactivity

**Project:** Cell therapeutics for prion diseases (19-023B); BSL2 in vitro BSL1 in vivo, rDNA. NIH Guidelines category non-exempt rDNA: N/A

# 4. BRB shutdown/renovation - update

Dr. Ellis reported that much of the renovation has been completed. Air balancing and commissioning will begin soon. The move back will involve a lot of shuffling but is anticipated to be complete by mid-October. The committee requested information regarding how long the imaging suite will remain open for use.

## 5. October Biosafety Month

a. Biosafety Poster Contest

Ms. Johnson reported that the poster contest information is being sent out. Submissions will be due on September  $18^{th}$ .

b. Biosafety Fair - October 16, 2019, 10am - 2pm

Ms. Johnson reported that planning is going well. IBC members are requested to plan to attend the event and spend some time at an IBC information table. Volunteers are also needed.

## IV. New Business

None

## V.Reports.

## 1. Coordinator's report.

- a. Next IBC meeting: Wednesday, September 11<sup>th</sup>, 2019
- Open RICRO Position: Protocol Specialist and Post Approval Monitor (IACUC)
   IBC members are encouraged to send the information for this position to potential applicants.

# 2. Biosafety Officer's report.

# a. Incident reports-

- i. Bite An individual was performing a physical exam on a mouse with CWD that wasn't moving. The individual coaxed the mouse to move and it bit their pointer finger on the right hand. No obvious puncture of the glove or hand. The individual contacted occupational health and did see a small cuticle break the next morning but it is unclear if it is related to the bite. No additional reporting required.
- ii. Near miss report An individual noticed liquid underneath glass bottles inoculated with Mycobacterium tuberculosis and was concerned about possible cracks in the glass. The individual notified biosafety and their supervisor who went in and treated it as a spill. It was determined that it was not a spill and rather the liquid was disinfectant that did not evaporate after the incubator cleaning and was trapped under the bottle.
- iii. Bite An individual was examining a mouse reported for paraphimosis and had the mouse restrained at the base of the tail on top of a wire cage in preparation to restrain by scruffing the mouse when it turned and bit the right-hand pointer finger. The finger was examined for punctures and washed. The individual contacted their supervisor and filed a biosafety incident report. The investigation of this incident is in process. No additional reporting required.
- iv. Near miss report An individual was using a needle to filter material and punctured their finger with the clean needle. The injury was washed. Occupational health has been notified and the PI is training the individual on proper procedures for filtering material.
- v. Near miss report A PAPR malfunctioned and died while an individual was performing job duties in a bat room. The bats were not yet infected. This PAPR had previous problems and should have been out of use. Biosafety will conduct an incident review.
- **b. Inspections-** the Select Agent Program renewal inspection report follow up was sent on August 1<sup>st</sup>. This was the best inspection so far, most items were just clarifications.
- c. Laboratory audit reports- nothing to report.

# VI. Agent and Project Approval Request Forms Reviewed at Previous IBC Meeting and Approved After Modification to be read into the minutes.

1. Geiss, Brian

Agent: Influenza A virus—Strain: H1N1; A/Swine/1976/31, BSL2

**Project:** <u>Detection of Influenza A virus on thermoplastic electrodes (</u>19-066B); BSL2 in vitro. NIH Guidelines category non-exempt rDNA: N/A

2. Winger, Quinton

**Project:** <u>Trophoblast Gene Regulation by the ARID3B complex</u> (19-064B); BSL2 in vitro and in vivo in sheep, human samples. NIH Guidelines category non-exempt rDNA: III-D-4

3. Izzo, Angelo

**Project:** Advanced Small Animal Models for the Testing of Candidate Preventative Intervention Against Mycobacterium tuberculosis (19-070B); BSL3 in vitro and in vivo in mice and guinea pig. NIH Guidelines category non-exempt rDNA: III-D-1

4. Kading, Rebekah

**Project**: Rift Valley fever virus vaccine safety studies in mosquito vectors (19-073B); BSL3 in vitro and BSL3 in vivo in mosquitoes. NIH Guidelines category non-exempt rDNA: III-D-4

5. Easley, Jeremiah

Agent: Lentivirus—Strain: lentiCRISPRv2 plasmid; BSL2

- VII. Amended Project or Agent approval Request Forms Reviewed at Previous IBC Meeting and Approved After Modification to be read into the minutes.
- VIII. New or Amended Agent Approval Request Forms Reviewed and Approved by the <u>Biosafety Officer</u> or Chair to be read into the minutes.
- IX. New or Amended Project Approval Request Forms Reviewed and Approved by the <u>Biosafety Officer</u> or Chair to be read into the minutes.
  - 1. Bowen, Richard

**Project:** <u>Vaccine Efficacy: H7N9 Influenza Virus (Tria)</u> (19-068B); BSL3 in vitro and in vivo. NIH Guidelines category non-exempt rDNA: N/A

2. Hamilton, Karyn

**Project**: Nrf2 Activation, Mobility, and Energetics: A pilot and feasibility clinical trial of PB125 treatment for improving musculoskeletal and pain outcomes in osteoarthritis. "The NAME Trial" (19-069B); BSL2 Human Samples. NIH guidelines category non-exempt rDNA: N/A

3. Robertson, Gregory

**Project**: Impact of Sterilizing and Non-sterilizing Antibiotics on M. Tuberculosis rRNA Synthesis (19-060B); BSL2 in vitro. NIH Guidelines category non-exempt rDNA: N/A

4. Ordway, Diane

**Project**: Impact of reinfection on Mycobacterium abscessus in a cystic fibrosis mouse model (19-062B); BSL2 in vitro and in vivo in mice. NIH Guidelines category non-exempt rDNA: N/A

5. VandeWoude, Sue

**Project:** <u>Pathogenesis and Development of a Rapid Diagnostic Test for Superficial Fungal Infections (19-063B); BSL2 in vitro. NIH Guidelines category non-exempt rDNA: N/A</u>

6. Mathiason, Candace

**Project:** Characterization of immune profile at the maternal-fetal interface during subclinical ZIKV infection (19-065B); BSL2 in vitro. NIH Guidelines category non-exempt rDNA: N/A

Meeting adjourned: 1:20pm

# APPROVED MINUTES Institutional Biosafety Committee

# September 11, 2019

Check if Attending (Members):	Check if Attending (Alternate Members):	
□ Jessica Ayers, Animal expert	Lon Kendall, <b>Director LAR</b>	
☑Donald Bade, <b>Unaffiliated</b>	Robert Ellis, Director of Biosafety*	
Richard Bowen, Associate Chair	Christine Johnson, Senior IBC Coordinator,	
	Alternate-at-Large*	
Patrick Byrne, <b>Plant expert</b>		
Chaoping Chen, <b>Chair</b>	*non-voting at this meeting	
Sara Cope, Assistant Biosafety Officer		
Angelo Izzo, <b>Mycobacteria Immunology,</b> left at 12:55		
⊠Nicole Marlenee, <b>Lab tech rep</b>		
□ June Medford, Plant/syn bio expert		
Edwin Neas, Unaffiliated		
Ken Olson, Virology		
Ann Powers, Virology		
Bernard Rollin, <b>Bioethicist</b>		
Non-Voting Members:		
James Graham, EHS Director		
RICRO Staff (non-voting):	Regular Guests (non-voting):	
Karen Dobos, RICRO Director	Claudia Gentry-Weeks, <b>Associate BSO</b>	
Christa Johnson, Associate VP for Research	Heather Blair, Associate Biosafety Officer	
	Joni Van Sickle, Occupational Health Coord.	
Other: Dr. John Wyckoff, BioMARC Director		

This meeting was convened at 12:02. Quorum was maintained throughout. Any member with a conflict of interest left the room during discussion and/or committee determination on the conflicted item.

#### I. Guest visitor – Dr. John Wyckoff

Dr. John Wyckoff is the BioMARC Director and PI on an AARF and PARF under current IBC review. He was invited to attend the IBC meeting to discuss his project so that any questions could be addressed upfront. This project involves the development of a highly attenuated live viral vaccine candidate against Rift Valley Fever called They will be developing material for pre-clinical studies in rats and goats. They are purposing to do the work at BSL2. The vaccine has been excluded from the Select Agent list and is more attenuated than MP12 (the current vaccine strain). There was discussion and questions regarding the different safety aspects of the virus; the virus has been shown to be safe in mice, the chances of reversion are minimal, and they will not be working with wild type virus at the same time. Vaccine virus from these initial studies will be used by collaborators (at the same time) to conduct safety and efficacy studies in animal models to develop data sets supporting an Investigational New Drug application to FDA to gain approval for moving forward into human clinical trials. After answering the rest of the IBC questions, the IBC thanked Dr. Wyckoff and he left the meeting.

## II. Review of August 14, 2019 IBC meeting minutes.

The committee unanimously approved the August minutes with no changes.

## III. Review of Agent and Project Request Forms (https://protocols.research.colostate.edu/rco).

## 1. Zabel, Mark

**Project:** <u>Light-inducible Prion Aggregation in C. elegans</u> (19-096B); BSL2 in vivo in C. elegans. NIH Guidelines category non-exempt rDNA: III-D-4

## The committee unanimously approved the above project with the following items to be addressed:

- 1. The IBC requests confirmation of personnel eID.
- 2. The IBC requests a brief (one sentence) description of what C. elegans is be added to the overview.
- 3. The IBC requests the PI describe how C. elegans will be contained/housed and disposal of transgenic worms.

There was discussion regarding what C. elegans is; C. elegans is small worm often used in research.

## 2. Wyckoff, John

**Agent:** Rift Valley fever virus—Strain:

The committee unanimously approved the above agent without changes.

**Project:** Human Vaccine Development Against Rift Valley Fever (19-097B); BSL2 in vitro. NIH Guidelines category non-exempt rDNA: III-D-6

## The committee unanimously approved of the above agent without changes.

As all questions/concerns were addressed by Dr. Wyckoff during his visit with the committee, the IBC had no additional concern regarding this project.

### 3. Gaines, Todd

Agent: Saccharomyces cerevisiae – Strain: any; BSL1

# The committee unanimously TABLED the above agent with the following to be addressed:

- 1. The IBC request that a bit more information be provided in the Agent Description. For example, *Saccharomyces cerevisiae* (commonly known as baker's yeast) is a single-celled eukaryote that is frequently used in scientific research may be found as a harmless and transient digestive commensal and colonizer of mucosal surfaces of normal individuals.
- 2. Will a chemical disinfectant be used? If yes, please specify.

**Project**: Functional genomics of herbicide resistance mechanisms (19-098B); BSL1 in vitro and in vivo in Arabidopsis. NIH Guidelines category non-exempt rDNA: III-E-2

## The committee unanimously TABLED the above project with the following to be addressed:

- 1. State whether using disarmed strains of Agro
- 2. A chemical for disinfecting lab should be added to containment procedures.
- 3. What kinds of DNA they are being cloned? What are the genes and species they come from?
- 4. Will plants be grown in a growth room or growth chamber?
- 5. Describe in more detail how seeds and plants will be moved between labs.
- 6. The IBC requests that the PI meet with one of our IBC plant experts, to discuss this project.

## 4. Henao-Tamayo, Marcela

Agent: Mycobacterium Avium Complex – Strain: any; BSL2

The committee unanimously approved the above agent with the following items to be addressed:

- 1. Pathogenic for animals should be changed from NO to YES.
- 2. What is the concentration of vesphene used for inactivation.
- 3. The PI should update the AARF with the specific room location once it is known.

**Project:** <u>Vaccine Induced Immunity to tuberculosis</u> (19-099B);BSL2 and BSL3 in vivo in mice and guinea pigs. NIH Guidelines category non-exempt rDNA: N/A

## The committee unanimously approved the above project with the following items to be addressed:

- 1. The IBC requests the PI state how animal waste/caging should be handled following exposure with Mycobacterium haemophilum and/or M. avium. Are any additional decontamination procedures required?
- 2. What is the concentration of M. avium being used in the drinking water?
- 3. The IBC requests the PI describe the procedures for disinfecting the NTM drinking water. Has this method been validated?
- 4. The IBC requests the PI describe the procedures for decontaminating a spill of NTM drinking water in the animal room.
- 5. The PI should update the PARF with the specific room location once that is known.

#### IV. Unfinished business

1. BRB shutdown/renovation - update

Moving back into the renovated space has been more complicated, as some have ongoing experiments. The lab will be one of the first groups to move.

## 2. October Biosafety Month

- a. **Biosafety Poster Contest** deadline Wednesday, September 18<sup>th</sup> the vote for the posters will be done online; the IBC will receive an email requesting that they vote.
- b. **Biosafety Fair** October 16, 2019, 10am 2pm: the planning for the fair is going well. There will a sign up for IBC members to volunteer one hour at the IBC table.

## **V.New Business**

None

# VI. Reports

- 1. Coordinator's report.
  - a. Next IBC meeting: Wednesday, October 9th, 2019
- 2. Biosafety Officer's report.
  - a. Incident reports
    - i. To be addressed next meeting.
  - b. Inspections
  - c. Laboratory audit reports
  - **d. Misc.** The Biosafety Office conducted a live drill with Poudre Fire Authority; it was a man down drill. The drill went well. There has been great communication with the first responders. PFA asked BSOs to come to monthly hazmat meeting.

# VII. Agent and Project Approval Request Forms Reviewed at Previous IBC Meeting and Approved After Modification to be read into the minutes.

1. Easley, Jeremiah

**Project**: Using lentivirus to modify genes in the sheep genome (19-072B); BSL2 in vitro. NIH Guidelines category non-exempt rDNA: III-D-1

2. Dean, Gregg

Agent: Lactobacillus acidophilus—Strain: any; BSL2

**Agent:** feline coronavirus – Strain: any; BSL2

**Project:** Recombinant Lactobacillus as an Oral Mucosal Vaccine Against Feline Enteric Coronavirus (19-080B); BSL2 in vitro and in vivo in cats. NIH Guidelines category non-exempt rDNA: III-D-2

## 3. Stenglein, Mark

Agent: Galbut virus—Strain: any; BSL1

**Project:** The impact of the virome on animal health and fitness (19-086B); BSL1 in vivo. NIH Guidelines category non-exempt rDNA: N/A

## 4. Bosco-Lauth, Angela

Agent: Coccidioides immitis/posadasii—Strain: any; BSL3

**Project**: Coccidioides pathogenicity and environmental transmission (19-088B); BSL3 in vitro and in vivo in rodents, armadillos, and bats. NIH Guidelines category non-exempt rDNA: N/A

## 5. Kading, Rebekah

**Project:** <u>Transstadial inhibition of Rift Valley Fever virus infection in mosquitoes (</u>19-089B); BSL3 in vitro and in vivo in mosquitoes. NIH Guidelines category non-exempt rDNA: N/A

# 6. Jackson, Mary

**Project**: Adjunct therapeutic potential of biofilm inhibitors in the treatment of nontuberculosis mycobacterial infections (19-090B); BSL2 in vitro. NIH Guidelines category non-exempt rDNA: III-D-1

**Project**: <u>Tailoring modifications of polysaccharides in Mycobacterium tuberculosis</u> (19-091B); BSL3 in vitro. NIH Guidelines category non-exempt rDNA: III-D-2

### 7. Gonzalez-Juarrero, Mercedes

**Project:** "Tailoring modifications of polysaccharides in Mycobacterium tuberculosis" (19-092B); BSL3 in vitro and in vivo in mice. NIH Guidelines category non-exempt rDNA: III-D-4

- VIII. Amended Project or Agent approval Request Forms Reviewed at Previous IBC Meeting and Approved After Modification to be read into the minutes.
- IX. New or Amended Agent Approval Request Forms Reviewed and Approved by the <u>Biosafety Officer</u> or Chair to be read into the minutes.
- X. New or Amended Project Approval Request Forms Reviewed and Approved by the <u>Biosafety Officer</u> or Chair to be read into the minutes.

# 1. Rovnak, Joel

**Project:** <u>Inhibition of CDK8 kinase activity reduces Zika virus pathogenesis (19-0748);</u> BSL2 in vitro and human samples. NIH Guidelines category non-exempt rDNA: N/A

## 2. Ordway, Diane

**Project:** SPR720 combination treatment against Mycobacterium avium in new C3HeB/FeJ model (19-082B); BSL2 in vitro and in vivo in mice. NIH Guidelines category non-exempt rDNA: N/A.

**Project:** Clinical Development of the Novel BisEDT Antibiotic for CF Lung Infections (19-083); BSL2 in vitro and in vivo in mice. NIH Guidelines category non-exempt rDNA: N/A. **Project:** Potentiating Rifampin in NTM Infections (19-084B); BSL2 in vitro and in vivo in mice. NIH Guidelines category non-exempt rDNA: N/A.

Meeting adjourned: 1:04pm

# APPROVED MINUTES Institutional Biosafety Committee

# October 9, 2019

Check if Attending (Members):	Check if Attending (Alternate Members):	
Jessica Ayers, Animal expert	Lon Kendall, <b>Director LAR</b>	
☑Donald Bade, <b>Unaffiliated</b>	Robert Ellis, <b>Director of Biosafety*</b>	
Richard Bowen, <b>Associate Chair</b>	Christine Johnson, Senior IBC Coordinator,	
	Alternate-at-Large*	
Patrick Byrne, <b>Plant expert</b>		
Chaoping Chen, <b>Chair</b>	*non-voting at this meeting	
Sara Cope, Assistant Biosafety Officer		
Angelo Izzo, Mycobacteria Immunology		
⊠Nicole Marlenee, <b>Lab tech rep</b>		
☑June Medford, <b>Plant/syn bio expert</b>		
Edwin Neas, <b>Unaffiliated</b>		
Ken Olson, <b>Virology</b>		
Ann Powers, <b>Virology</b>		
Bernard Rollin, <b>Bioethicist</b>		
Non-Voting Members:		
James Graham, EHS Director		
RICRO Staff (non-voting):	Regular Guests (non-voting):	
Karen Dobos, <b>RICRO Director</b>	Claudia Gentry-Weeks, <b>Associate BSO</b>	
Christa Johnson, Associate VP for Research	Heather Blair, Associate Biosafety Officer	
Joanie Ryan, <b>IBC Intern</b>	☐ Joni Van Sickle, Occupational Health Coord.	
Other: Lilly Halboth, RICRO Research Compliance Administrative Assistant		

This meeting was convened at 12:05. Quorum was maintained throughout. Any member with a conflict of interest left the room during discussion and/or committee determination on the conflicted item.

# I. Review of September 11, 2019 IBC meeting minutes.

The minutes were not available for review.

# II. Review of Agent and Project Request Forms (https://protocols.research.colostate.edu/rco).

## 1. Geornaras, Ifigenia

Agent: Salmonella enterica – Strain: any serotype (serovar), except Typhi and Paratyphi; BSL2 The committee unanimously approved the above agent without changes.

There was a question as to whether 5% bleach will kill this agent; the IBC determined that yes it should.

**Agent:** Escherichia coli – Strain: any (i) non-pathogenic, and (ii) Shiga toxin-producing E. coli **The committee unanimously approved the above agent without changes.** 

**Project:** Efficacy of antimicrobial treatments against inoculated bacterial populations on fresh meat products and ready-to-eat foods (19-107B); BSL2 in vitro. NIH Guidelines category non-exempt rDNA: N/A

# The committee unanimously approved the above project without changes.

There was questions/discussion regarding whether the meat spraying device was an enclosed environment. The Biosafety Officer has reviewed this system in the past for a previous approval. It is very well contained, in addition

PPE including a lab coat or Tyvek suit, disposable gloves, safety glasses and N95 mask (or full face mask), and rubber boots or disposable shoe covers are worn while operating the unit.

## 2. Bowen, Richard

**Project:** Pathogenesis and immune responses to anthrax in feral pigs (19-105B); BSL3 in vitro and BSL3 in vivo in swine. NIH Guidelines category non-exempt rDNA: N/A

## The committee unanimously approved the above project without changes.

There was a discussion regarding handling feral pigs as they can be difficult to work with. CSU has the correct facilities and this lab group has worked with this animal model before.

## 3. Kading, Rebekah

Agent: rabies virus – Strain: any; BSL3

The committee unanimously approved the above agent without changes.

**Project amendment request:** <u>Vaccination on the Fly: The Use of Mosquitoes to Vaccinate Bat Populations that Harbor Human Pathogens</u> (19-054B); BSL2 in vitro and BSL2 in vivo in mosquitoes. NIH Guidelines category non-exempt rDNA: III-D-2

**Amendment Request:** to add rabies virus to this project. "We will need to use infectious rabies virus in the rapid fluorescent focus inhibition test (RFFIT) to determine the neutralizing antibody titer in the serum of bats vaccinated with rabies virus antigen. We will also need to conduct cell culture work to maintain virus stocks. This testing will occur in ."

The committee unanimously approved the above project without changes.

## 4. Gaines, Todd

**Project:** Gene function validation for target site and non-target site herbicide resistance mechanisms (19-108B); BSL1 in vitro and BSL1 in vivo in Arabidopsis thaliana. NIH Guidelines category non-exempt rDNA: III-E-2

# The committee unanimously approved the above project with the following to be addressed:

1. The IBC requests confirmation that weedy species will not be transformed, and if weedy species are added a new PARF should be submitted.

## III. Unfinished business

1. Gaines, Todd – Tabled from September meeting – Dr. Gaines met with Dr. Medford; added more information to his PARF and separated out the work into two PARFs (new PARF above).

**Agent:** Saccharomyces cerevisiae – Strain: any; BSL1

The committee unanimously approved of the above agent with the following to be addressed:

- 1. The IBC requests the chemical disinfectant and concentration used be listed.
- 2. The IBC requests the building name be added to storage location.

**Project**: Functional genomics of herbicide resistance mechanisms (19-098B); BSL1 in vitro and in vivo in Arabidopsis. NIH Guidelines category non-exempt rDNA: III-E-2

## The committee unanimously approved of the above project with the following to be addressed:

1. The IBC requests confirmation that weedy species will not be transformed.

# 2. BRB shutdown/renovation - update

Getting close to moving back in. We've been playing musical chairs due to all of the changes. We are starting to move in clean equipment.

## 3. October Biosafety Month is here!!

- a. Biosafety Poster Contest the winners are a team of three veterinary students: Brooke MacNeill, Blaire MacNeill and Rowan Seabolt. The IBC members were given copies of the winning poster.
- b. **Biosafety and Biosecurity Fair** October 16, 2019, 10am 2pm; the IBC Coordinator is putting together a volunteer schedule for IBC members to staff the IBC table. Please sign up.
- **c. Take the RAM Safe Pledge** the 2019 RAM Safe Pledge drive began on October 1<sup>st</sup>. The IBC Coordinator urged the committee members to take the pledge.

#### IV. New Business

None

## V. Reports

# 1. Coordinator's report.

a. Next IBC meeting: Wednesday, November 13, 2019

## 2. Biosafety Officer's report.

## a. Incident reports

- i. Spill A mouse cage water bottle containing Mycobacterium avium was dropped; it cracked and spilled on the floor. The concentration of M. avium was similar to that found in drinking/tap water. The spill cleanup procedure was followed and an incident report was filed. Occupational Health was notified and the occ health doc consulted; the risk of exposure considered to be very low. No outside reporting required.
- ii. Needle stick An individual pricked their finger with a needle while filling it with saline. The needle was new out of the package. Individual took off gloves, expressed wound, washed and applied bandaid and filed a report. No exposure, no outside reporting.
- iii. Security breach An individual was using another lab member's badge to enter the lab. The PI was informed of the situation. The PI spoke to the lab members and reminded them not to use each other's badges. No additional reporting required.

#### iv. Near misses

- 1. There were two reports of items not being properly staged for autoclaving. Individuals were reminded of the procedures.
- An individual cut their finger at home; while setting up the autoclave, notice the finger was bleeding in the inner glove. The individual exited the barrier, cleaned the wound in the shower and notified biosafety. Biosafety recommended the individual use a waterproof band aid or liquid bandage to seal open wounds before entering BSL3 and discussed that it would be considered a near miss.
- 3. Biosafety was informed that there were red biohazard bags with autoclave tape on the floor in a BSL2 space and that some of the bags were broken and the tape was not activated/black. Upon investigation, it was determined that the bags contained supplies from a different BSL2 lab. The lab group was informed not to use biohazard bags to transport and move materials.
- **b. Inspections** the Biosafety Office has submitted their response to the CDC regarding the select agent renewal inspection; there has been a lot of follow up questions.
- c. Laboratory audit reports

- VI. Agent and Project Approval Request Forms Reviewed at Previous IBC Meeting and Approved After Modification to be read into the minutes.
  - 1. Zabel, Mark

**Project:** <u>Light-inducible Prion Aggregation in C. elegans</u> (19-096B); BSL2 in vivo in C. elegans. NIH Guidelines category non-exempt rDNA: III-D-4

2. Wyckoff, John

Agent: Rift Valley fever virus—Strain: DDVax; BSL2

**Project:** <u>Human Vaccine Development Against Rift Valley Fever (DDVax)</u> (19-097B); BSL2 in vitro. NIH Guidelines category non-exempt rDNA: III-D-6

3. Henao-Tamayo, Marcela

**Agent:** Mycobacterium Avium Complex – Strain: any; BSL2

**Project:** <u>Vaccine Induced Memory Immunity in tuberculosis</u> (19-099B); BSL3 in vivo in mice and guinea pigs. NIH Guidelines category non-exempt rDNA: N/A

- VII. Amended Project or Agent approval Request Forms Reviewed at Previous IBC Meeting and Approved After Modification to be read into the minutes.
- VIII. New or Amended Agent Approval Request Forms Reviewed and Approved by the <u>Biosafety Officer</u> or Chair to be read into the minutes.
- IX. New or Amended Project Approval Request Forms Reviewed and Approved by the <u>Biosafety Officer</u> or Chair to be read into the minutes.

Meeting adjourned: 12:37
Minutes recorded by C. Johnson

# APPROVED MINUTES Institutional Biosafety Committee

# November 13, 2019

Jessica Ayers, Animal expert	Check if Attending (Members):	Check if Attending (Alternate Members):
Richard Bowen, Associate Chair   Christine Johnson, Senior IBC Coordinator, Alternate-at-Large*     Patrick Byrne, Plant expert   *non-voting at this meeting     Sara Cope, Assistant Biosafety Officer     Angelo Izzo, Mycobacteria Immunology     Nicole Marlenee, Lab tech rep     June Medford, Plant/syn bio expert     Edwin Neas, Unaffiliated     Ken Olson, Virology     Ann Powers, Virology     Bernard Rollin, Bioethicist     James Graham, EHS Director     RICRO Staff (non-voting):   Regular Guests (non-voting):     Karen Dobos, RICRO Director   Claudia Gentry-Weeks, Associate BSO     Christa Johnson, Associate VP for Research   Joni Van Sickle, Occupational Health Coord.	Jessica Ayers, Animal expert	□ Lon Kendall, <b>Director LAR</b>
Alternate-at-Large*    Patrick Byrne, Plant expert     Chaoping Chen, Chair   *non-voting at this meeting     Sara Cope, Assistant Biosafety Officer     Angelo Izzo, Mycobacteria Immunology     Nicole Marlenee, Lab tech rep     June Medford, Plant/syn bio expert     Edwin Neas, Unaffiliated     Ken Olson, Virology     Ann Powers, Virology     Bernard Rollin, Bioethicist     Non-Voting Members:     James Graham, EHS Director     RICRO Staff (non-voting):     Karen Dobos, RICRO Director   Claudia Gentry-Weeks, Associate BSO     Christa Johnson, Associate VP for Research   Joni Van Sickle, Occupational Health Coord.	☑ Donald Bade, <b>Unaffiliated</b>	Robert Ellis, <b>Director of Biosafety*</b>
□ Patrick Byrne, Plant expert *non-voting at this meeting   □ Sara Cope, Assistant Biosafety Officer   Angelo Izzo, Mycobacteria Immunology   □ Angelo Izzo, Mycobacteria Immunology   Angelo Izzo, Mycobacteria Immunology   □ Nicole Marlenee, Lab tech rep   June Medford, Plant/syn bio expert   □ Edwin Neas, Unaffiliated   Ken Olson, Virology   □ Ann Powers, Virology   Ann Powers, Virology   □ Bernard Rollin, Bioethicist   Ann Powers of the property of t	Richard Bowen, Associate Chair	Christine Johnson, Senior IBC Coordinator,
		Alternate-at-Large*
Sara Cope, Assistant Biosafety Officer   Angelo Izzo, Mycobacteria Immunology   Nicole Marlenee, Lab tech rep   June Medford, Plant/syn bio expert   Edwin Neas, Unaffiliated   Ken Olson, Virology   Ann Powers, Virology   Bernard Rollin, Bioethicist   Non-Voting Members:   James Graham, EHS Director   RICRO Staff (non-voting): Regular Guests (non-voting):   Karen Dobos, RICRO Director Claudia Gentry-Weeks, Associate BSO   Christa Johnson, Associate VP for Research Heather Blair, Associate Biosafety Officer   Joanie Ryan, IBC Intern Joni Van Sickle, Occupational Health Coord.	Patrick Byrne, <b>Plant expert</b>	
Angelo Izzo, Mycobacteria Immunology  Nicole Marlenee, Lab tech rep  June Medford, Plant/syn bio expert  Edwin Neas, Unaffiliated  Ken Olson, Virology  Ann Powers, Virology  Bernard Rollin, Bioethicist  Non-Voting Members:  James Graham, EHS Director  RICRO Staff (non-voting):  Regular Guests (non-voting):  Karen Dobos, RICRO Director  Christa Johnson, Associate VP for Research  Joanie Ryan, IBC Intern  Nicole Marlenee, Lab tech rep  Regular Guests (non-voting):  Claudia Gentry-Weeks, Associate BSO  Heather Blair, Associate Biosafety Officer	Chaoping Chen, <b>Chair</b>	*non-voting at this meeting
Nicole Marlenee, Lab tech rep   June Medford, Plant/syn bio expert     Edwin Neas, Unaffiliated     Ken Olson, Virology     Ann Powers, Virology     Bernard Rollin, Bioethicist     Non-Voting Members:     James Graham, EHS Director     RICRO Staff (non-voting):   Regular Guests (non-voting):     Karen Dobos, RICRO Director   Claudia Gentry-Weeks, Associate BSO     Christa Johnson, Associate VP for Research   Heather Blair, Associate Biosafety Officer     Joanie Ryan, IBC Intern   Joni Van Sickle, Occupational Health Coord.	Sara Cope, Assistant Biosafety Officer	
June Medford, Plant/syn bio expert     Edwin Neas, Unaffiliated     Ken Olson, Virology     Ann Powers, Virology     Bernard Rollin, Bioethicist     Non-Voting Members:     James Graham, EHS Director     RICRO Staff (non-voting):     Karen Dobos, RICRO Director     Claudia Gentry-Weeks, Associate BSO     Christa Johnson, Associate VP for Research     Joanie Ryan, IBC Intern     Joni Van Sickle, Occupational Health Coord.	Angelo Izzo, Mycobacteria Immunology	
□ Edwin Neas, Unaffiliated   □ Ken Olson, Virology   □ Ann Powers, Virology   □ Bernard Rollin, Bioethicist   Non-Voting Members:   □ James Graham, EHS Director   RICRO Staff (non-voting): Regular Guests (non-voting):   □ Karen Dobos, RICRO Director □ Claudia Gentry-Weeks, Associate BSO   □ Christa Johnson, Associate VP for Research □ Heather Blair, Associate Biosafety Officer   □ Jonie Ryan, IBC Intern □ Joni Van Sickle, Occupational Health Coord.	⊠Nicole Marlenee, <b>Lab tech rep</b>	
☑ Ken Olson, Virology   ☑ Ann Powers, Virology   ☑ Bernard Rollin, Bioethicist   Non-Voting Members:   ☑ James Graham, EHS Director   RICRO Staff (non-voting): Regular Guests (non-voting):   ☑ Karen Dobos, RICRO Director ☐ Claudia Gentry-Weeks, Associate BSO   ☐ Christa Johnson, Associate VP for Research ☐ Heather Blair, Associate Biosafety Officer   ☑ Joanie Ryan, IBC Intern ☑ Joni Van Sickle, Occupational Health Coord.	June Medford, <b>Plant/syn bio expert</b>	
Ann Powers, Virology	Edwin Neas, <b>Unaffiliated</b>	
Bernard Rollin, Bioethicist   Non-Voting Members:	Ken Olson, Virology	
Non-Voting Members:	Ann Powers, Virology	
Sames Graham, EHS Director   RICRO Staff (non-voting):   Regular Guests (non-voting):   Claudia Gentry-Weeks, Associate BSO   Christa Johnson, Associate VP for Research   Heather Blair, Associate Biosafety Officer   Joanie Ryan, IBC Intern   Joni Van Sickle, Occupational Health Coord.	Bernard Rollin, <b>Bioethicist</b>	
Sames Graham, EHS Director   RICRO Staff (non-voting):   Regular Guests (non-voting):   Claudia Gentry-Weeks, Associate BSO   Christa Johnson, Associate VP for Research   Heather Blair, Associate Biosafety Officer   Joanie Ryan, IBC Intern   Joni Van Sickle, Occupational Health Coord.		
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☑ Karen Dobos, RICRO Director       ☐ Claudia Gentry-Weeks, Associate BSO         ☐ Christa Johnson, Associate VP for Research       ☑ Heather Blair, Associate Biosafety Officer         ☑ Joanie Ryan, IBC Intern       ☑ Joni Van Sickle, Occupational Health Coord.		
☑ Karen Dobos, RICRO Director       ☐ Claudia Gentry-Weeks, Associate BSO         ☐ Christa Johnson, Associate VP for Research       ☑ Heather Blair, Associate Biosafety Officer         ☑ Joanie Ryan, IBC Intern       ☑ Joni Van Sickle, Occupational Health Coord.		
☐ Christa Johnson, Associate VP for Research       ☐ Heather Blair, Associate Biosafety Officer         ☐ Joanie Ryan, IBC Intern       ☐ Joni Van Sickle, Occupational Health Coord.	RICRO Staff (non-voting):	Regular Guests (non-voting):
☐ Joanie Ryan, IBC Intern ☐ Joni Van Sickle, Occupational Health Coord.	Karen Dobos, <b>RICRO Director</b>	Claudia Gentry-Weeks, <b>Associate BSO</b>
	Christa Johnson, Associate VP for Research	Heather Blair, Associate Biosafety Officer
Other: Anthony Appleton, Research Safety Culture Coordinator		

This meeting was convened at 12:03. Quorum was maintained throughout. Any member with a conflict of interest left the room during discussion and/or committee determination on the conflicted item.

# I. Review of September 11, 2019 and October 9, 2019 IBC meeting minutes.

The committee unanimously approved both the September and October minutes with no changes.

# II. Review of Agent and Project Request Forms (https://protocols.research.colostate.edu/rco).

## 1. Myers, Brent

**Project:** Cortical-Medullary Circuitry Preventing the Cardiovascular Consequences of Chronic Stress (19-115B); BSL1 in vivo in rats, rDNA. NIH Guidelines category non-exempt rDNA: III-E-1

# The committee unanimously approved of the above project with the following recommendation:

The IBC requests confirmation once personnel have completed the IBC at CSU training and have signed up for the Biosafety Cabinet Training.

# 2. Peccoud, Jean

**Project:** Automated Prioritization and Design of Experiments to Validate and Improve Mathematical Models of Molecular Regulatory Systems (19-116B); BSL1 in vitro, rDNA. NIH Guidelines category non-exempt rDNA: III-E-1

The committee unanimously approved of the above project with the following recommendation:

The IBC requests that Dr. Peccoud update his Statement of Experience with biohazardous materials and update personnel list.

This project involves using rDNA from E. coli to E. coli, and yeast to yeast.

## III. Amendments to be reviewed by full committee

## 1. Chen, Chaoping

**Project:** Assay Development for Identification of HIV-1 Protease Autoprocessing Specific Inhibitors (14-057B); BSL2 in vitro, rDNA. NIH Guidelines category non-exempt rDNA: III-D-3 Amendment request for an extended coverage to include a new proposal (PASS# because the proposed experiments are similar to what are currently covered by the existing PARF

The committee unanimously approved of the above project without changes.

#### IV. Unfinished business

# 1. BRB shutdown/renovation – update

They are mostly done, just minor things to fix now. The plan is for the labs to go hot on Monday. Imaging suite will be deconed on Thursday.

# 2. October Biosafety Month was a huge success!

- a. See recent SOURCE article: <a href="https://source.colostate.edu/national-biosafety-and-biosecurity-month-saw-much-success-in-october/">https://source.colostate.edu/national-biosafety-and-biosecurity-month-saw-much-success-in-october/</a>
- b. We are working on determining the RAM Safe Pledge winners based on percent of participation.

## **V.New Business**

No new business.

# VI. Reports

## 1. Coordinator's report.

a. Next IBC meeting: Wednesday, December 11, 2019

## 2. Biosafety Officer's report.

## a. Incident reports

- i. There were 2 near misses surrounding communication issues regarding the shutdown. Exposure risk considered to be low as PPE was worn. Biosafety recommended signage posted at the personnel locator board during future shutdowns to prevent reoccurrences.
- ii. Protocol breach involving large volume bottles that were incorrectly staged for autoclaving. The group was notified of the correct procedures. No outside reporting required.
- **iii.** Protocol breach signage not placed on door to inform others of open caging following agent exposure, thus the correct PPE was not worn. Risk of exposure considered low as individual still had on standard PPE. The group was contacted regarding adding signage. No outside reporting required.

## b. Inspections

The select agent renewal inspection is closed. They rejected the RVFV amendment and once that was removed, the renewal was approved.

c. Laboratory audit reports

The select agent audits are going well; everyone is doing a good job labeling.

- VII. Agent and Project Approval Request Forms Reviewed at Previous IBC Meeting and Approved After Modification to be read into the minutes.
- VIII. Amended Project or Agent approval Request Forms Reviewed at Previous IBC Meeting and Approved After Modification to be read into the minutes.
- IX. New or Amended Agent Approval Request Forms Reviewed and Approved by the <u>Biosafety Officer</u> or Chair to be read into the minutes.
- X. New or Amended Project Approval Request Forms Reviewed and Approved by the <u>Biosafety Officer</u> or Chair to be read into the minutes.
  - 1. Ordway, Diane

Project: Gallium Citrate Activity against Intracellular Nontuberculosis mycobacterial infections (19-102B); BSL2 in vitro, BSL3 in vivo in mice. NIH Guidelines category non-exempt rDNA: N/A Project: Inhaled Nitrite Immune Effects and Antimicrobial Activity against Intracellular Drug Sensitive and Drug Resistant M. tuberculosis Infections and M. abscessus In Vitro and In Vivo (19-103B); BSL3 in vitro and in vivo in mice. NIH Guidelines category non-exempt rDNA: N/A Project: Adjunct therapeutic potential of biofilm inhibitors in the treatment of nontuberculosis mycobacterial infections (19-104B); BSL2 in vitro and in vivo in mice. NIH Guidelines category non-exempt rDNA: N/A

2. Kading, Rebekah

**Project:** West Nile virus immune status or birds at the Rocky Mountain Raptor Program (19-106B); BSL3 in vitro. NIH Guidelines category non-exempt rDNA: N/A

3. Robertson, Gregory

**Project:** INVITRO ASSESSMENTS OF ANTI-MYCROBIAL ACTIVTY Task Order A07-" Anti-mycobacterial Target or Mechanism Identification contract (AToMIc)" (19-110B); BSL3 in vitro. NIH Guidelines category non-exempt rDNA: N/A

Meeting adjourned: 12:25PM Minutes recorded by C.Johnson

# APPROVED MINUTES Institutional Biosafety Committee

# December 11, 2019

Check if Attending (Alternate Members):		
Lon Kendall, Director LAR		
Robert Ellis, Director of Biosafety*		
Christine Johnson, Senior IBC Coordinator,		
Alternate-at-Large*		
*non-voting at this meeting		
Regular Guests (non-voting):		
Heather Blair, Associate Biosafety Officer		
☐ Joni Van Sickle, Occupational Health Coord.		
Other: Anthony Appleton, Research Safety Culture Coordinator		

This meeting was convened at 12:02PM. Quorum was maintained throughout. Any member with a conflict of interest left the room during discussion and/or committee determination on the conflicted item.

# I. Review of November 13, 2019 IBC meeting minutes.

The committee unanimously approved the November minutes with a minor correction.

# II. Review of Agent and Project Request Forms (https://protocols.research.colostate.edu/rco).

1. Borlee, Brad

Agent: Asaia bogorensis – Strain: any; BSL2

## The committee unanimously approved of the above agent with the following to be addressed:

- 1. The IBC requests that a chemical disinfectant and its percentage be added to the methods of inactivation.
- 2. A PARF is required for working with this agent and the IBC requests that a new PARF be submitted or a current PARF amended prior to beginning work.

## 2. Pearce, Stephen

**Project:** Optimization of Potato (Solanum tuberosum) Transformation (19-120B); BSL1 in vitro, rDNA/transgenic plants. NIH Guidelines category non-exempt rDNA: III-E-2

# The committee unanimously approved of the above project with the following to be addressed:

1. The IBC requests that the screening surrounding the exhaust fans be inspected after inclement weather such as heavy snow to ensure barrier integrity.

2. The IBC requests that the source of the promoters be added to the PARF.

#### 3. Santangelo, Kelly

Agent: Adeno-associated viral (AAV) vector – Strain: Serotype 2 and 5; BSL2

# The committee unanimously approved of the above agent with the following to be addressed:

1. The IBC requests the building and room number for the storage location.

**Project:** Intra-articular viral vectors for use in rodents: A pilot study (19-122B); BSL2 in vivo in guinea pigs, mice, and rats; rDNA. NIH Guidelines category non-exempt rDNA: III-D-4

# The committee unanimously approved of the above project with the following to be addressed:

- The IBC requests that the following procedures and statement be added to the Mechanisms in place
  for containment and disposition of infected animals or plants: Any unused AAV will be inactivated
  via autoclave. Following infection in the mice, AAV are reported to no longer be excreted 72 hours
  after inoculation, nor are they active in the bedding waste. Cages are labeled with a biohazard
  sticker for the first 72 hours and no cages are open during that time unless absolutely necessary. In
  which case they are opened in a BSC.
- 2. The IBC requests that all investigators complete a Statement of Experience in the Online IBC Database and complete the IBC at CSU training, also on the Online IBC Database.
- 3. The IBC requests that all individuals who will be using a Biosafety Cabinet complete the Biosafety Cabinet Training through the Biosafety Office.

# 4. Garrity, Deborah

**Project:** Characterization of Zebrafish Models of Filamin C Cardiomyopathy (19-123B); BSL1 in vivo in zebrafish; rDNA. NIH Guidelines category non-exempt rDNA: III-D-4

### The committee unanimously approved of the above project with the following recommendation:

1. The IBC requests that all investigators complete a Statement of Experience in the Online IBC Database and complete the IBC at CSU training, also on the Online IBC Database.

## III. Amendments to be reviewed by full committee

1. Belisle, John

**Project:** Metabolic evaluation of leprosy and M. leprae (13-073B); BSL2 in vitro, rDNA. NIH Guidelines category non-exempt rDNA: III-D-2

**Amendment request:** to add Mycobacterium bovis (attenuated) BCG to the list of agents for this project. Also the statement for recombinant DNA should be modified to read "We will clone and express genes of M. leprae that are proposed to be involved in metabolic processes in M. smegmatis mc2 155 or M. bovis BCG. The recombinant M. smegmatis or BCG strains will be evaluated for biochemical activity and biological activity with in vitro culture"

The committee unanimously approved of the above amendment without changes.

#### IV. Unfinished business

1. Todd Gaines PARF (19-098B)

The committee unanimously approved of the above project without changes.

It was discussed that the investigator is going to look at the feasibility of using Kanamycin to reduce concerns of potentiating herbicide resistance.

## 2. BRB shutdown/renovation – update

## **V.New Business**

## 1. PI seeking IBC advice on project utilizing sputum from TB patients

A PI has requested IBC input on risks to consider for experiments involving administration of clinical, TB positive sputum samples to mice. The committee discussed the following:

- a. If the samples are of international origin, a CDC import permit may be required. Depending on the areas in which the samples will be used, it may be very straightforward since there are CDC import permits for most of the BSL-3 TB areas.
- b. It is vital to consider what other organisms are in the sputum samples. A metagenomic analysis to assess the microbiome for these samples is strongly recommended.
- c. The logistics of performing an aerosolization inoculation was also discussed. It may be difficult to get enough bacilli for infection. Additionally, the nebulizer is calibrated for the aerodynamics of cultured bacteria and not sputum. Synthetic sputum is suggested for optimizing these conditions. If possible, an intra-nasal or intra-tracheal administration might be more effective.
- d. During aerosolization with the clinical samples, it is recommended that signs be posted and other people in the area be informed of the work.

## 2. ABSA International Award

Christine Johnson, Sr. IBC Coordinator, received the First Place Biosafety and Biosecurity Month Promotional Award at the annual ABSA conference in October for the Biosafety Fair and other Biosafety Month activities.

## VI. Reports

## 1. Coordinator's report

- a. Inaugural NExTRAC Meeting Video cast (<a href="https://videocast.nih.gov/pastevents">https://videocast.nih.gov/pastevents</a>)

  The Novel and Exceptional Technology and Research Advisory Committee (formally the RAC) is a federal advisory committee that provides recommendations to the NIH Director and a public forum for the discussion of the scientific, safety, and ethical issues associated with emerging biotechnologies. Talks given by Dr. Kenneth Oye and Dr. Zach Adelman may be of particular interest given their recent work with CSU.
- b. Next IBC meeting: Wednesday, January 15, 2020
- c. Kelley Anderson started with RICRO as the IACUC Protocol Liaison and PAM Coordinator.

## 2. Biosafety Officer's report

## a. Incident reports:

- A leak from an autoclave that passes through from a BSL3 area was noticed. It did not occur during BSL3 work or during an autoclave run. It was treated as a spill and an autoclave technician came to fix the problem.
- Near miss reports include individuals not using room logs correctly and incorrect storage of dirty cages. All individuals involved were identified and reminded of the correct procedures.
- One near miss occurred when an individual was moving an aerosol basket to the autoclave in a bag and a wire poked out, cutting both gloves but not the individual's hand. Aerosol basket users were asked to clip and file the baskets again to remove sharp points.
- An when individual discovered that the plug for a flask non-virulent tuberculosis had been knocked off inside the shaking incubator, likely when someone was cleaning. The incubator was thoroughly cleaned, and the SOPs were reviewed with the staff. Incident closed, no outside reporting required.
- An individual was filling syringes with M. bovis BCG and the syringe had a dead volume and tight total volume so they decided to suck back the total volume in a leur lock syringe, remove the capped needle, and draw the material from the leur lock with an insulin syringe. During this process the individual stuck their finger with

the needle. The wound was washed and the individual is in contact with Occupational Health. They do not believe any liquid was injected into their hand. The researcher agreed to ensure that correct syringes are used in the future and that dead volumes are accounted for. No outside reporting required.

## b. Inspections

There have not been any inspections since May. However, the CDC informed the BSO that PETA requested a FOIA of CSU select agent documents from January 2016 through October 2019 for BSL3 work. The request included inspections, import permits, and email communications. The CDC performed a redaction of personal identification information, then gave the BSO the opportunity to review the documents in consultation with CSU general counsel and VPR representatives prior to the information being released.

# c. Laboratory audit reports

BSL2 self-audits are under way and being reviewed by the BSO upon completion.

## d. Personnel updates

Dr. Gentry-Weeks is no longer a BSO for main campus. The search for a new ABSO is underway. The search for a new BSO director will be starting soon to prepare for Dr. Ellis's retirement in July.

# VII. Agent and Project Approval Request Forms Reviewed at Previous IBC Meeting and Approved After Modification to be read into the minutes.

1. Gaines, Todd

**Agent:** Saccharomyces cerevisiae – Strain: any; BSL1

**Project:** Gene function validation for target site and non-target site herbicide resistance mechanisms (19-108B); BSL1 in vitro and BSL1 in vivo in Arabidopsis thaliana. NIH Guidelines category non-exempt rDNA: III-E-2

2. Myers, Brent

**Project:** Cortical-Medullary Circuitry Preventing the Cardiovascular Consequences of Chronic Stress (19-115B); BSL1 in vivo in rats, rDNA. NIH Guidelines category non-exempt rDNA: III-E-1

3. Peccoud, Jean

**Project:** <u>Automated Prioritization and Design of Experiments to Validate and Improve</u> <u>Mathematical Models of Molecular Regulatory Systems</u> (19-116B); BSL1 in vitro, rDNA. NIH Guidelines category non-exempt rDNA: III-E-1

- VIII. Amended Project or Agent approval Request Forms Reviewed at Previous IBC Meeting and Approved After Modification to be read into the minutes.
- IX. New or Amended Agent Approval Request Forms Reviewed and Approved by the <u>Biosafety Officer</u> or Chair to be read into the minutes.
- X. New or Amended Project Approval Request Forms Reviewed and Approved by the <u>Biosafety Officer</u> or <u>Chair</u> to be read into the minutes.
  - 1. Ordway, Diane

**Project:** Adjunct therapeutic efficacy of DosRS inhibitors in the treatment of NTM infections: mouse models (19-111B); BSL2 in vitro and in vivo in mice. NIH Guidelines category non-exempt rDNA: N/A

**Project:** Evaluation of epetraborole against MAC in an in vivo acute beige M. intracellulare infection model (19-112B); BSL 2 in vitro and in vivo in mice. NIH Guidelines category non-exempt rDNA: N/A

**Project:** In Vitro Assessments of Anti-Microbial Activity Task Order – "Anti-mycobacterial Target or Mechanism Identification contract (AToMIc)" (19-113B); BSL 2 in vitro and in vivo in mice. NIH Guidelines category non-exempt rDNA: N/A

**Project:** Proof-of-Concept for superior in-vivo efficacy of apramycin in chronic mycobacterial <u>lung infections</u> (19-114B); BSL 2 in vitro and in vivo in mice. NIH Guidelines category non-exempt rDNA: N/A

# 2. Johnson, Valerie

**Project:** Safety and Efficacy of administration of allogeneic and autologous mesenchymal stem cells in captive large exotic species for treatment of osteoarthriti (19-117B); BSL1 in vitro; NHP samples. NIH Guidelines category non-exempt rDNA: N/A

Meeting adjourned: 1:05PM Minutes recorded by C.Johnson

# APPROVED MINUTES Institutional Biosafety Committee

# January 15, 2020

Check if Attending (Members):	Check if Attending (Alternate Members):	
<b>⊠</b> Jessica Ayers, Animal expert	Lon Kendall, Director LAR	
☐ Donald Bade, Unaffiliated	Robert Ellis, Director of Biosafety*	
Richard Bowen, Associate Chair	Christine Johnson, Senior IBC Coordinator,	
	Alternate-at-Large*	
Patrick Byrne, Plant expert		
Chaoping Chen, Chair	*non-voting at this meeting	
Sara Cope, Assistant Biosafety Officer, called in		
Angelo Izzo, Mycobacteria Immunology, arrived		
12:05PM		
⊠Nicole Marlenee, Lab tech rep		
June Medford, Plant/syn bio expert		
Edwin Neas, Unaffiliated		
Ken Olson, Virology		
Ann Powers, Virology		
Bernard Rollin, Bioethicist		
Non-Voting Members:		
□ James Graham, EHS Director		
RICRO Staff (non-voting):	Regular Guests (non-voting):	
Karen Dobos, RICRO Director	Heather Blair, Associate Biosafety Officer	
Christa Johnson, Associate VP for Research	☐ Joni Van Sickle, Occupational Health Coord.	
Other: Anthony Appleton, Research Safety Culture Coordinator		

This meeting was convened at 12:00PM. Quorum was maintained throughout. Any member with a conflict of interest left the room during discussion and/or committee determination on the conflicted item.

## I. Review of December 11, 2019 IBC meeting minutes.

The committee unanimously approved the December minutes with a minor correction.

# II. Review of Agent and Project Request Forms (https://protocols.research.colostate.edu/rco).

1. Bosco-Lauth, Angela

Agent: Severe fever with thrombocytopenia syndrome virus – Strain: any; BSL3

The committee unanimously approved of the above agent with the following to be addressed:

- 1. The IBC requests that a chemical method of inactivation be added.
- 2. The IBC asks that the PI verify whether a permit is required even though the agent is coming from the CDC.

This is a tick born bunyavirus.

**Project:** <u>Vector competence of Haemaphysalis longicornis ticks for severe fever with thrombocytopenia syndrome virus using goats as a host feeding model</u> (19-128B); BSL3 in vitro and in vivo in goats; NIH Guidelines category non-exempt rDNA: N/A

The committee unanimously approved of the above project without changes pending final approval of the above agent.

# 2. Ebel, Gregory

Agent: Yellow Fever virus – Strain: any; BSL3

## The committee unanimously approved of the above agent with the following to be addressed:

- 1. The IBC requests the room number of the storage location be specified.
- 2. Yellow fever virus vaccine is in very limited supply at this time. The IBC requests that anyone who will have access to the virus get vaccinated prior to beginning work with the agent. Personnel in need of vaccination must work with the Occupational Health Coordinator to accomplish this task.

**Project:** Flavivirus cellular tropisms driving dissemination and transmission in mosquito vectors (20-001B); BSL3 in vitro and in vivo in mosquitoes and mice; NIH Guidelines category non-exempt rDNA: III-E-1

# The committee unanimously approved of the above project with the following to be addressed:

- 1. The IBC requests clarification of which activities will be performed at CSU and which activities will be performed at the CDC.
- 2. The IBC requests the specific room numbers for in vitro and in vivo work as soon as they are known.
- 3. Yellow fever virus vaccine is in very limited supply at this time. The IBC requests that anyone who will have access to the virus get vaccinated prior to beginning work. Personnel in need of vaccination must work with the Occupational Health Coordinator to accomplish this task.

## 3. Stenglein, Mark

Agent: Pseudomonas aeruginosa – Strain: any; BSL2

### The committee unanimously approved of the above agent with the following to be addressed:

- The IBC requests that 10% hypochlorite be changed to 10% bleach or 0.525% hypochlorite for chemical inactivation.
- 2. The IBC requests that autoclaving be included as a method for inactivation.
- 3. The IBC requests that information covered in the Project Approval Request Form be removed from this Agent Approval Request Form.

Agent: Kallithea virus - Strain: any; BSL1

The committee unanimously approved of the above agent without changes.

This is a new virus of Drosophila melanogaster.

Agent: Mouse rotavirus – Strain: any; BSL2

## The committee unanimously approved of the above agent with the following to be addressed:

- The IBC requests that 10% hypochlorite be changed to 10% bleach or 0.525% hypochlorite for chemical inactivation.
- 2. The IBC requests that autoclaving be included as a method for inactivation.
- 3. The IBC reminds the investigator that a PARF must be submitted prior to working with this agent.

#### III. Amendments to be reviewed by full committee

None

## IV. Unfinished business

None

## **V.New Business**

#### 1. AAV information sheet

The IBC reviewed a document with information regarding hazards and containment for Adeno-Associated Virus prepared by the IBC intern. Two typos were identified. After correction, this sheet will be posted on the IBC website and shared with the Occupational Health Coordinator.

## 2. Direct blood feeding of mosquitoes

It was brought to the attention of one of the BSOs that some projects involve feeding mosquitoes on blood drawn from the researchers in the group and direct mosquito feeding on the researchers. There was a question about whether these practices are included on the PARF(s) for the relevant projects. Also, the risk of a mosquito becoming infected from the human researcher and then infecting another researcher was discussed. The potential increased risk of exposure to viruses from Africa was discussed due to the nature of this research group's work. An IBC member indicated that direct mosquito feeding is sometimes necessary for studies involving repellent efficacy and for generating of new mosquito, but that the mosquitos are typically killed after feeding and do not feed on a second individual. The IBC requested to get more information from the PI to make sure the safety practices are spelled out in the PARF and to verify that there are some exclusion criteria for individuals who have recently travelled internationally. Because this is also a human subject concern, this matter is to be brought to the attention to the IRB for discussion.

# VI. Reports

#### 1. Coordinator's report

- a. Next IBC meeting: Wednesday, February 12, 2020
- b. Biosafety month 2019: the results for the RAM SAFE pledge drive were given to the committee. To address concerns of equity from last year, the award was based on total percentage of participation in a department rather than just number of pledges. The results were:
  - 1<sup>st</sup> Place & Golden Goggles Recipient: Lab Animal Resources
  - 2<sup>nd</sup> Place: Infectious Disease Research Center
  - 3<sup>rd</sup> Place: Microbiology, Immunology, and Pathology
  - 4<sup>th</sup> Place: Biochemistry and Molecular Biology
  - 5<sup>th</sup> Place: Health and Exercise Science

Honorable mentions were given to MIP for the highest number of faculty pledges and to BMB for the highest number of undergraduate pledges.

# 2. Biosafety Officer's report

- a. Incident reports: Two near misses have been reported since the last meeting.
  - While working in the BSL3 an individual plugged a microfuge into the wall and the breaker failed resulting in loss of power to the biosafety cabinet. The individual followed procedures for a power failure, closing the sash immediately. Power returned within five minutes and the BSC was allowed to re-equilibrate before work was continued. At the time of power loss, samples were being stained for flow cytometry. No outside reporting required.
  - The custodial staff reported biohazard bags in the regular trash. They did not dispose of the biohazardous bags with the regular trash. The PI was contacted and retrained staff. Biosafety is following up on why the bags were improperly placed in the regular trash. No outside reporting required.
- b. **Inspections** none to report
- c. Laboratory audit reports

Select Agent laboratory audits are being finished up. BSL2 self-audits are under way and being reviewed by the BSO upon completion.

VII. Agent and Project Approval Request Forms Reviewed at Previous IBC Meeting and Approved After Modification to be read into the minutes.

1. Borlee, Brad

Agent: Asaia bogorensis – Strain: any; BSL2

2. Santangelo, Kelly

Agent: Adeno-associated viral (AAV) vector – Strain: Serotype 2 and 5; BSL2

**Project:** Intra-articular viral vectors for use in rodents: A pilot study (19-122B); BSL2 in vivo in guinea pigs, mice, and rats; rDNA. NIH Guidelines category non-exempt rDNA: III-D-4

3. Peccoud, Jean

**Project:** <u>Automated Prioritization and Design of Experiments to Validate and Improve</u>
<u>Mathematical Models of Molecular Regulatory Systems</u> (19-116B); BSL1 in vitro, rDNA. NIH
Guidelines category non-exempt rDNA: III-E-1

- VIII. Amended Project or Agent approval Request Forms Reviewed at Previous IBC Meeting and Approved After Modification to be read into the minutes.
- IX. New or Amended Agent Approval Request Forms Reviewed and Approved by the <u>Biosafety Officer</u> or Chair to be read into the minutes.
  - 1. Reardon, Kenneth

Agent: Pichia kudriavzevii - Strain: any; BSL1

2. Lappin, Michael

Agent: Babesia gibsoni – Strain: any; BSL1

- X. New or Amended Project Approval Request Forms Reviewed and Approved by the <u>Biosafety Officer</u> or Chair to be read into the minutes.
  - 1. Erhart, Nicole

**Project:** Optimize Regeneration Therapies through Preservation of Stem Cell Niche (19-124B); BSL2 in vivo. NIH Guidelines category non-exempt rDNA: N/A

2. McGilvray, Kirk

**Project:** Human Chronic Rotator Cuff Degeneration: A Correlation Between Histopathologic and <u>Viscoelastic Manifestations</u> (19-125B); Human Samples. NIH Guidelines category non-exempt rDNA: N/A

3. Jackson, Mary

**Project:** Genetic Basis of an Environmental Survival Phenotype for M. abcessus (19-126B); BSL2 in vitro. NIH Guidelines category non-exempt rDNA: N/A

4. Lappin, Michael

**Project:** Experimental Babesia spp. infection in dogs (19-127B); BSL1 in vitro and in vivo in dogs. NIH Guidelines category non-exempt rDNA: N/A

Meeting adjourned: 12:51PM Minutes recorded by CJohnson

# APPROVED MINUTES Institutional Biosafety Committee

# February 12, 2020

Check if Attending (Members):	Check if Attending (Alternate Members):	
Jessica Ayers, Animal expert	Lon Kendall, Director LAR	
☑Donald Bade, Unaffiliated	Robert Ellis, Director of Biosafety*	
Richard Bowen, Associate Chair	Christine Johnson, Senior IBC Coordinator,	
	Alternate-at-Large	
Patrick Byrne, Plant expert, departed at 12:45PM		
Chaoping Chen, Chair	*non-voting at this meeting	
Sara Cope, Assistant Biosafety Officer, called in		
Angelo Izzo, Mycobacteria Immunology		
☐ Nicole Marlenee, Lab tech rep		
☐ June Medford, Plant/syn bio expert, departed at		
1:02PM		
Edwin Neas, Unaffiliated, departed at 1:03PM		
Ken Olson, Virology		
Ann Powers, Virology, departed at 1:28PM		
Bernard Rollin, Bioethicist, arrived at 12:45PM		
Non-Voting Members:		
☐ James Graham, EHS Director		
RICRO Staff (non-voting):	Regular Guests (non-voting):	
Karen Dobos, RICRO Director	Heather Blair, Associate Biosafety Officer	
Christa Johnson, Associate VP for Research	☐ Joni Van Sickle, Occupational Health Coord.	
Joanie Ryan, IBC Intern		
Angie Chromiak, Admin Staff		
Other: Tony Schountz (PI MIP), Mike Hooker (Public Relations), Meghan Suter (OVPR), James Owiny (Assoc.		
Attending Veterinarian – LAR)		

This meeting was convened at 12:00PM. Quorum was maintained throughout. Any member with a conflict of interest left the room during discussion and/or committee determination on the conflicted item.

## I. Discussion regarding the new SARS-CoV-2 and COVID-19 projects

Due to the growing public concern regarding the current coronavirus outbreak, it was decided to invite the PIs proposing to work with the new agent to the IBC meeting to discuss their projects. Representatives from the Public Relations Teams and OVPR were also invited to provide their perspectives. The Biosafety Office Director gave an overview of what is known about the new coronavirus, how it compares to previous coronavirus outbreaks, and CDC's current recommendations for labs working with the new coronavirus. Both Drs. Schountz and Bowen discussed their proposed projects. The IBC discussed containment procedures for the various animal models, whether or not baseline serology should be considered, and the protocol for what to do if a BSL3 researcher becomes ill (due to exposure or otherwise). The current containment procedures and protocol for an ill BSL3 researcher were determined to be appropriate for this new work. Collection of baseline serology would be burdensome and was determined to not be necessary. It was also suggested that the PI could provide care for infected animals, but this was determined to not be necessary. Bottom line, all work with this new coronavirus will be conducted by highly experienced researchers, in BSL3 laboratories, and all standard BSL3 practices will be followed. Occupational Health is working on the Exposure Control Plan for the new agent, and will soon have a draft to be reviewed by the

subject matter experts. The plan is to start the research as soon as possible; the PI should receive the virus next week and start animal studies within two weeks. After all questions were answered, the guests were thanked for their time and attendance, and left the meeting.

# II. Review of January 15, 2020 IBC meeting minutes.

The January minutes were not available and will be added to the March meeting agenda.

- III. Review of Agent and Project Request Forms (https://protocols.research.colostate.edu/rco).
  - 1. Bowen, Richard A.

**Agent:** 2019 Novel Coronavirus – Strain: any; BSL3

# The committee unanimously approved of the above agent with the following to be addressed:

1. The IBC requests that the name of the agent be updated to the official WHO designated name SARS-CoV-2

**Project:** Host Range Investigations of 2019 nCoV (20-009); BSL3 in any vertebrate except primates. NIH Guidelines category non-exempt rDNA: N/A

# The committee unanimously approved of the above project with the following to be addressed:

- 1. Under in vivo species, the IBC requests that the wording be changed to "any vertebrate except primates."
- **2.** The IBC recommends updating the sponsor, as it is currently listed as "self" which implies that the PI is paying out of their own pocket.

**Project:** Broadly neutralizing single chain antibodies to coronaviruses (20-016B); BSL3 in vitro and BSL3 in vivo in Alpaca. NIH Guidelines category non-exempt rDNA: N/A

### The committee unanimously approved of the above agent with the following to be addressed:

1. The IBC requests that the acronym "PBMCs" be spelled out.

## 2. Schountz, Tony

Agent: 2019-nCoV (Wuhan novel coronavirus) – Strain: any; BSL3

# The committee unanimously approved of the above agent with the following to be addressed:

- 1. The IBC requests that the name of the agent be updated to the official WHO designated name SARS-CoV-2
- 2. The IBC requests that the human risk group be changed from 4 to 3.
- 3. The IBC requests a chemical disinfectant and its percentage be added to the Methods of Inactivation for Disposal

**Project:** Experimental infection of Jamaican fruit bats with 2019-nCov coronavirus (20-008B); BSL3 in vitro and in vivo in fruit bats, rDNA. NIH Guidelines category non-exempt rDNA: N/A

The committee unanimously approved of the above project without changes pending final approval of the above agent.

**Agent:** Puumala virus – Strain: any; BSL3

The committee unanimously approved of the above agent without changes.

Agent: Choclo virus – Strain: any; BSL3

The committee unanimously approved of the above agent without changes.

**Project:** Therapeutic monoclonal antibody for hantavirus neutralization (20-003B); BSL3 in vitro, rDNA. NIH Guidelines category non-exempt rDNA: N/A

The committee unanimously approved of the above project without changes.

	Agent: Enterobacter cloacae – Strain: any; BSL2
The cor	nmittee unanimously approved of the above agent with the following to be addressed:
1.	The IBC requests the room number for the storage location in the
	Agent: Streptococcus agalactiae – Strain: any; BSL2
The cor	nmittee unanimously approved of the above agent with the following to be addressed:
1.	The IBC requests the room number for the storage location in the
	Agent: Streptococcus pyogenes – Strain: any; BSL2
	nmittee unanimously approved of the above agent with the following to be addressed:
1.	The IBC requests the room number for the storage location in the
2.	The IBC requests clarification regarding antibiotic resistance and whether it is naturally occurring. It is
	marked YES, however it is not discussed in the agent description.
	Agent: Streptococcus pneumoniae – Strain: any; BSL2
The cor	nmittee unanimously approved of the above agent with the following to be addressed:
1.	The IBC requests the room number for the storage location in the
2.	The IBC requests clarification regarding antibiotic resistance and whether it is naturally occurring. It is
	marked YES, however it is not discussed in the agent description.
	Agent: Enterococcus faecalis – Strain: any; BSL2
	nmittee unanimously approved of the above agent with the following to be addressed:
1.	The IBC requests the room number for the storage location in the
2.	Due to the agent description, the IBC requests confirmation that the answer to antibiotic resistant be
	marked YES.
	Agent: Enterococcus faecium – Strain: any; BSL2
	nmittee unanimously approved of the above agent with the following to be addressed:
1.	The IBC requests the room number for the storage location in the
2.	Due to the agent description, the IBC requests confirmation that the answer to antibiotic resistant be marked YES.
	Agent: Staphylococcus aureus – Strain: any; BSL2
	nmittee unanimously approved of the above agent with the following to be addressed:
1.	The IBC requests the room number for the storage location in the
	Agent: Escherichia coli – Strain: any; BSL2
	nmittee unanimously approved of the above agent with the following to be addressed:
1.	The IBC requests the room number for the storage location in the
_	Agent: Enterobacter aerogenes – Strain: any; BSL2
	nmittee unanimously approved of the above agent with the following to be addressed:
2.	The IBC requests the room number for the storage location in the

**Agent:** Acinetobacter baumannii – Strain: any; BSL2

1. The IBC requests the room number for the storage location in the

The committee unanimously approved of the above agent with the following to be addressed:

3. Slayden, Richard

Agent: Klebsiella pneumoniae – Strain: any; BSL2

1. The IBC requests the room number for the storage location in the

The committee unanimously approved of the above agent with the following to be addressed:

#### 4. Nishimura, Marc

Agent: Pseudomonas syringae – Strain: any; BSL1

# The committee unanimously approved of the above agent with the following to be addressed:

1. The IBC recommends that the containment be changed to BSL2.

Agent: Xanthomonas citri – Strain: any; BSL1

## The committee unanimously approved of the above agent with the following to be addressed:

1. The IBC recommends that the containment be changed to BSL2.

**Project:** <u>BZ480 Crispr Theory and Application</u> (20-005B); BSL1 in vitro and BSL1P, rDNA. NIH Guidelines category non-exempt rDNA: III-E-2

## The committee unanimously approved of the above project with the following to be addressed:

- 1. The IBC recommends that the students also wear lab coats.
- 2. The IBC suggests that gloves be considered to avoid contamination of experimental materials.

This is an upper level class, designed to give student research experience with CRISPR.

## 5. Bosco-Lauth, Angela

Agent: Burkholderia pseudomallei – Strain: any; BSL3

## The committee unanimously approved of the above agent with the following to be addressed:

1. The IBC requests the addition of the percentage of Neutral Q used to inactivate the agent for disposal.

Agent: Francisella tularensis – Strain: any; BSL3

## The committee unanimously approved of the above agent with the following to be addressed:

- 1. The IBC requests the addition of the percentage of Neutral Q used to inactivate the agent for disposal.
- 2. The IBC requests the room number for the storage location in the

Project: Environmental characteristics of Burkholderia pseudomallei and Francisella tularensis

(20-007B); BSL3 in vitro and in vivo in plants, hamsters, rats, and rabbits, rDNA. NIH Guidelines category non-exempt rDNA: N/A

The committee unanimously approved of the above project without changes pending final approval of the above agents.

There was a discussion regarding why rice plants were being used. It's because rice is susceptible to Burkholderia infections. This is a terra forma project.

## 6. Guth, Amanda (Zoetis)

Agent: Pasteurella multocida – Strain: AHDRCC #46572, Serotype 4; BSL2

#### The committee unanimously approved of the above agent with the following to be addressed:

- The IBC requests that the PI's statement of experience be updated to reflect her current laboratory group.
- 2. The IBC recommends that the human risk group be changed from 3 to 2.

**Project:** <u>Pasteurella multocida as a model of bovine respiratory disease</u> (20-015B); BSL2 in vitro and BSL2 in vivo in mice. NIH Guidelines category non-exempt rDNA: N/A

# The committee unanimously approved of the above project with the following to be addressed:

- 1. The IBC requests that the PI's statement of experience be updated to reflect her current laboratory group.
- 2. The IBC requests that all investigators update their information and statements of experience to reflect the current sponsor.

3. The IBC requests that all investigators update their biosafety training and register with the IBC database.

## 7. Hansen, Thomas

Agent: Adenovirus associated-virus – Strain: AAV2, AAV5, AAV9, AAV-B1; BSL1

The committee unanimously approved of the above agent without changes.

**Project:** <u>ISGs in the corpus luteum are necessary for maintenance of pregnancy in ruminants (20-011B);</u> BSL1 in vivo in sheep. NIH Guidelines category non-exempt rDNA: III-D-4

The committee unanimously approved of the above project without changes.

## 8. Perera, Rushika

Agent: Wolbachia - Strain: Strains wMEL and wMELPop; BSL1

The committee unanimously approved of the above agent with the following to be addressed:

- 1. The IBC request the room number of the insectary location and the laboratory work in
- 2. The IBC requests that a chemical disinfectant and its percentage be added to the methods of inactivation for disposal.

**Project:** Metabolic basis of mosquito-endosymbiont-virus interactions (20-013B); BSL2 in vitro and BSL3 in vivo in mosquitoes. NIH Guidelines category non-exempt rDNA: III-D-4

The committee unanimously approved of the above project with the following to be addressed:

- 1. The IBC request the room numbers for the in vivo mosquito work.
  - 2. The IBC requests all investigators register with the IBC database, fill out a statement of experience, and complete the IBC at CSU training.

### IV. Amendments to be reviewed by full committee

1. Belisle, John

**Project:** CD1-Restricted T-Cell Responses in Skin (10-059B); BSL2 in vitro, rDNA. NIH Guidelines category non-exempt rDNA: III-D-2

The committee unanimously approved the amendment to add Mycobacterium heamophilum as a host for expression.

#### V.Unfinished business

1. Direct blood feeding of mosquitoes

This will be discussed at the March meeting.

# VI. New Business

#### 1. N95 Shortage

Due to the SARS-CoV-2 outbreak, there is a nationwide shortage of N95 respirators and suppliers are filling respirator orders on a priority basis. These are critical PPE for the safety of many of our researchers. Thus the Occupational Health Coordinator has spearheaded an effort to secure a source of respirators. A letter was written and signed by the VPR, BSO, and IBC Chair highlighting the importance of the research at CSU and the need for it to continue. The letter has been received by 3M and CSU is waiting to hear back. Other options being considered include using a different type of respirator, this would require new fit testing. In meantime, researchers have been encouraged limit unnecessary trips into the barrier whenever possible.

## VII. Reports

- 1. Coordinator's report
  - a. Next IBC meeting: Wednesday, March 11, 2020
- 2. Biosafety Officer's report
  - a. Incident reports: Two near misses and one spill have been reported since the last meeting.
    - An individual was going to use an autoclave and discovered mis-labeled animal carcass waste that needed a second autoclave bag. The individual double bagged the carcasses, relabeled the waste, and placed them in the correct location for proper autoclaving. The research group generating the waste was contacted and reminded about proper procedures. No outside reporting required.
    - An individual discovered a 5mL pipet in the regular trash and inconsistencies in BSC sign in and out in the area. Biosafety sent an email to the groups using the space reminding them of the proper procedures. No outside reporting required.
    - An individual looked into the warm room in the on the floor. It was determined to be a spill from a crack in a Fernbach flask. Four people including one biosafety officer assisted with the spill cleanup. Because it occurred in the warm room, precautions regarding heat were taken. An incident review meeting is being scheduled. No outside reporting required.
  - b. Inspections
  - c. Laboratory audit reports
- VIII. Agent and Project Approval Request Forms Reviewed at Previous IBC Meeting and Approved After Modification to be read into the minutes.
  - 1. Bosco-Lauth, Angela

**Agent:** Severe fever with thrombocytopenia syndrome virus – Strain: any; BSL3 **Project:** Vector competence of Haemaphysalis longicornis ticks for severe fever with thrombocytopenia syndrome virus using goats as a host feeding model (19-128B); BSL3 in vitro and in vivo in goats; NIH Guidelines category non-exempt rDNA: N/A

2. Ebel, Gregory

**Agent:** Yellow Fever virus – Strain: any; BSL3

**Project:** Flavivirus cellular tropisms driving dissemination and transmission in mosquito vectors (20-001B); BSL3 in vitro and in vivo in mosquitoes and mice; NIH Guidelines category non-exempt rDNA: III-E-1

3. Stenglein, Mark

**Agent:** Pseudomonas aeruginosa – Strain: any; BSL2

Agent: Mouse rotavirus – Strain: any; BSL2

- IX. Amended Project or Agent approval Request Forms Reviewed at Previous IBC Meeting and Approved After Modification to be read into the minutes.
- X. New or Amended Agent Approval Request Forms Reviewed and Approved by the <u>Biosafety Officer</u> or Chair to be read into the minutes.
- XI. New or Amended Project Approval Request Forms Reviewed and Approved by the <u>Biosafety Officer</u> or <u>Chair</u> to be read into the minutes.
  - 1. Wilson, Jesse

**Project:** Sub-picosecond spectroscopy and imaging of mitochondrial respiratory chain redox (19-129B); Human Samples; NIH Guidelines category non-exempt rDNA: N/A

2. Wiley, Mark

**Project:** Bovine Immunology Research Cell Culture (20-004B); BSL2 in vitro and Human Samples; NIH Guidelines category non-exempt rDNA: N/A

Meeting adjourned: 1:37PM Minutes recorded by C.Johnson

# APPROVED MINUTES Institutional Biosafety Committee

# March 11, 2020

Check if Attending (Members):	Check if Attending (Alternate Members):	
<b>⊠</b> Jessica Ayers, Animal expert, departed at 1:21PM	Lon Kendall, Director LAR	
☐ Donald Bade, Unaffiliated	Robert Ellis, Director of Biosafety*	
Richard Bowen, Associate Chair	Christine Johnson, Senior IBC Coordinator,	
	Alternate-at-Large	
Patrick Byrne, Plant expert, departed at 12:45PM		
Chaoping Chen, Chair	*non-voting at this meeting	
Sara Cope, Assistant Biosafety Officer		
Angelo Izzo, Mycobacteria Immunology		
⊠Nicole Marlenee, Lab tech rep		
Edwin Neas, Unaffiliated		
Ken Olson, Virology		
Ann Powers, Virology, called in		
Bernard Rollin, Bioethicist, called in		
Non-Voting Members:		
RICRO Staff (non-voting):	Regular Guests (non-voting):	
Karen Dobos, RICRO Director	Heather Blair, Associate Biosafety Officer	
Christa Johnson, Associate VP for Research	☐ Joni Van Sickle, Occupational Health Coord.	
Angie Chromiak, Admin Staff		
Other: Anthony Appleton, Research Safety Culture Coordinator		

This meeting was convened at 12:12PM. Quorum was maintained throughout. Any member with a conflict of interest left the room during discussion and/or committee determination on the conflicted item.

# I. Review of January 15, 2020 and February 12, 2020 IBC meeting minutes.

The committee approved of the January minutes without correction and the February minutes with minor corrections.

II. Review of Agent and Project Request Forms (<a href="https://protocols.research.colostate.edu/rco">https://protocols.research.colostate.edu/rco</a>).

1. Spencer, John

Agent: Mycobacteria tuberculosis – Strain: mc2700 deletion mutant panCD and esx1; BSL2

The committee unanimously approved of the above agent with the following to be addressed:

- 1. The IBC requests that the name of the agent be corrected to Mycobacterium tuberculosis.
- 2. The IBC requests that BSL2 rated cabinets be changed to BSL2 rated labs.
  - 2. Bowen, Richard A.

Agent: Equine parvovirus – Strain: any; BSL2

The committee unanimously approved of the above agent with the following to be addressed:

1. The IBC requests that the last line of the agent description be changed from "There is no hint that this is zoonotic." to "There is no evidence that this is zoonotic."

2. The IBC requests that autoclaving and the percentage of Neutral Q be added to the Methods used to inactivate agent for disposal.

**Project:** <u>Development of a live virus assay for equine parvovirus</u> (20-018B); BSL2 in vitro. NIH Guidelines category non-exempt rDNA: N/A

The committee unanimously approved of the above project without changes pending final approval of the above agent.

**Project:** CEPI: Immunogenicity, Safety and Efficacy of Rift Valley Fever Vaccine (20-023B); BSL3 in vitro and in vivo in goats and rats. NIH Guidelines category non-exempt rDNA: N/A

The committee unanimously approved of the above project with the following to be addressed:

- 1. The IBC requests that the location of work be corrected from
- 2. Because the In vitro uses lists and this space is a locker room, the IBC requests verification of the correct room number.
- 3. The IBC requests that a sentence or two be added to the Project Overview to clarify that goats will only be immunized with vaccine strains of RVFV (not challenged), and that rats will be immunized and challenged with RVFV.
- 4. The IBC requests clarification of the statement under Mechanisms in place for containment and disposition of infected animals: "All animals will be euthanized at incinerated or autoclaved/incinerated."

**Project:** Pathogenesis of Burkholderia pseudomallei infection in reptiles and fish (20-031B); BSL3 in vitro and in vivo in reptiles and fish. NIH Guidelines category non-exempt rDNA: N/A

The committee unanimously approved of the above project without changes pending approval of the CDC amendment to use of this select agent in fish.

## 3. Linke, Lyndsey

**Project:** E. coli laboratory cloning strain transformation and molecular cloning activities - CSU (20-026B); BSL1 in vitro and in vivo in mice and chickens. NIH Guidelines category non-exempt rDNA: III-D-4

The committee unanimously approved of the above project with the following to be addressed:

- 1. The IBC requests that the phrase "do not pose any known safety concerns" in the Project Overview be removed.
- 2. The IBC requests that if other individuals are working on this project, they be added to the PARF.

## 4. Gonzales Juarerro, Mercedes

Agent: Mycobacterium haemophilum – Strain: any; BSL2

The committee unanimously approved of the above agent with the following to be addressed:

- 1. The IBC requests the human risk group be changed from 1 to 2.
- 2. The IBC requests that the building be added under storage location.
- 3. The IBC requests that the typo in agent description be corrected: M. haemophilus should be M. haemophilum.
- 4. The IBC requests clarification for the use of 100% ethanol or acetone for inactivation for disposal instead of 70%.

## 5. Schissler, Jennifer R

**Agent:** Staphylococcus epidermidis – Strain: any; BSL2

The committee unanimously approved of the above agent with the following to be addressed:

- 1. The IBC requests the human risk group be changed from 1 to 2.
- 2. The IBC requests a room number for the storage location.
- 3. The IBC requests the addition of a chemical method of inactivation for disposal.

**Project:** Assessment of examination room Staphylococcus contamination following use by canine patients with superficial pyoderma and efficacy of a quaternary ammonium disinfectant and a hydrogen peroxide and silver fogging system Staphylococcus disinfection of a (20-021B); BSL2 in vitro. NIH Guidelines category non-exempt rDNA: N/A

## The committee unanimously approved of the above agent with the following to be addressed:

- 1. The IBC requests that all individuals working on this project include a Statement of Experience working with biohazardous materials and complete the IBC at CSU online training through the IBC database.
- 2. The IBC requests a room number for the work location.
- 3. The IBC requests clarification in the Project Overview statement: "3. After use of the Hallofogger, directly following Aimt"
- 4. Since the entire project title does not fit in the space provided, the IBC recommends that the title be shortened to fit.

## 6. Kading, Rebekah

**Project**: Rift Valley Fever Virus Reassortment in the Mosquito Vector (20-024B); BSL3 in vitro and in vivo in mosquitoes. NIH Guidelines category non-exempt rDNA: N/A

The committee unanimously approved of the above project pending approval of a CDC Select Agent Amendment.

## 7. Nishimura, Marc

Agent: Pseudomonas fluorescens – Strain: Pf0-1, Pf0-1 EtHAN; BSL1

#### The committee unanimously approved of the above agent with the following to be addressed:

1. Pseudomonas fluorescens can cause infections in immunocompromised individuals. Because of the open lab concept in the Building, the IBC requests that signage be posted in the lab and/or outside the lab door informing people of the potential risk to immunocompromised individuals.

**Project:** <u>Structure-Function Analyses of Plant NLR Receptors</u> (20-025B); BSL1 in vitro and in vivo in Arabidopsis, Brachypodium, and Nicotiana. NIH Guidelines category non-exempt rDNA: III-E-2

# The committee unanimously approved of the above project with the following to be addressed:

- 1. The IBC requests more details regarding containment and inactivation of plant pathogens and recombinant/transgenic material.
- 2. The IBC requests a description for the assays with sprayed bacteria.
- 3. The IBC requests that the PI set up a lab visit with the Biosafety Officer and a plant specialist.

## III. Amendments to be reviewed by full committee

## IV. Unfinished business

#### 1. Direct blood feeding of mosquitoes

It was confirmed by the PI that when mosquitoes are direct fed they never feed on a different individual. This matter was also reviewed by the IRB and clarifications were given regarding the actual practices. The consent form for the IRB was updated. The group is taking all of the necessary precautions to reduce the risk of passing unknown infectious organisms through the mosquitoes.

## 2. N95 Shortage

A partial shipment of N95s has been received. LAR is the main area of concern for supply shortage. Dr. Ellis received communication from the CDC about using expired respirators, although NIOSH has not supported this. The CDC recommends a thorough visual inspection by checking the seal, the straps, and the material as per usual protocol. These may be given to CSU personnel who are quarantined at home. It was also discussed that Tyvek may become difficult to obtain. Ms. Blair has a supply in the teaching lab if needed.

#### V.New Business None

#### VI. Reports

#### 1. Coordinator's report

- a. Next IBC meeting: Wednesday, April 8, 2020
- b. Anonymous report letter:

The committee was presented with a summative letter following the conclusion of a RICRO investigation into an anonymous concern. Most of the concerns were IACUC related, however some of the concerns and findings were relevant to the IBC. The PI involved has been responsive in working with the IBC chair, coordinator, and BSO to investigate and address the concerns. No additional corrective action or reporting required.

c. IBC Membership - Laboratory technician representative: Because Nikki will be transitioning to the biosafety office, the committee will need a new laboratory technician representative. Because this is a recommended and not required position, it is not vital to have the transition complete by next meeting. The committee discussed a potential person and the coordinator will reach out to him.

#### 2. Biosafety Officer's report

a. Incident reports:

There was one incident report of protocol breaches within the non-select agent area. Individuals were not using the BSC correctly, not covering caging correctly, and disrupting air flow by not waiting for doors to be closed before opening others. The Biosafety office is in contact with the research group for further inquiry and re-training. No outside reporting required.

- b. Inspections: None
- c. Laboratory audit reports: None
- d. Emergency planning:

Due to the COVID-19 pandemic, UC Boulder just announced that they go to all virtual learning by March 30<sup>th</sup>. It is expected that CSU will follow similar steps in going virtual and potentially reducing on-site research activities. The biosafety office is considered a critical unit, however there will be some changes to regular activity in order to comply with social distancing recommendations as best as possible. Updates will be provided as available.

# VII. Agent and Project Approval Request Forms Reviewed at Previous IBC Meeting and Approved After Modification to be read into the minutes.

1. Bowen, Richard A.

Agent: 2019 Novel Coronavirus – Strain: any; BSL3

**Project:** Host Range Investigations of 2019 nCoV (20-009); BSL3 in any vertebrate except primates. NIH Guidelines category non-exempt rDNA: N/A

**Project:** Broadly neutralizing single chain antibodies to coronaviruses (20-016B); BSL3 in vitro and BSL3 in vivo in Alpaca. NIH Guidelines category non-exempt rDNA: N/A

2. Schountz, Tony

Agent: 2019-nCoV (Wuhan novel coronavirus) – Strain: any; BSL3

3. Nishimura, Marc

**Project:** <u>BZ480 Crispr Theory and Application</u> (20-005B); BSL1 in vitro and BSL1P, rDNA. NIH Guidelines category non-exempt rDNA: III-E-2

4. Slayden, Richard

**Agent:** Klebsiella pneumoniae – Strain: any; BSL2 **Agent:** Enterobacter cloacae – Strain: any; BSL2

Agent: Streptococcus agalactiae – Strain: any; BSL2
Agent: Streptococcus pyogenes – Strain: any; BSL2
Agent: Streptococcus pneumoniae – Strain: any; BSL2
Agent: Enterococcus faecalis – Strain: any; BSL2
Agent: Enterococcus faecium – Strain: any; BSL2
Agent: Staphylococcus aureus – Strain: any; BSL2

**Agent:** Escherichia coli – Strain: any; BSL2

**Agent:** Enterobacter aerogenes – Strain: any; BSL2 **Agent:** Acinetobacter baumannii – Strain: any; BSL2

5. Bosco-Lauth, Angela

**Agent:** Burkholderia pseudomallei – Strain: any; BSL3 **Agent:** Francisella tularensis – Strain: any; BSL3

6. Guth, Amanda

Agent: Pasteurella multocida – Strain: AHDRCC #46572, Serotype 4; BSL2

**Project:** Pasteurella multocida as a model of bovine respiratory disease (20-015B); BSL2 in vitro and BSL2 in vivo in mice. NIH Guidelines category non-exempt rDNA: N/A

7. Perera, Rushika

Agent: Wolbachia – Strain: Strains wMEL and wMELPop; BSL1

**Project:** Metabolic basis of mosquito-endosymbiont-virus interactions (20-013B); BSL2 in vitro and BSL3 in vivo in mosquitoes. NIH Guidelines category non-exempt rDNA: III-D-3

- VIII. Amended Project or Agent approval Request Forms Reviewed at Previous IBC Meeting and Approved After Modification to be read into the minutes.
- IX. New or Amended Agent Approval Request Forms Reviewed and Approved by the <u>Biosafety Officer</u> or Chair to be read into the minutes.
- X. New or Amended Project Approval Request Forms Reviewed and Approved by the <u>Biosafety Officer</u> or <u>Chair</u> to be read into the minutes.
  - 1. Ryan, Elizabeth

**Project:** <u>Dietary Biomarkers of intake in people (</u>20-014B); Human samples. NIH Guidelines category non-exempt rDNA: N/A

2. Coatsworth, James Douglas

**Project:** <u>Treating Young Adult Cannabis Use Disorder with Text Message-Delivered Peer Network Counseling (</u>20-017B); Human samples. NIH Guidelines category non-exempt rDNA: N/A

3. Mehaffy, Martha

**Project**: Development of a chemiluminescent ELISA for the detection of Mycobacterium tuberculosis proteins in host serum exosomes and diagnosis of Latent TB infection (20-020B); Human samples. NIH Guidelines category non-exempt rDNA: N/A

Meeting adjourned: 1:32PM Minutes recorded by C.Johnson

#### **APPROVED MINUTES**

## Institutional Biosafety Committee

#### Microsoft Teams April 8, 2020

Check if Attending (Members):	Check if Attending (Alternate Members):	
<b>⊠</b> Jessica Ayers, Animal expert	Lon Kendall, Director LAR	
☑Donald Bade, Unaffiliated, joined at 12:05PM	Robert Ellis, Director of Biosafety*	
Richard Bowen, Associate Chair	Christine Johnson, Senior IBC Coordinator,	
	Alternate-at-Large	
Patrick Byrne, Plant expert		
Chaoping Chen, Chair	*non-voting at this meeting	
Sara Cope, Assistant Biosafety Officer		
☐ Angelo Izzo, Mycobacteria Immunology		
<b>⊠</b> June Medford, Plant/syn bio expert		
Edwin Neas, Unaffiliated		
Ken Olson, Virology		
Ann Powers, Virology, joined at 12:08PM		
Bernard Rollin, Bioethicist		
Non-Voting Members:		
☐ James Graham, EHS Director		
RICRO Staff (non-voting):	Regular Guests (non-voting):	
Karen Dobos, RICRO Director	Heather Blair, Associate Biosafety Officer	
Christa Johnson, Associate VP for Research	☐ Joni Van Sickle, Occupational Health Coord.	
☐ Joanie Ryan, IBC Intern		
Angie Chromiak, Admin Staff		
Other: Anthony Appleton, Research Safety Culture Coordinator; JJ Nelson, Assistant IACUC Coordinator; Kelly		
Anderson, IACUC Post Approval Monitor		

This meeting was convened at 12:02PM. Quorum was maintained throughout. Any member with a conflict of interest disconnected from the call during discussion and/or committee determination on the conflicted item.

#### I. Review of March 11, 2020 IBC meeting minutes.

The committee approved of the March minutes without correction.

II. Review of Agent and Project Request Forms (https://protocols.research.colostate.edu/rco).

1. Bosco-Lauth, Angela

**Agent:** Influenza virus – Strain: any; BSL3

The committee unanimously approved of the above agent with the following to be addressed:

1. The IBC recommends that individuals working with influenza virus be vaccinated against seasonal flu.

**Project:** <u>Transmission of H7N9 in an artificial barnyard setting</u> (20-034B); BSL3 in vitro and in vivo in poultry and rabbits. NIH Guidelines category non-exempt rDNA: N/A

The committee unanimously approved of the above project with the following to be addressed:

- 1. The IBC requests that the following statement be added regarding PPE: During the N95 shortage, personnel will use only PAPRs for respiratory protection.
  - 2. Kading, Rebekah

Agent: Enterobacter asburiae – Strain: any; BSL2

#### The committee unanimously approved of the above agent with the following to be addressed:

1. The IBC recommends that the concentration of Microchem Plus be added.

#### 3. Jackson, Mary

**Project:** Inhibitors of Mycobacterium tuberculosis FAS-II dehydratases (20-046B); BSL3 in vitro. NIH Guidelines category non-exempt rDNA: III-D-2

#### The committee unanimously approved of the above project with the following to be addressed:

1. The IBC requests that the following statement be added regarding PPE: During the N95 shortage, personnel will use only PAPRs for respiratory protection.

#### III. Review of Coronavirus Agent and Project Request Forms reviewed/approved by Biosafety Officer

#### 1. Bowen, Richard

**Project: UQ Vaccines:** Efficacy against SARS-CoV-2 (20-027B); BSL3 in vitro and in vivo in hamsters. NIH Guidelines category non-exempt rDNA: N/A

Project: Establishment of Small Animal Models for Screening MCMs for the 2019 Novel
Coronavirus (SARS-CoV-2) (20-029B); BSL3 in vitro and in vivo in hamsters, ferrets, and guinea pigs. NIH Guidelines category non-exempt rDNA: N/A

**Project:** Interstitial Fluid Collection for Monitoring of Infectious Diseases (20-030B); BSL3 in vitro and in vivo in pigs. NIH Guidelines category non-exempt rDNA: N/A

**Project:** <u>Testing human convalescent plasma for antibodies to SARS-2 Virus (</u>20-044B); BSL3 in vitro and human samples. NIH Guidelines category non-exempt rDNA: N/A

#### 2. Perera, Rushika

**Agent:** Severe Acute Respiratory Syndrome Coronavirus (SARS-CoV-2) – Strain: any; BSL3 **Project:** Coronavirus pathogenesis (20-036B); BSL3 invitro. NIH Guidelines category non-exempt rDNA: N/A

#### 3. Foy, Brian (Pending)

Agent: SARS-CoV-2 - Strain: any; BSL3

**Project:** Antiviral immunity research on SARS-CoV-2: in vitro and in vivo (20-037B); BSL3 in vitro and in vivo in mice and bats, human samples. NIH Guidelines category non-exempt rDNA: N/A

#### 4. Ebel, Greg

**Agent:** SARS-CoV-2 – Strain: any; BSL3

**Project:** <u>SARS-CoV-2 surveillance</u> (20-032B); Human samples. NIH Guidelines category non-exempt rDNA: N/A

#### 5. Pabilonia, Kristy

Agent: SARS-CoV-2 - Strain: any; BSL3

**Project:** <u>Diagnostic testing of 2019 nCoV-2 human samples (</u>20-038B); BSL3 Human samples. NIH Guidelines category non-exempt rDNA: N/A

#### 6. Bosco-Lauth, Angela

**Agent:** SARS-CoV-2 – Strain: any; BSL3

**Project:** <u>SARS2 experimental research</u> (20-039B); BSL3 in vitro and in vivo. NIH Guidelines category non-exempt rDNA: N/A

#### 7. Henao-Tamayo, Marcela

**Agent:** SARS-CoV-2 – Strain: any; BSL3

**Project:** COVID-19 vaccine Rapid Response Technical/Operations/Research Teams (RAPTORS) (20-040B); BSL3 in vitro. NIH Guidelines category non-exempt rDNA: N/A

#### 8. Dow, Steve

Agent: Human coronavirus 229E - Strain: any; BSL2

Agent: Mouse hepatitis virus – Strain: 59; BSL1

Agent: Feline coronavirus – Strain: donated by Kelly Santangelo; BSL1

**Project:** Nonpathogenic coronavirus for immune suppression evaluation (20-041B); BSL2 in vitro. NIH Guidelines category non-exempt rDNA: N/A

#### 9. Podell, Brendan (Pending)

**Agent:** Severe acute respiratory syndrome coronavirus 2 – Strain: any; BSL3

**Project:** Guinea Pig in vitro and in vivo model of SARS-CoV2 infection and characterization of the immune response (20-042B); BSL3 in vitro and in vivo in guinea pigs. NIH Guidelines category non-exempt rDNA: N/A

#### 10. VandeWoude, Sue (Pending)

**Project:** <u>Serologic testing for SARS CoV 2 (</u>20-043B); BSL2 in vitro. NIH Guidelines category non-exempt rDNA: N/A

#### 11. Wyckoff, John (Under BSO Review)

Agent: SARS-CoV-2 - Strain: any; BSL3

**Project:** Manufacture of SARS-CoV-2 viral stocks and development of inactivated vaccine and/or antigen (20-045B); BSL3 in vitro. NIH Guidelines category non-exempt rDNA: N/A

The committee acknowledged and appreciated the amount of work that has gone in to reviewing these agents and projects. There was discussion as to why some of the SARS-CoV-2 AARFs have a minimum BSL-2 and others BSL-3. The minimum BSL-2 level is for projects involving human diagnostic samples. When the samples are received, they are handled at enhanced BSL-2. Part of the sample is used for RNA extraction, which inactivates the virus if it is present. If the sample is found to contain the virus, the remainder of the sample is transferred to BSL-3 for confirmatory diagnostics and storage for potential future use. This is currently the standard procedure for other diagnostic laboratories as well. The committee also discussed that this work is considered essential, and is currently being performed at only a few locations, the

#### IV. Amendments to be reviewed by full committee

#### V. Unfinished business

#### 1. N95 Shortage

Ms. Van Sickle reported that the remainder of the 55 cases have been received. Due to evolving circumstances, these N95s are being managed at a very high level and there is consideration of CSU research needs as well as county public health needs.

CSU research areas have transitioned to PAPR usage only. Ms. Blair reported that cabinets and PAPRs were decontaminated and moved so that researchers can don the PAPR in a clean area without an N95. There is a shortage and back order for PAPR hoods. Current SARS-CoV-2 and TB animal researchers have enough, but there are not any for additional projects or users. It is possible to share a hood by wiping the inside with 70% ethanol, however this is not ideal. The committee members were asked to notify BSO of any PAPR stockpiles that might be in storage.

#### VI. New Business

#### 1. COVID-19 Research Policy

The committee reviewed a new policy which was put in place because of the COVID-19 pandemic disruptions to CSU. This is a slight deviation from normal procedures, so this policy serves as a written explanation. The AARFs would normally go to full committee but are now going to the BSO to expedite the process. If a PARF arises with rsNA work, it will still need to be reviewed by the committee. This policy will be reviewed by the committee again in six months to determine if it is still needed

The committee unanimously voted to adopt this policy without changes.

#### VII. Reports

#### 1. Coordinator's report

a. Next IBC meeting: Wednesday, May 13, 2020 through Microsoft Teams. Any comments or suggestions for improvement of remote meeting facilitation are welcome and encouraged.

#### 2. Biosafety Officer's report

a. Incident reports: Noneb. Inspections: None

c. Laboratory audit reports: None

#### d. Emergency planning:

The biosafety office has transitioned to as much remote work as possible. The BSOs are working hard to keep essential research running smoothly.

# VIII. Agent and Project Approval Request Forms Reviewed at Previous IBC Meeting and Approved After Modification to be read into the minutes.

1. Spencer, John

Agent: Mycobacteria tuberculosis - Strain: mc2700 deletion mutant panCD and esx1; BSL2

2. Bowen, Richard

**Agent:** Equine parvovirus – Strain: any; BSL2

**Project:** CEPI: Immunogenicity, Safety and Efficacy of DDVax Rift Valley Fever Vaccine (20-023B); BSL3 in vitro and in vivo in goats and rats. NIH Guidelines category non-exempt rDNA: N/A

3. Linke, Lyndsey

**Project:** E. coli laboratory cloning strain transformation and molecular cloning activities - CSU (20-026B); BSL1 in vitro and in vivo in mice and chickens. NIH Guidelines category non-exempt rDNA: III-D-4

4. Gonzales Juarerro, Mercedes

**Agent:** Mycobacterium haemophilum – Strain: any; BSL2

5. Schissler, Jennifer R

**Agent:** Staphylococcus epidermidis – Strain: any; BSL2

**Project:** Assessment of examination room Staphylococcus contamination following use by canine patients with superficial pyoderma and efficacy of a quaternary ammonium disinfectant and a hydrogen peroxide and silver fogging system Staphylococcus disinfection of a (20-021B); BSL2 in vitro. NIH Guidelines category non-exempt rDNA: N/A

- IX. Amended Project or Agent approval Request Forms Reviewed at Previous IBC Meeting and Approved After Modification to be read into the minutes.
- X. New or Amended Agent Approval Request Forms Reviewed and Approved by the <u>Biosafety Officer</u> or Chair to be read into the minutes.
- XI. New or Amended Project Approval Request Forms Reviewed and Approved by the <u>Biosafety Officer</u> or Chair to be read into the minutes.
  - 1. Bowen, Richard

**Project:** <u>Blocking alphavirus infection with anti-receptor antibodies (</u>20-028B); BSL3 in vitro and in vivo in sparrows. NIH Guidelines category non-exempt rDNA: N/A

Meeting adjourned: 12:41 PM Minutes recorded by C.Johnson

## APPROVED MINUTES

## Institutional Biosafety Committee

Special Meeting Microsoft Teams April 17, 2020

Check if Attending (Members):	Check if Attending (Alternate Members):
<b>⊠</b> Jessica Ayers, Animal expert	Lon Kendall, Director LAR
☑Donald Bade, Unaffiliated, joined at 12:05PM	Robert Ellis, Director of Biosafety*
Richard Bowen, Associate Chair	Christine Johnson, Senior IBC Coordinator, Alternate-at-Large*
Patrick Byrne, Plant expert	
Chaoping Chen, Chair	*non-voting at this meeting
Sara Cope, Assistant Biosafety Officer	
Angelo Izzo, Mycobacteria Immunology	
<b>☐</b> June Medford, Plant/syn bio expert	
Edwin Neas, Unaffiliated	
Ken Olson, Virology	
Bernard Rollin, Bioethicist	
Non-Voting Members:	
☐ James Graham, EHS Director	
RICRO Staff (non-voting):	Regular Guests (non-voting):
Karen Dobos, RICRO Director	Heather Blair, Associate Biosafety Officer
Christa Johnson, Associate VP for Research	☐ Joni Van Sickle, Occupational Health Coord.
Angie Chromiak, Admin Staff	
Other:	

This meeting was convened at 9:03AM. Quorum was maintained throughout. Any member with a conflict of interest disconnected from the call during discussion and/or committee determination on the conflicted item.

A special IBC meeting was called to review a COVID19 related project that involves non-exempt rDNA.

- I. Review of Agent and Project Request Forms (https://protocols.research.colostate.edu/rco).
  - 1. Dean, Gregg

**Project:** <u>RECOMBINANT LACTOBACILLUS AS AN ORAL MUCOSAL VACCINE AGAINST HUMAN CORONAVIRUS SARS-CoV-2 (</u>20-048B); BSL2 in vitro and in vivo in mice. NIH Guidelines category non-exempt rDNA: III-D-2

The committee unanimously approved of the above project with the following to be addressed:

- 1. The IBC requests that under mechanisms in place for containment and disposition of infected animals more details be provide on how animal care staff should handle bedding, water in water bottles, and cages. For example, if shedding is a concern and should these materials also be autoclaved.
  - 2. Geiss, Brian

**Project:** Expression and purification of recombinant SARS-CoV-2 proteins (20-050B); BSL2 in vitro. NIH Guidelines category non-exempt rDNA: III-E-1

The committee unanimously approved of the above project with the following to be addressed:

1. The IBC requests that all individuals working on this project register with the IBC Online Database, complete the IBC at CSU training, complete the Blood Borne Pathogens online training, and update their Occupational Health risk assessment.

Meeting adjourned: 9:22 AM Minutes recorded by C.Johnson

#### **APPROVED MINUTES**

## Institutional Biosafety Committee

#### Microsoft Teams May 13, 2020

Check if Attending (Members):	Check if Attending (Alternate Members):
<b>⊠</b> Jessica Ayers, Animal expert	Lon Kendall, Director LAR
☑Donald Bade, Unaffiliated, joined at 12:23PM	Robert Ellis, Director of Biosafety*
Richard Bowen, Associate Chair	Christine Johnson, Senior IBC Coordinator,
	Alternate-at-Large*
Patrick Byrne, Plant expert	
Chaoping Chen, Chair	*non-voting at this meeting
Sara Cope, Assistant Biosafety Officer	
Angelo Izzo, Mycobacteria Immunology	
Edwin Neas, Unaffiliated	
Ken Olson, Virology	
Ann Powers, Virology	
Bernard Rollin, Bioethicist	
Non-Voting Members:	
RICRO Staff (non-voting):	Regular Guests (non-voting):
Karen Dobos, RICRO Director	Heather Blair, Associate Biosafety Officer
Christa Johnson, Associate VP for Research	☐ Joni Van Sickle, Occupational Health Coord.
☐ Joanie Ryan, IBC Intern	
Angie Chromiak, Admin Staff	
Other:	

This meeting was convened at 12:03PM. Quorum was maintained throughout. Any member with a conflict of interest disconnected during discussion and/or committee determination on the conflicted item.

#### I. Review of April 8, 2020 and April 17, 2020 IBC meeting minutes.

The committee approved of both April minutes without correction.

II. Review of Agent and Project Request Forms (https://protocols.research.colostate.edu/rco).

1. Moreno, Julie

Agent: Prion – Strain: RML, 22L, and CWD; BSL2

The committee unanimously approved of the above agent with the following to be addressed:

- 1. The IBC requests that the specific prions be identified under the strain; for example Scrapie, CWD, etc.,
- 2. The IBC requests the room number for the storage location.

**Project:** Cell therapeutics for prion diseases (20-060B); BSL2 in vitro and in vivo in mice. NIH Guidelines category non-exempt rDNA: III-D-4

The committee unanimously approved of the above project with the following to be addressed:

- 1. The IBC requests that the specific prion strains be added under the list of infectious agents.
  - 2. Jackson, Mary

**Project:** Recombinant BCG-based SARS-CoV-2 vaccine (20-061B); BSL2 in vitro. NIH Guidelines category non-exempt rDNA: III-D-2

The committee unanimously approved of the above project without changes.

#### 3. MacNeill, Amy

**Project:** Poxvirus vaccine vectors (20-062B); BSL2 in vitro and in vivo in rodents, cats, and dogs. NIH Guidelines category non-exempt rDNA: III-D-3

#### The committee unanimously approved of the above project with the following to be addressed:

- 1. The IBC requests that the Project Overview be revised. Currently it states: Poxviruses are classified as biosafety level-2 organisms. However there are several which are BSL3 agent, thus this statement should be modified.
- 2. The IBC requests that the question "Does any part of the molecule(s) or construct(s) encode a gene product from a Select Agent or Toxin?" be changed from YES to NO.
- 3. The IBC recommends that when the PI completes the ABSL2 form, they should allow plenty of time to talk with LAR and biosafety regarding ABSL2 for dogs and cats as these procedures are not currently in place.
- **4.** The IBC requests confirmation of investigators on the project.

#### 4. Chen, Chaoping

**Project:** HTS for Inhibitors Targeting 3C-like Protease Maturation of SARS-CoV-2 (20-063B); BSL2 in vitro. NIH Guidelines category non-exempt rDNA: III-D-2

The committee unanimously approved of the above project without changes.

#### 5. Medford, June

**Project:** Functional Engineering of a Photosynthetic Desalination Flow Circuit – CSU (20-064B); BSL1P in Arabidopsis, watermelon, and tomato. NIH Guidelines category non-exempt rDNA: III-E-2

The committee unanimously approved of the above project without changes.

**Project:** Functional Engineering of a Photosynthetic Desalination Flow Circuit – Phytodetectors (20-065B); BSL1P in Arabidopsis, watermelon, and tomato. NIH Guidelines category non-exempt rDNA: III-E-2

#### The committee unanimously approved of the above project with the following to be addressed:

1. The IBC requests clarification regarding where Phytodetectors work versus CSU work will be conducted.

Two PARFs were submitted to distinguish between the PI's company vs. their CSU work.

#### III. Review of Coronavirus Agent and Project Request Forms reviewed/approved by Biosafety Officer

#### 1. Kendall, Lon

**Project:** Resterilization of PPE by VHP (20-047B); BSL3 in vitro, human samples. NIH Guidelines category non-exempt rDNA: N/A

#### 2. Kruh-Garcia, Nicole

**Agent:** Severe Acute Respiratory Syndrome Coronavirus (SARS-CoV-2) – Strain: any; BSL3 **Project:** <u>Testing Antimicrobial Textiles for Efficacy Against SARS-CoV-2</u> (20-051B); BSL3 in vitro. NIH Guidelines category non-exempt rDNA: N/A

#### 3. Bowen, Richard

**Project:** Pathogenesis and Vaccine Efficacy for SARS-CoV-2 Infection in Cats (20-052B); BSL3 in vitro and in vivo in cats. NIH Guidelines category non-exempt rDNA: N/A

#### 4. Akkina, Ramesh

**Agent:** SARS-CoV-2 – Strain: any; BSL3

**Project:** SARS-CoV-2 human immune response and pathogenesis in UCB-humanized mice (20-055B); BSL3 in vitro and in vivo in mice. NIH Guidelines category non-exempt rDNA: N/A

5. Ryan, Elizabeth

Agent: SARS-CoV-2 isolates from human patients – Strain: any; BSL3

**Project:** Biorepository for evaluating immune responses and gut microbiota composition in acute and convalescent Coloradans infected with SARS CoV-2 (20-057B); Human samples. NIH Guidelines category non-exempt rDNA: N/A

#### 6. Nett, Terry

**Project:** <u>Development of a Radioimmunotitration Assay to Measure IgG/IgM in Serum from COVID19 Patients, for Surveillance (20-038B); BSL2 in vitro, Human samples. NIH Guidelines category non-exempt rDNA: N/A</u>

The committee had no comments or clarifying questions for the above submissions.

#### IV. Amendments to be reviewed by full committee

#### 1. Schountz, Tony

**Project:** Experimental infection of Jamaican fruit bats with MERS-CoV coronavirus (12-104B); BSL3 in vitro and in vivo in bats. NIH Guidelines category non-exempt rDNA: III-D-4 Amended to add rDNA section during renewal process.

The committee unanimously approved of the above project amendment without changes.

#### V. Unfinished business

- 1. IBC Membership update and nominations
  - a. Jason Cummings Jason was nominated to replace Nikk,i who is now a biosafety officer.

The committee unanimously approved of the above candidate as a laboratory representative.

**b. Stephen Pearce** – Stephen was nominated to replace Pat, who is retiring. **The committee unanimously approved of the above candidate as a plant expert.** 

- c. Nikki Marlenee Nikki will replace Sara as the Biosafety Officer for FY21.
- d. Heather Blair Heather will replace Dr. Ellis as Alternate BSO upon his retirement.
- e. Renewing IBC Members Chaoping Chen, Richard Bowen, Angelo Izzo, June Medford, Ann Powers

#### VI. New Business

None

#### VII. Reports

- 1. Coordinator's report
  - a. Next IBC meeting: Wednesday, June 10, 2020 through Microsoft Teams
  - b. **Save the Date** -- Biosafety and Biosecurity Fair October 20, 2020- moving ahead cautiously due to current uncertainty about return to campus for the fall.

#### 2. Biosafety Officer's report

- a. Incident reports:
  - Near miss: a airflow went down due to humidity while a PI was in an animal room. The PI was wearing a PAPR at the time and followed proper protocols.
  - Laboratory acquired infection: While research was being ramped down and stopped for change to critical operations only in March, an individual had cold symptoms and a rash. The individual believed the cold was passed from their partner, and the rash was not uncommon for this individual during stressful times. Some time later the individual realized this could have been a Zika infection because the individual

did manipulations with infected mosquitoes before the symptoms occurred. The individual contacted Biosafety and Occupational Health for diagnostic testing. While waiting for the results the individual was feeling better and receive the go ahead to return to work. The initial PCR test was negative, but further testing confirmed Zika infection. The individual does not recall any off counts of mosquitoes, and typically does not experience symptoms of a mosquito bite. There were no reports of loose mosquitoes at the time and other people working in the area during this time frame were asked about symptoms with none reported. Most likely this was a mosquito bite that went undetected during a chaotic time due to COVID-19 shut downs and changes.

- Near miss: Autoclave bags were breaking during the autoclave cycle out from . The bags were double bagged but fell apart upon removal. The autoclave cycles were successful, so this is not considered an exposure or spill. It was determined that the bags were of poor construction and changing the bags out has solved the problem.
- Protocol breach: An individual entered the BRB for work during the shutdown. At the time the work involved with the shutdown was not occurring in or impacting the area in which the individual went, and the individual wore a PAPR and used a biosafety cabinet. Because there have been three incidents like this, biosafety is reviewing the process to prevent another incident.
- Animal bite: An individual was working with an SARS-CoV-2 infected hamster and was bitten. The individual followed proper procedures and contacted biosafety and occupational health. Because of the transmission routes for the agent, it is considered a low risk incident but follow up is occurring. No outside reporting required.
- Protocol breach: An individual forgot to don an N95 when entering to dust the deer facility. The individual had noticed eye irritation and donned eye protection then forgot about the N95 before entering the infected deer room; when realized, exited and put on mask and entered to finish work. The individual is doing well. The agent used in the deer is very low risk for human infection, but the individual is being monitored.
- Cut: An individual was mincing infected tissue with a razor blade when they cut their finger. This happened today so biosafety and occupational health are currently investigating the incident and helping the individual.

The increase in incident frequency was discussed by the committee. It seems that an increase in stress due to COVID-19 situations both at home and at work may be impacting this. There is also a mandate to be on campus as little as possible for critical research functions, which may be causing people to rush. Changes from N95 to PAPR use in these environments can interfere with peoples' normal functioning, and has impacted the process of entering and exiting the area including lines building up to allow social distancing in the locker rooms. The committee discussed the IBC and biosafety working together to get feedback from users and addressing any issues, as nothing has been reported to biosafety. It was discussed that people may be hesitant to come forward because they do not want to have already restricted research limited further. Some suggestions for managing this include requesting researcher feedback, posting helpful guidance, and potentially starting a scheduling system to prevent locker room buildup. It was also discussed that in looking toward reopening, these challenges may increase and it is important that administrators be involved in the return to research process understand the limitations.

b. Inspections: None

c. Laboratory audit reports: Ms. Blair is planning to do a TB lab audit walk through. She will have PIs or lab managers fill out a form instead of going in together with each group. Select Agent inventory audits are needed for . Dr. Ellis and Nikki will be working on

this with the labs, PIs, and managers starting the last full week of May into the first week of lune.

# VIII. Agent and Project Approval Request Forms Reviewed at Previous IBC Meeting and Approved After Modification to be read into the minutes.

1. Bosco-Lauth, Angela

**Agent:** Influenza virus – Strain: any; BSL3

**Project:** <u>Transmission of H7N9 in an artificial barnyard setting</u> (20-034B); BSL3 in vitro and in vivo in poultry and rabbits. NIH Guidelines category non-exempt rDNA: N/A

2. Kading, Rebekah

Agent: Enterobacter asburiae – Strain: any; BSL2

3. Jackson, Mary

**Project:** <u>Inhibitors of Mycobacterium tuberculosis FAS-II dehydratases</u> (20-046B); BSL3 in vitro. NIH Guidelines category non-exempt rDNA: III-D-2

4. Dean, Gregg

**Project:** <u>RECOMBINANT LACTOBACILLUS AS AN ORAL MUCOSAL VACCINE AGAINST HUMAN CORONAVIRUS SARS-CoV-2 (20-048B)</u>; BSL2 in vitro and in vivo in mice. NIH Guidelines category non-exempt rDNA: III-D-2

5. Geiss, Brian

**Project:** Expression and purification of recombinant SARS-CoV-2 proteins (20-050B); BSL2 in vitro. NIH Guidelines category non-exempt rDNA: III-E-1

- IX. Amended Project or Agent approval Request Forms Reviewed at Previous IBC Meeting and Approved After Modification to be read into the minutes.
- X. New or Amended Agent Approval Request Forms Reviewed and Approved by the <u>Biosafety Officer</u> or Chair to be read into the minutes.
- XI. New or Amended Project Approval Request Forms Reviewed and Approved by the <u>Biosafety Officer</u> or <u>Chair</u> to be read into the minutes.
  - 1. Robertson, Gregory

**Project:** <u>Inhibitors of Mycobacterium tuberculosis FAS-II dehydratases</u> (20-049B); BSL3 in vivo in mice. NIH Guidelines category non-exempt rDNA: N/A

2. Ordway, Diane

**Project:** Adjunct therapeutic potential of a repurposed drug inhibiting Mycobacterium abscessus biofilm formation (20-054B); BSL2 in vitro and in vivo in mice. NIH Guidelines category non-exempt rDNA: N/A

3. Geiss, Brian

Agent: E. coli BL21 – Strain: any; BSL1

Meeting adjourned: 1:35 PM Minutes recorded by C.Johnson

## APPROVED MINUTES

## Institutional Biosafety Committee

#### Microsoft Teams June 10, 2020

Check if Attending (Members):	Check if Attending (Alternate Members):
<b>⊠</b> Jessica Ayers, Animal expert	Lon Kendall, Director LAR
☑Donald Bade, Unaffiliated, joined at 12:23PM	Robert Ellis, Director of Biosafety
Richard Bowen, Associate Chair	Christine Johnson, Senior IBC Coordinator,
	Alternate-at-Large*
Patrick Byrne, Plant expert	
Chaoping Chen, Chair	*non-voting at this meeting
Sara Cope, Assistant Biosafety Officer	
Edwin Neas, Unaffiliated	
Ken Olson, Virology	
Ann Powers, Virology	
Bernard Rollin, Bioethicist	
Non-Voting Members:	
RICRO Staff (non-voting):	Regular Guests (non-voting):
Karen Dobos, RICRO Director	Heather Blair, Associate Biosafety Officer
Christa Johnson, Associate VP for Research	
	☐ Joni Van Sickle, Occupational Health Coord.
Angie Chromiak, Admin Staff	
Other:	

This meeting was convened at 12:03PM. Quorum was maintained throughout. Any member with a conflict of interest disconnected during discussion and/or committee determination on the conflicted item.

#### I. Review of May 13, 2020 meeting minutes.

The committee approved of May minutes without correction.

#### II. Review of Agent and Project Request Forms (https://protocols.research.colostate.edu/rco).

1. Nishimura, Erin

**Project:** Mechanisms and dynamics of gene expression during cellular differentiation and development (20-068B); BSL1 in vitro. NIH Guidelines category non-exempt rDNA: III-D-4

#### The committee unanimously approved of the above project with the following to be addressed:

- 1. The IBC requests the concentration of bleach used for 10 minutes of bleach soaking.
- 2. The IBC requests the E. coli strains used for C. elegans to feed on.
- 3. The IBC requests that all individuals working on this project complete the statement of experience and IBC at CSU online training through the IBC Database.

**Project:** Deciphering the molecular hallmarks of cellular differentiation in animal and cancer models (20-069B); BSL1 in vitro. NIH Guidelines category non-exempt rDNA: III-D-4

#### The committee unanimously approved of the above project with the following to be addressed:

1. The IBC requests the concentration of bleach used for 10 minutes of bleach soaking.

- 2. The IBC requests the E. coli strains used for C. elegans to feed on.
- 3. The IBC requests that all individuals working on this project complete the statement of experience and IBC at CSU online training through the IBC Database.

#### 2. Geiss, Brian

**Agent:** SARS-CoV-2 – Strain: any; BSL3

#### The committee unanimously approved of the above agent with the following to be addressed:

- 1. The IBC requests clarification on what samples, if any, will be moved from BSL3 to BSL2.
- 2. The IBC requests clarification of the statement regarding verification of inactivation for autoclaved material as this is typically not required.
- 3. The IBC requests more information for the TCID50 assay including what the material is and the limits of sensitivity of the assay.

**Project:** <u>Development of an SARS-CoV-2 reporter cell line</u> (20-072B); BSL3 in vitro. NIH Guidelines category non-exempt rDNA: III-D-3

#### The committee unanimously approved of the above project with the following to be addressed:

- 1. The IBC requests the PI contact the lab manager of the BSL3 spaces to coordinate research activities.
- 2. The IBC requests that PAPR, back closing gown, and facility socks and shoes/clogs be added to PPE use

#### 3. Kruh-Garcia, Nicole

Agent: Influenza virus type A – Strain: BSL2 strains only; BSL2

#### The committee unanimously approved of the above agent with the following to be addressed:

1. The IBC requests clarification of the use of 60-95% ethanol when typically 70% is used.

Agent: Influenza virus B - Strain: any; BSL2

#### The committee unanimously approved of the above agent with the following to be addressed:

- 1. The IBC requests a brief statement regarding the type of disease caused by this virus.
- 2. The IBC requests that pathogenic for animals including humans be changed from NO to YES.
- 3. The IBC requests clarification of the use of 60-95% ethanol when typically 70% is used.

**Agent:** enterovirus – Strain: any; BSL2

#### The committee unanimously approved of the above agent with the following to be addressed:

- 1. The IBC requests the name of the agent be changed as there are about 50 different enteroviruses. Please specify what/which enterovirus(es) will be used. If using multiple enteroviruses may need to submit separate AARFs.
- 2. The IBC requests that pathogenic for animals including humans be changed from NO to YES.
- 3. The IBC requests clarification of the use of 5% bleach.

Agent: Candida albicans – Strain: any; BSL2

The committee unanimously approved of the above agent without changes.

**Agent:** Streptococcus pyogenes – Strain: any; BSL2

The committee unanimously approved of the above agent without changes.

Agent: Streptococcus pneumoniae – Strain: any; BSL2

The committee unanimously approved of the above agent without changes.

**Agent:** Rhinovirus – Strain: any; BSL2

#### The committee unanimously approved of the above agent with the following to be addressed:

- 1. The IBC requests that the human risk group be changed from 1 to 2.
- 2. The IBC requests that the minimum biosafety level be changed from 1 to 2.

Agent: Human Parainfulenza virus – Strain: any; BSL2

#### The committee unanimously approved of the above agent with the following to be addressed:

1. The IBC requests that the spelling be corrected to Human Parainfluenza virus

Agent: Human Coronavirus – Strain: 229E, NL63, OC43; BSL2

The committee unanimously approved of the above agent without changes.

Agent: Adenovirus – Strain: any; BSL2

The committee unanimously approved of the above agent without changes.

**Agent:** Haemophilus influenzae – Strain: any; BSL2

The committee unanimously approved of the above agent without changes.

**Agent:** Respiratory syncytial virus – Strain: any; BSL2

The committee unanimously approved of the above agent without changes.

Project: Optimization of SARS-CoV-2 diagnostic assay (20-073B); BSL3 in vitro. NIH Guidelines

category non-exempt rDNA: N/A

#### The committee unanimously approved of the above project with the following to be addressed:

1. The IBC requests that the Project Overview include a statement indicating that challenges with SARS-CoV-2 will be done at BSL3.

#### 4. Thamm, Douglas

Agent: Salmonella typhimurium – Strain: VPN20009 (msbB-, Purl-); BSL2

#### The committee unanimously approved of the above agent with the following to be addressed:

1. The IBC requests clarification as to whether the antibiotic resistance is naturally occurring or if the agent has been modified.

**Project:** Evaluation of tumor-targeted Salmonella efficacy. (20-078B); BSL2 in vivo in mice. NIH Guidelines category non-exempt rDNA: III-D-1

#### The committee unanimously approved of the above project with the following to be addressed:

- 1. The IBC requests that in vitro uses be changed from NO to YES under infectious agents list.
- 2. The IBC requests confirmation of spelling for additional investigator's EID.
- 3. The IBC recommends that infected mice be handled in a biosafety cabinet

#### 5. Kading, Rebekah

Agent: Rocky Mountain bat coronavirus – Strain: any; BSL2

#### The committee unanimously approved of the above agent with the following to be addressed:

1. The IBC requests that pathogenic for animals including humans be changed from NO to YES

**Project:** <u>Isolation and detection of coronaviruses in Colorado bats and other wildlife</u> (20-075B); BSL2 in vitro. NIH Guidelines category non-exempt rDNA: N/A

#### The committee unanimously approved of the above project with the following to be addressed:

- 1. The IBC requests clarification regarding the biosafety level for in vitro work.
- 2. The IBC requests that rabies virus be removed from the infectious agent list because the work does not involve manipulating this virus.
- 3. The IBC requests that all individuals complete the IBC at CSU online training.

#### 6. Bosco-Lauth, Angela

Agent: Rabbit hemorrhagic disease virus 2 – Strain: any, BSL3

#### The committee unanimously approved of the above agent with the following to be addressed:

1. The IBC requests that pathogenic for animals including humans be changed from NO to YES

**Project:** RHDV2 pathogenesis and vaccine efficacy (20-076B); BSL3 in vitro in rabbits. NIH Guidelines category non-exempt rDNA: N/A

#### The committee unanimously approved of the above project with the following to be addressed:

- 1. The IBC asks whether the virus will be propagated in vitro.
- 2. The IBC requests that all investigators register with the IBC database, fill out a statement of experience, and complete the IBC at CSU online training.

#### 7. Bowen, Richard

**Project:** Project: Shed-spread and safety testing for Coccidioides vaccine in dogs (20-066B); BSL2 in vitro and in vivo in dogs. NIH Guidelines category non-exempt rDNA: III-D-4

#### The committee unanimously approved of the above project with the following to be addressed:

1. The IBC requests clarification of use of N95 or PAPR during in vitro work and in vivo work.

#### 8. Schountz, Tony

Agent: PMV11 (Myotis bat morbillivirus) – Strain: any; BSL2

#### The committee unanimously approved of the above agent with the following to be addressed:

1. The IBC requests a chemical method of inactivation.

There was a discussion regarding the BSL; the risk group is indicated as RG1 however the agent will be handled at BSL2.

**Project:** Infection of Jamaican fruit bats with bat morbillivirus PMV11 (20-077B); BSL2 in vitro and in vivo in bats. NIH Guidelines category non-exempt rDNA: N/A

#### The committee unanimously approved of the above project with the following to be addressed:

1. Respiratory protection is recommended while working with bats to protect the bats from potential SARS-CoV-2 human carriers. The IBC requests the PI indicate whether N95s or PAPRs will be used.

#### III. Review of Coronavirus Agent and Project Request Forms reviewed/approved by Biosafety Officer

#### 1. Wilusz, Carol (APPROVED)

**Project:** Extraction of RNA from wastewater for SARS CoV 2 quantification (20-067B); BSL2 in vitro. NIH Guidelines category non-exempt rDNA: N/A

#### 2. Schaeffer, Joshua (SUBMITTED)

**Project:** Characterization and Assessment of SARS-2 Aerosols During In-Patient Surgical Procedures (20-070B); BSL3 in vitro. NIH Guidelines category non-exempt rDNA: N/A

#### 3. Tjalkens, Ronald (SUBMITTED)

**Agent:** Coronavirus, 2B β-coronavirus – Strain: SARS-CoV-2, USA-WA1-2020; BSL3 **Project:** Neuroinvasion of SARS-CoV2 (20-052B); BSL3 in vitro and in vivo in mice. NIH Guidelines category non-exempt rDNA: N/A

The committee requests clarification for items 2 and 3. For item 2, clarification regarding shipping was requested, ie, will samples be shipped as dangerous goods. For item 3, more details are needed regarding who is doing what work and where, where the virus is coming from, and the experience and training of one of the investigators. It is recommended that the PI collaborate with one of the other researchers in the BSL3.

# IV. Amendments to be reviewed by full committee None

#### V.Unfinished business

#### 1. BSL3 ingress/egress issues

Dr. Ellis is working on gathering information from PIs and researchers regarding current issues and concerns for research restart.

#### VI. New Business

#### 1. IBC Meetings for FY21

Due to uncertainty regarding future public health guidelines and budget reductions as a result of COVID-19, meetings will continue to be held via Microsoft Teams through fiscal year 2021.

#### VII. Reports

#### 1. Coordinator's report

- a. Next IBC meeting: Wednesday, July 8, 2020 through Microsoft Teams
- b. **Save the Date** -- Biosafety and Biosecurity Fair October 20, 2020- this event will be virtual. All suggestions and ideas for this event are welcome and encouraged to be shared with the senior coordinator.

#### 2. Biosafety Officer's report

#### a. Incident reports:

- There have been issues with people not signing out PAPRs and using other people's hoods. The PI investigated and determined who was responsible, then set up a calendar for people to sign out PAPRs for use. No outside reporting required.
- During a shipment of potentially SARS-CoV-2 infected PPE from a healthcare facility to CSU, there was no secondary containment and PPE was sticking out. Couriers were reminded to check for proper packaging of material before transport. No outside reporting required.
- An individual entered a non-respiratory protection area of BSL3 without a cloth face
  mask or social distancing. Additional cloth masks have been received for the area
  and the requirements for social distancing re-communicated. No outside reporting
  required.
- An individual noticed that the clean side door of an MTA was open. After egressing
  from the BSL3 they closed the door and contacted biosafety. No outside reporting
  required.
- **b. Inspections:** There have been none recently, and there are not any expected for some time though unannounced inspections are always possible.
- **c. Laboratory audit reports:** Dr. Ellis and Dr. Marlenee are doing select agent inventory audits, which are going well.
- **d. Dr. Ellis' retirement:** This being Dr. Ellis' last IBC meeting, the RICRO staff put together a slide show and had virtual celebration to honor Dr. Ellis' 30+ years of service with biosafety and the IBC.

# VIII. Agent and Project Approval Request Forms Reviewed at Previous IBC Meeting and Approved After Modification to be read into the minutes.

#### 1. Moreno, Julie

Agent: Prion – Strain: RML, 22L, and CWD; BSL2

**Project:** Cell therapeutics for prion diseases (20-060B); BSL2 in vitro and in vivo in mice. NIH Guidelines category non-exempt rDNA: III-D-4

#### 2. MacNeill, Amy

**Project:** Poxvirus vaccine vectors (20-062B); BSL2 in vitro and in vivo in rodents, cats, and dogs. NIH Guidelines category non-exempt rDNA: III-D-3

- IX. Amended Project or Agent approval Request Forms Reviewed at Previous IBC Meeting and Approved After Modification to be read into the minutes.
- X. New or Amended Agent Approval Request Forms Reviewed and Approved by the <u>Biosafety Officer</u> or Chair to be read into the minutes.
- XI. New or Amended Project Approval Request Forms Reviewed and Approved by the <u>Biosafety Officer</u> or <u>Chair</u> to be read into the minutes.

Meeting adjourned: 1:51 PM Minutes recorded by C.Johnson

#### **APPROVED MINUTES**

## Institutional Biosafety Committee

Special Meeting Microsoft Teams June 29, 2020

Check if Attending (Members):	Check if Attending (Alternate Members):
Jessica Ayers, Animal expert	Lon Kendall, Director LAR
<b>⊠</b> Donald Bade, Unaffiliated	Robert Ellis, Director of Biosafety
Richard Bowen, Associate Chair	Christine Johnson, Senior IBC Coordinator,
	Alternate-at-Large*
Patrick Byrne, Plant expert	
Chaoping Chen, Chair	*non-voting at this meeting
Sara Cope, Assistant Biosafety Officer, joined at	
1:15PM	
Angelo Izzo, Mycobacteria Immunology	
June Medford, Plant/syn bio expert	
Edwin Neas, Unaffiliated	
Ken Olson, Virology	
Ann Powers, Virology	
Bernard Rollin, Bioethicist	
Non-Voting Members:	
RICRO Staff (non-voting):	Regular Guests (non-voting):
Karen Dobos, RICRO Director	Heather Blair, Associate Biosafety Officer
Christa Johnson, Associate VP for Research	
	joined at 1:05 PM
🔀 Joanie Ryan, IBC Intern	☑ Joni Van Sickle, Occupational Health Coord.
Angie Chromiak, Admin Staff	
Other:	

This meeting was convened at 1:03PM. Quorum was maintained throughout. Any member with a conflict of interest disconnected during discussion and/or committee determination on the conflicted item.

A special IBC meeting was called to review a COVID19 related project that involves non-exempt rDNA.

I. Review of June 10, 2020 meeting minutes

The minutes are not yet available.

- II. Review of Agent and Project Request Forms (https://protocols.research.colostate.edu/rco).
  - 1. Tjalkens, Ronald

Agent: Adeno-associated virus (AAV) – Strain: any; BSL1

The committee unanimously approved of the above agent with the following to be addressed:

1. The IBC requests the concentration of bleach be increased to 10%.

**Project:** <u>Stereotactic injection of adeno-associated virus (</u>20-080B); BSL1 in vitro and in vivo in mice. NIH Guidelines category non-exempt rDNA: III-D-4

The committee unanimously approved of the above project with the following to be addressed:

1. The IBC requests a description of the project goals.

- 2. The IBC requests that 10% bleach be used.
- 3. The IBC requests clarification that work with AAV will be conducted in a biosafety cabinet and not a laminar flow hood.

#### 2. Duval, Dawn

**Project:** Development of a comparative oncology functional genomics screening platform using a CRISPR-Cas9 library to identify critical dependencies and mechanisms of treatment resistance in canine cancers (20-081B); BSL2 in vitro. NIH Guidelines category non-exempt rDNA: III-D-3

#### The committee unanimously approved of the above project with the following to be addressed:

- 1. The IBC requests that lentivirus be added to the list of infectious agents.
- 2. The IBC requests clarification regarding whether the guide RNA and Cas9 endonuclease will be on the same plasmid or separate plasmids.
- 3. The IBC requests the species of origin for the Cas9 endonuclease.
- 4. The IBC requests all individuals listed on this project complete biosafety cabinet training.

#### 3. Bowen, Richard

**Project:** <u>COVID vaccine testing (20-083B)</u>; BSL3 in vitro and in vivo in hamsters and ferrets. NIH Guidelines category non-exempt rDNA: III-D-2

#### The committee unanimously approved of the above project with the following to be addressed:

- 1. The IBC requests that a list of the specific vectors be given and updated with each new vaccine candidate.
- 2. The IBC requests that under in vitro PPE the PAPR be marked Y and the N95 marked N.

This is somewhat of a blanket PARF, the PI is testing vaccines in animal models from several different sources. The PI is not making the vaccines. Each time a new vaccine candidate is received, the PI will amended the PARF to include the specific vectors and funding source.

# III. Review of Coronavirus Agent and Project Request Forms reviewed/approved by Biosafety Officer The following submissions have not yet been reviewed by the BSO and thus the full IBC will review.

#### 1. Fahrner, Scott (SUBMITTED)

**Project:** RESTART Colorado: Rational Effective Surveillance Testing Accelerating Return to Tasks (20-084B); Human Samples. NIH Guidelines category non-exempt rDNA: N/A

#### The committee unanimously approved of the above project with the following to be addressed:

- 1. The IBC requests more information regarding "self-collection of nasal swab samples." How is this done and is it less cough inducing than the usual method? If participants are likely to cough, it is recommended for lab personnel to wear a face shield.
- 2. The IBC requests that a specific room number be given for each location of work.
- 3. The IBC requests that all individuals listed on the project provide a statement of experience working with biohazardous materials.

#### 2. Goodrich, Raymond (SUBMITTED)

Agent: SARS-CoV-2 - Strain: USA-WA 1/2020; BSL3

#### The committee unanimously approved of the above agent with the following to be addressed:

1. The IBC requests the concentration of Neutral Q used to inactivate the agent for disposal.

**Project:** <u>COVID-19: Vaccine Development for COVID-19 Using SolaVAX (</u>20-086B); BSL3 in vitro. NIH Guidelines category non-exempt rDNA: N/A

#### The committee unanimously approved of the above project with the following to be addressed:

- 1. The IBC requests more information regarding the upper limit of live/infectious SARS-CoV-2 to be tested.
- 2. The IBC requests clarification regarding the use of Tyvec coveralls versus a back closing gown.

#### IV. Amendments to be reviewed by full committee

1. Clay, Colin

**Project:** Role of estrogen in regulating of GnRH receptor expression (10-047B); BSL2 in vitro. NIH Guidelines category non-exempt rDNA: III-D-3

Amendment request to add lentivirus as a vector

The committee unanimously approved of the above amendment request without changes.

The PI has several other projects working with this vector.

V. Agent and Project Approval Request Forms Reviewed at Previous IBC Meeting and Approved After Modification to be read into the minutes.

#### 1. Kruh-Garcia, Nicole

Agent: Influenza virus type A – Strain: BSL2 strains only; BSL2

**Agent:** Influenza virus B – Strain: any; BSL2 **Agent:** enterovirus – Strain: any; BSL2 **Agent:** Rhinovirus – Strain: any; BSL2

Agent: Human Parainfulenza virus – Strain: any; BSL2

Project: Optimization of SARS-CoV-2 diagnostic assay (20-073B); BSL3 in vitro. NIH Guidelines

category non-exempt rDNA: N/A

#### 2. Thamm, Douglas

Agent: Salmonella typhimurium – Strain: VPN20009 (msbB-, Purl-); BSL2

**Project:** Evaluation of tumor-targeted Salmonella efficacy. (20-078B); BSL2 in vivo in mice. NIH Guidelines category non-exempt rDNA: III-D-1

#### 3. Kading, Rebekah

Agent: Rocky Mountain bat coronavirus – Strain: any; BSL2

**Project:** <u>Isolation and detection of coronaviruses in Colorado bats and other wildlife</u> (20-075B); BSL2 in vitro. NIH Guidelines category non-exempt rDNA: N/A

#### 4. Bosco-Lauth, Angela

Agent: Rabbit hemorrhagic disease virus 2 – Strain: any, BSL3

**Project:** RHDV2 pathogenesis and vaccine efficacy (20-076B); BSL3 in vitro in rabbits. NIH Guidelines category non-exempt rDNA: N/A

#### 5. Bowen, Richard

**Project:** Shed-spread and safety testing for Coccidioides vaccine in dogs (20-066B); BSL2 in vitro and in vivo in dogs. NIH Guidelines category non-exempt rDNA: III-D-4

#### 6. Schountz, Tony

Agent: PMV11 (Myotis bat morbillivirus) – Strain: any; BSL2

**Project:** <u>Infection of Jamaican fruit bats with bat morbillivirus PMV11</u> (20-077B); BSL2 in vitro and in vivo in bats. NIH Guidelines category non-exempt rDNA: N/A

- VI. Amended Project or Agent approval Request Forms Reviewed at Previous IBC Meeting and Approved After Modification to be read into the minutes.
- VII. New or Amended Agent Approval Request Forms Reviewed and Approved by the <u>Biosafety Officer</u> or Chair to be read into the minutes.
- VIII. New or Amended Project Approval Request Forms Reviewed and Approved by the <u>Biosafety Officer</u> or Chair to be read into the minutes.

#### 1. Geornaras, Ifigenia

**Project:** The impact of supplementing cattle diets with direct-fed microbial products on Salmonella prevalence in lymph nodes (20-074B); BSL2 in vitro. NIH Guidelines category nonexempt rDNA: N/A

## 2. Slayden, Richard

**Project**: Efficacy evaluation of Novel therapeutics against Biodefense Pathogens (17-095B); BSL3 in vitro and invivo in mice. NIH guidelines category non-exempt rDNA: N/A Amendment to change location.

Meeting adjourned: 1:41 PM Minutes recorded by C.Johnson

# APPROVED MINUTES Institutional Biosafety Committee Microsoft Teams – REMOTE July 29, 2020

Check if Attending (Members):	Check if Attending (Alternate Members):
□ Jessica Ayers, Animal expert	Lon Kendall, Director LAR
☑Donald Bade, Unaffiliated	Heather Blair, Interim Biosafety Director*
Richard Bowen, Associate Chair	Christine Johnson, Senior IBC Coordinator,
	Alternate-at-Large*
Chaoping Chen, Chair	
☐ Jason Cummings, lab rep	*non-voting at this meeting
Angelo Izzo, Mycobacteria Immunology	
⊠Nicole Marlenee, Assistant Biosafety Officer	
☐ June Medford, Plant/syn bio expert	
Edwin Neas, Unaffiliated	
Ken Olson, Virology	
Stephen Pearce, Plant expert	
Ann Powers, Virology	
Bernard Rollin, Bioethicist	
Non-Voting Members:	
☐ James Graham, EHS Director	
RICRO Staff (non-voting):	Regular Guests (non-voting):
Karen Dobos, RICRO Director	Sara Cope, Assistant Biosafety Officer
Christa Johnson, Associate VP for Research	☐ Joanie Ryan, Biosafety Office Intern
Angie Chromiak, Admin Staff	☐ Joni Van Sickle, Occupational Health Coord.
Adrianna Burney, IBC Intern	
Other:	

This meeting was convened at 12:03PM. Quorum was maintained throughout. Any member with a conflict of interest disconnected during discussion and/or committee determination on the conflicted item.

I. Review of June 10, 2020 and June 29, 2020 IBC meeting minutes.

The committee approved of both sets of June minutes without correction.

II.Review of Agent and Project Request Forms (https://protocols.research.colostate.edu/rco).

1. Peccoud, Jean

Agent: SARS-CoV-2 – Strain: any; BSL2

The committee unanimously approved of the above agent with the following modifications:

To indicate that lab is not receiving isolated virus, the IBC requests the Strain be changed from ANY to Clinical Samples.

**Project:** Pooled saliva COVID-19 testing at CSU (20-087B); Human Samples, BSL2. NIH Guidelines category non-exempt rDNA: N/A

#### The committee unanimously approved of the above project with the following modifications:

- 1. The IBC requests that a statement be added to the Project Overview confirming that there will be no attempt to isolate or grow SARS-CoV-2.
- 2. The IBC requests that one of the Biosafety Officers watch the first time samples are processed and pooled.
- 3. The IBC requests that all individuals update their Statement of Experience in the Online IBC Database to reflect any recent trainings that have been completed.

#### 2. Karoly, Hollis

**Project:** Exploring the Effects of Cannabinoids on Alcohol Consumption and the Microbiota-Gut-Brain Axis (20-088B); Human Samples. NIH Guidelines category non-exempt rDNA: N/A

#### The committee unanimously approved of the above project with the following modifications:

- 1. Additional personnel working on the project need to be added to the PARF.
- 2. All personnel working on the project will need to complete online BSL1/BSL2 training, Blood Borne Pathogen training, and an Occupational Health Risk Assessment.
- 3. The IBC requests more details on what sample collections/work is being done in which locations.

The IBC requests the following clarifications on procedure:

- 4. Who will be doing the blood draws?
- 5. How will the samples (blood and fecal) be processed? And what equipment will be used? What PPE will be worn (gloves, lab coat, safety glasses, etc) for protection against unknown infectious materials?
- 6. Will the samples be inactivated?
- 7. How and where will samples be disposed of?
- 9. What is the anticipated start date for the project?

#### 3. Jackson, Mary

**Project:** Assembly and export of mycobacterial lipoglycans (20-089B); BSL3 in vitro. NIH Guidelines category non-exempt rDNA: III-D-1

#### The committee unanimously approved of the above project with the following modifications:

- 1. The IBC request the Locations of work be updated.
- 2. Under in vitro PPE please specify the difference in PPE used at BSL2 and BSL3.
- 3. All individuals listed needs to provide a statement of experience in the online IBC database, and complete the IBC at CSU online training.
- 4. Additionally, all individuals listed must complete BSL3 training, and the Occupational Health Risk assessment.

#### 4. Bowen, Richard

**Project:** <u>Protective Function of GreFlueVie Influenza Vaccine in Ferrets</u>. (20-092B); BSL3 in vitro and in vivo in ferrets. NIH Guidelines category non-exempt rDNA: III-D-2 and III-D-4

#### The committee unanimously approved of the above project with the following modifications:

- 1. Under the list of PPE used, the in vitro section indicates PAPR and the in vivo section indicates N95. Please verify which one is correct.
- 2. One of the work locations is not approved for HPAIV and should be removed.

**Project**: Ecology and Transmission of Burkholderia pseudomallei in Fish Tanks (20-095B); BSL3 in vitro and BSL3 in vivo in fish. NIH Guidelines category non-exempt rDNA: N/A

#### The committee unanimously approved of the above project with the following modifications:

All individuals listed must complete the IBC at CSU online training.

#### 5. Nalam, Vamsi

**Agent:** Potato Virus Y – Strain: any; BSL1

**Agent:** Potato Mop-top virus – Strain: any; BSL1 **Agent:** Tobacco rattle virus – Strain: any; BSL1

**Project:** Development of molecular tools to study movement of Potato virus Y in susceptible and resistant varieties (20-093B); BSL1P in vitro and in vivo. NIH Guidelines category non-exempt rDNA: III-E-1

#### The above agents and projects have been TABLED pending additional information, specifically:

- 1. For each of the three Agent Approval Requests, Pathogenic for plants? Should be changed from NO to YES; the plant biosafety level should be indicated; and the chemical disinfectant and the percentage used should be provided.
- 2. The IBC requests more details about how the agents will be contained, and as well as whether there are concerns regarding aphids or nematodes and transmission outside of the lab.
- 3. The IBC requests that the PI meet with a Biosafety Officer and IBC plant members to review the project and containment procedures.
- 4. All individuals listed on the approval need to provide a Statement of Experience and complete the IBC at CSU online training.

#### 6. Ehrhart, Nicole

**Project:** The Combination of Coacervate Technology and Adult Muscle Stem Cells as a new Drug Delivery System for Articular Cartilage Repair (20-094B); Human Samples. NIH Guidelines category non-exempt rDNA: III-D-4

#### The committee unanimously approved of the above project with the following modifications:

- 1. Lentivirus infection of stem cells should be handled at BSL-2 unless already stably transduced. Please specify whether you will be receiving the cells already stably transduced or making them yourselves.
- 2. Delivery of stem cells transfected with lenti-viral techniques to express GFP falls under III-D-4 of the NIH Guidelines; the rDNA questions need to be filled out.

#### 7. Dean, Gregg

Agent: Bacillus Calamette – Guerin – Strain: any; BSL2

#### The committee unanimously approved of the above agent with the following modifications:

The IBC requests the agent name be changed to Mycobacterium bovis BCG.

**Project:** Recombinant BCG as a vaccine against SARS-CoV-2 (20-097B); BSL2 in vitro and in vivo in dogs. NIH Guidelines category non-exempt rDNA: III-D-2

#### The committee unanimously approved of the above project with the following modifications:

- 1. Under Mechanisms in place for containment and disposition of infected animals or plants, the statement should be changed to indicate that infected animals should be handled under BSL2 precautions for the duration of the infection, cages should be opened in a BSC, and bedding discarded as BSL2 waste.
- 2. All individuals listed should register with the Online IBC Database, fill out a Statement of Experience, and complete the IBC at CSU online training.
- 3. All individuals working with M. bovis BCG, including samples and mice infected with M. bovis, BCG should update their Occupational Health Risk Assessment to include this agent.

#### 8. Wiese, Claudia

Agent: Third-generation lentiviral packaging vectors (Dull et al., 1998) – Strain: any; BSL2

#### The committee unanimously approved of the above agent with the following modifications:

The IBC asks for clarification on whether autoclave will be use as a method of inactivation and disposal.

**Project:** <u>Production of replication-incompetent lentivirus particles</u> (20-098B); BSL2 in vitro. NIH Guidelines category non-exempt rDNA: III-E-1

#### The committee unanimously approved of the above project with the following modifications:

- 1. The description of PPE mentions safety goggles, thus safety goggles should be added to the list of PPE.
- 2. Has a biosafety lab audit been conducted within the last 3 years?
- 4. All individuals listed should register with the Online IBC Database, fill out a Statement of Experience, and complete the IBC at CSU online training.

#### 9. Moreno, Julie

**Agent:** HSV1 – Strain: MacIntyre; BSL2

#### The committee unanimously approved of the above agent with the following modifications:

The IBC requests the percentage of bleach that will be used for inactivation.

**Project:** Misfolded neurotoxic proteins in HSV1 induced Alzheimer's disease (20-101B); BSL2 in vitro and in vivo in mice. NIH Guidelines category non-exempt rDNA: N/A

#### The committee unanimously approved of the above project with the following modifications:

- 1. The IBC requests information regarding the source of AdMSC-EV and confirmation no rDNA is involved.
- 2. Under in vivo PPE, use of N95 was marked YES. The IBC requests confirmation whether this is correct.
- 3. The IBC requests information regarding how animal bedding and waste should be handled? For example, is there a risk of viral shedding? Should cage changes be performed in the biosafety cabinet and bedding/waste be autoclaved?
- 4. All individuals listed should register with the Online IBC Database, fill out a Statement of Experience, and complete the IBC at CSU online training.

#### 10. Mayo, Christie

**Agent**: Epizootic hemorrhagic disease virus – Strain: US prototype strains and multiple US field strains; BSL2

#### The committee unanimously approved of the above project with the following modifications:

- 1. The IBC requests more information be added to the agent description, including its virulence, host range and what type of disease it causes.
- 2. Additionally, a comment regarding whether the agent is pathogenic for animals.

# III. Review of Coronavirus Agent and Project Request Forms reviewed/approved by Biosafety Officer

#### 1. Bowen, Richard

**APPROVED Project:** Transfusion transmission risk assessment for SARS-CoV-2 (20-090B); BSL3 in vitro and in vivo in hamsters. NIH Guidelines category non-exempt rDNA: N/A **APPROVED Project:** Antiviral therapy for COVID-19 (20-099B); BSL3 in vitro and in vivo in hamsters. NIH Guidelines category non-exempt rDNA: N/A

#### 2. Geiss, Brian

**PENDING Project:** <u>Testing of SARS-CoV-2 antigen and RNA diagnostic assays (20-100B);</u> BSL2 in vitro, human samples. NIH Guidelines category non-exempt rDNA: N/A

#### IV. Amendments to be reviewed by full committee

#### 1. Wilusz, Carol

**APPROVED Project:** Extraction of RNA from wastewater for SARS-CoV-2 quantification (20-067B); BSL2 in vitro. NIH Guidelines category non-exempt rDNA: N/A **Amendment request:** We wish to expand the project to include collection of wastewater from sites on campus using the following procedure.

- Personnel will don PPE including face shield, surgical face mask, tyvek suit, gloves.
- Retrieve autosampler containing 2.5L bottle of wastewater from manhole.
- Remove wastewater collection bottle from sampler. Put lid on and invert to homogenize the sample.
- Use a disposable ladle to remove 3 x 40ml of sample from the bottle into 50ml falcon tubes.

- Seal the tube and spray outside with 10% bleach. Wipe with paper towel.
- Place the tubes into a cooler containing absorbent material and ice pack for transportation.
- Dispose of the remaining liquid into the sewer by pouring.
- Rinse the bottle with 10% bleach and then with water disposing liquid into the sewer.
- Insert into autosampler and lower sampler into the manhole.
- Remove gloves, face shield before entering vehicle to move to next location or to lab.
- After all samples are collected, the technician will deliver samples to the lab for processing.
- At end of day, remove tyvek suit, spray down vehicle seats and steering wheel etc with disinfectant.
- Technicians will complete BBP, BSL1/2 training and training in hazards of sanitary sewers/manholes.

The committee conditionally approved of the above amendment request, on the condition that the members of the Biosafety Office are present during the first sample collection.

#### V. Unfinished business

None

#### VI. New Business

#### 1. SARS-CoV-PPE recommendations

- 1.BSL3 in vitro and in vivo There was a discussion regarding when surgical gowns are required for SARS-CoV-2 work in the BSL3. Gowns are required for in vivo work, but not in vitro work. Bowen's group using back closing gowns for everything.
- 2.BSL2 clinical samples due to the N95 shortage, individuals working with clinical samples at BSL2 and in a BSC have not been using N95s. However many are asking for them because of high volume/concentration they are working with. Now that N95s are being decontaminated, these individuals can use N95s.

#### 2. Use of barrier/filter tips for work in the BSL3

There was a discussion whether the use of barrier tips should be a requirement in the BSL3. It is a good idea for protection of the samples, the equipment, and the personnel. Most groups are using them, but one is not citing cost as the reason. The IBC voted and approved making the use of barrier tips a requirement in the BSL3.

3. Letter to VPR with concerns regarding SARS-CoV-2 research and resources

A draft letter was presented to the IBC for review. The letter identifies concerns raised regarding the large number of research projects involving SARS-CoV-2 which has put strains on resources such as PPE, lab space, and personnel. The IBC discussed that and its intent and supported sending it the VPR. The committee members will send their edits/comments to the IBC Coordinator by Monday, and the updated letter will be sent to the VPR.

#### VII. Reports

1. Coordinator's report.

#### 1.Open records request(s) -

- 1. Jessica Blake/Allison Young NIH Incident Reports (2015-June 2020) these have been sent
- 2. Prickly Research (Ed Hammond) IBC Minutes (July 2019-July 2020) these are being prepared
- 2.Next IBC meeting: Wednesday, August 12, 2020
- 3. Save the Date 2020 Biosafety and Biosecurity Fair October 20, 2020 this will be an online event
- 2. Biosafety Officer's report.
  - a. **Incident reports** There was a report of loose mouse found in \_\_\_\_\_, It was confirmed to be a wild mouse and all research mice were accounted for.
  - b. Inspections
  - c. Laboratory audit reports
- VIII. Agent and Project Approval Request Forms Reviewed at Previous IBC Meeting and Approved After Modification to be read into the minutes.
  - 1. Tjalkens, Ronald

Agent: Adeno-associated virus (AAV) – Strain: any; BSL1

**Project:** Stereotactic injection of adeno-associated virus (20-080B); BSL1 in vitro and in vivo in mice and chickens. NIH Guidelines category non-exempt rDNA: III-D-4

2. Duval, Dawn

**Project:** Development of a comparative oncology functional genomics screening platform using a CRISPR-Cas9 library to identify critical dependencies and mechanisms of treatment resistance in canine cancers (20-081B); BSL2 in vitro. NIH Guidelines category non-exempt rDNA: III-D-3

3. Bowen, Richard

**Project:** COVID vaccine testing (20-083B); BSL3 in vitro and in vivo in hamsters and ferrets. NIH Guidelines category non-exempt rDNA: III-D-2

4. Fahrner, Scott

**Project:** RESTART Colorado: Rational Effective Surveillance Testing Accelerating Return to Tasks (20-084B); Human Samples. NIH Guidelines category non-exempt rDNA: N/A

5. Goodrich, Raymond

Agent: SARS-CoV-2 – Strain: USA-WA 1/2020; BSL3

**Project:** COVID-19: Vaccine Development for COVID-19 Using SolaVAX (20-086B); BSL3 in vitro. NIH Guidelines category non-exempt rDNA: N/A

6. Nishimura, Erin

**Project:** Mechanisms and dynamics of gene expression during cellular differentiation and development (20-068B); BSL1 in vitro. NIH Guidelines category non-exempt rDNA: III-D-4

**Project:** Deciphering the molecular hallmarks of cellular differentiation in animal and cancer models (20-069B); BSL1. NIH Guidelines category non-exempt rDNA: III-D-4

IX. Amended Project or Agent approval Request Forms Reviewed at Previous IBC Meeting and Approved After Modification to be read into the minutes.

- X. New or Amended Agent Approval Request Forms Reviewed and Approved by the <u>Biosafety</u> Officer or Chair to be read into the minutes.
- XI. New or Amended Project Approval Request Forms Reviewed and Approved by the <u>Biosafety</u> Officer or <u>Chair</u> to be read into the minutes.
  - 1. VandeWoude, Sue

**Project:** Impacts of antiretroviral therapy on oral cavity homeostasis in an FIV animal model (20-085B); BSL2 in vitro and in vivo in cats. NIH Guidelines category non-exempt rDNA: N/A

2. Funk, W.

**Agent:** Batrachochytrium dendrobatidis (Bd; aka – Strain: any; BSL1 **Project:** <u>Understanding intraspecific variation in boreal toad response to amphibian chytrid fungus (20-079B); BSL1 in vivo in toads. NIH Guidelines category non-exempt rDNA: N/A</u>

3. Pearce, Stephen

**Project:** Wheat Streak Mosaic Virus Resistance in wheat (20-053B); BSL1 in vivo in Brachypodium distachyon and Trit. NIH Guidelines category non-exempt rDNA: N/A

4. Bowen, Richard

**Project:** Three year duration of immunity to rabies in dogs and cats (20-091B); BSL2 in vitro and in vivo in dogs and cats. NIH Guidelines category non-exempt rDNA: N/A

Meeting adjourned: 2:08 PM Minutes recorded by C.Johnson