

RML Institutional Bio-Safety Committee Minutes

Meeting Date: 02/15/2018

Meeting Time: 1:03 PM **Adjourned:** 1:55 PM

Building A Seminar Room

Members:

	P	A		P	A		P	A
Sue Priola, Chair	<input checked="" type="checkbox"/>	<input type="checkbox"/>	(b)(6)	<input type="checkbox"/>	<input checked="" type="checkbox"/>	(b)(6)	<input type="checkbox"/>	<input checked="" type="checkbox"/>
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(P=present; A=absent)

Guests:

Minutes: Meeting minutes from 1/18/18 meeting

approved **not-approved**

Old Business: Summarized discussion not resolved at last meeting

Item 1:	<p>Minutes from 1/18/18</p> <ul style="list-style-type: none"> ▪ (b)(6) pointed out on page 2, the third bullet in Item 1 should be changed from "onto" to "into". ▪ Sue Priola pointed out minor typos. <p><u>Action:</u> Meeting minutes for 1/18/18 were unanimously approved with the above minor modifications.</p>
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New Business: Summarized discussion of new items the committee addresses

Item 1:	Non-responsive
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	Non-responsive
Item 2:	

	Non-responsive
<p>Item 3:</p>	<p><u>Registration of Material (Potentially) Infectious for Humans, Plants, or Animals (Amendment)</u></p> <ul style="list-style-type: none"> ▪ (b)(6) ▪ PRD#13-91 Amend: Henipaviruses (Nipah, Hendra, and Cedar) ▪ (b)(6) described the amendment and presented the risk assessment. The (b)(6) lab would like to add bats to the Henipavirus PRD. The bats will specifically be added for Cedar virus only, which is a non-select agent virus. To add bats to Hendra and Nipah, the (b)(6) lab would need to obtain DSAT approval. These studies will focus on characterizing the course of Cedar virus infection in a pteropid bat, <i>Rousettus aegyptiacus</i>, to identify the localization and timing of virus replication and shedding. The primary hazards of working with bats, include teeth and nails that pose a risk for bites and scratches. To mitigate these hazards, studies with Cedar virus will be conducted in the BSL-4 according to the IBC approved <i>SOP#4-28-56 Husbandry Procedures for Bats in Level 4 Biocontainment</i>. PPE will include: positive pressure suit and additional protective gloves (leather or sheep skin gloves) over the suit gloves when manually restraining bats. <ul style="list-style-type: none"> ▪ The biosafety level for work with Cedar virus is BSL-4/ABSL-4. ▪ Animal studies with bats were proposed for Cedar virus only. ▪ The committee discussed the dual-use potential of these experiments. The committee agreed that there were no dual-use concerns with the proposal. <p><u>Action:</u> The committee approved ((b)(6) abstained) PRD#13-91 Amend as</p>

	written.
Item 4:	Non-responsive
Item 5:	
Item 6:	

Non-responsive

Other issues	▪ None.
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Next Meeting:

- Date: 3/15/18
- Place: Library conference room
- Time: 1:00 PM

RML Biosafety Committee Meeting
February 15, 2018
Biosafety Officer/Responsible Official Report

1) Requests approved by BSO since last meeting:

a) *None*

2) New requests approved by committee via electronic review:

a) *None*

3) New requests

Non-responsive

RML Biosafety Committee Meeting
February 15, 2018
Biosafety Officer/Responsible Official Report

Non-responsive

- 6) **Other Issues –**
 - a) *None*

RML Institutional Bio-Safety Committee Minutes

Meeting Date: 05/17/2018

Meeting Time: 1:02 PM **Adjourned:** 2:21 PM

Building A Seminar Room

Members:

	P	A		P	A		P	A
Sue Priola, Chair	<input checked="" type="checkbox"/>	<input type="checkbox"/>	(b)(6)	<input type="checkbox"/>	<input checked="" type="checkbox"/>	(b)(6)	<input checked="" type="checkbox"/>	<input type="checkbox"/>
(b)(6)	<input checked="" type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input checked="" type="checkbox"/>		<input type="checkbox"/>	<input checked="" type="checkbox"/>
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(P=present; A=absent)

Guests (b)(6)

Minutes: Meeting minutes from 4/19/18 meeting

approved **not-approved**

Old Business: Summarized discussion not resolved at last meeting

Item 1:	<p>Minutes from 4/19/18</p> <ul style="list-style-type: none"> Sue Priola pointed out minor typos <p><u>Action:</u> Meeting minutes for 4/19/18 were unanimously approved with the above minor corrections.</p>
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New Business: Summarized discussion of new items the committee addresses

Item 1:	<p><u>Registration of Material (Potentially) Infectious for Humans, Plants, or Animals (Amendment)</u></p> <ul style="list-style-type: none"> (b)(6) PRD#13-91 Amend: Paramyxoviridae, Henipavirus
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▪ (b)(6) presented the risk assessment. The (b)(6) lab would like to add bats to the Henipavirus PRD. Animal work with bats will now be added to the entire PRD, DSAT approval was obtained 5/2/18. These studies will focus on characterizing the course of infection in a pteropid bat, *Rousettus aegyptiacus*, to identify the localization and timing of virus replication and shedding. Studies will be conducted in the BSL-4 according to IBC approved *SOP#4-28-56 Husbandry Procedures for Bats in Level 4 Biocontainment*.

- PPE includes: Positive pressure suit and additional protective gloves (leather or sheep skin gloves) over the suit gloves are worn when manually restraining bats
- The biosafety level for work with the listed Henipaviruses is BSL-4/ABSL-4.
- Animal studies with bats were proposed.
- The committee discussed the dual-use potential of these experiments. The committee agreed that there were no dual-use concerns with the proposal.

Action: The committee approved (b)(6) abstained) **PRD#13-91 Amend** as written.

Item 2: Non-responsive

	Non-responsive
Item 3:	
Item 4:	

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Item 5:	

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Item 6:	

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Item 7:	
Item 8:	

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Item 9:	

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Item 10:	
Item 11:	
Item 12:	

	Non-responsive
Item 13:	
Item 14:	
Item 15:	
Report:	

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Other issues	▪ None.
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Next Meeting:

- Date: 6/21/18
- Place: Library conference room
- Time: 1:00 PM

RML Institutional Bio-Safety Committee Minutes

Meeting Date: 07/19/2018

Meeting Time: 1:06 PM **Adjourned:** 2:22 PM

Building A Seminar Room

Members:

	P	A		P	A		P	A
Sue Priola, Chair	<input checked="" type="checkbox"/>	<input type="checkbox"/>	(b)(6)	<input type="checkbox"/>	<input checked="" type="checkbox"/>	(b)(6)	<input checked="" type="checkbox"/>	<input type="checkbox"/>
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(P=present; A=absent)

Guests (b)(6)

Minutes: Meeting minutes from 6/21/18 meeting

approved **not-approved**

Old Business: Summarized discussion not resolved at last meeting

Item 1:	Minutes from 6/21/18
	Non-responsive
	<u>Action:</u> Meeting minutes for 5/17/18 were unanimously approved with the minor corrections.

New Business: Summarized discussion of new items the committee addresses

Item 1:	Non-responsive
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<p>Item 2:</p>	<p><u>Registration of Material (Potentially) Infectious for Humans, Plants, or Animals (Renewal)</u></p> <ul style="list-style-type: none"> ▪ (b)(6) ▪ PRD#18-91: Paramyxoviridae (Hendra, Nipah, and Cedar virus) ▪ (b)(6) presented the risk assessment. <ul style="list-style-type: none"> ○ Nipah Virus—many cases are mild or sub-clinical. Symptomatic cases present with high fever, severe headache and muscle pain. The disease can progress to inflammation of the brain with drowsiness, disorientation, convulsions and coma. Approximately 40% of clinically apparent diseases are fatal. ○ Hendra—only 3 cases have been recognized and 2 of the 3 were fatal. Symptoms include flu-like symptoms, fever, headache, shortness of breath, dizziness, drowsiness and confusion. Death can occur by either severe encephalitis or septic pneumonia. ○ Cedar virus is a recently discovered virus that was identified by isolation from flying fox urine in Australia during a field study for Hendra virus. Preliminary animal studies have indicated that Cedar virus is less pathogenic than Hendra or Nipah. To date, no known cases of human infection have been identified. ▪ Natural transmission occurs through contact with infected hosts: Nipah-pigs, humans, and bats, Hendra—horses and humans, and Cedar Virus—bats, unknown. Ribavirin has been shown to be effective <i>in vitro</i>, but the <i>in vivo</i> effect is not clear. ▪ The primary lab hazards include: direct contact with broken skin or mucous membranes, accidental parenteral inoculation, exposure to infectious aerosols, animal bites and scratches.

- The biosafety level for work with Paramyxoviridae is BSL-4/ABSL-4.
- Animal studies with mice, hamsters, non-human primates, and bats were proposed.
- The committee discussed the dual-use potential of these experiments. The committee agreed that there were no dual-use concerns with the proposal.

Action: The committee approved (b)(6) abstained) **PRD#18-91** as written.

Item 3:

Non-responsive

Item 4:

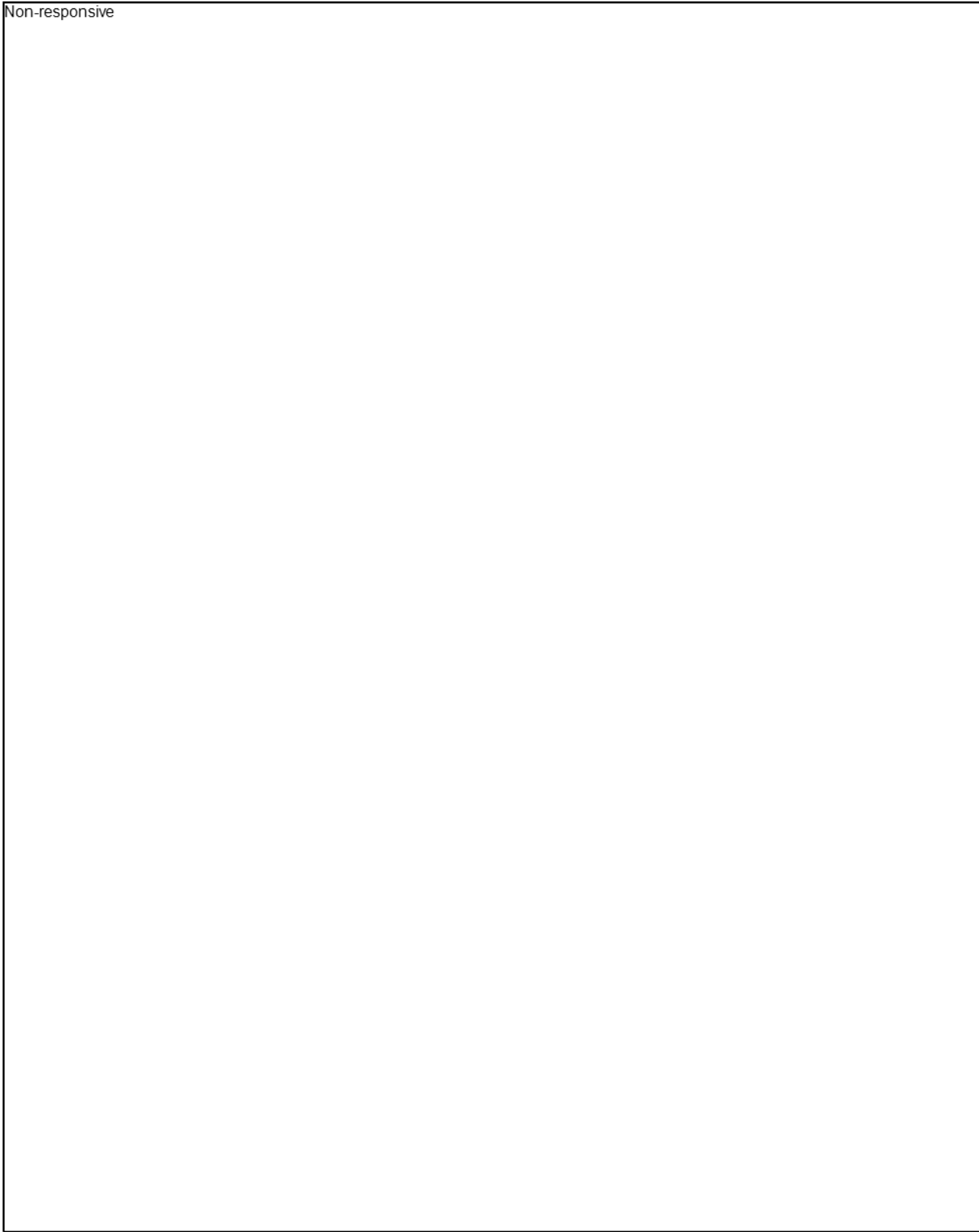
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Item 5:	
Item 6:	

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Item 7:	

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Item 8:	

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Other issues	▪ None
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Next Meeting:

- Date: 8/16/18
- Place: Library conference room
- Time: 1:00 PM

RML Biosafety Committee Meeting
July 19, 2018
Biosafety Officer/Responsible Official Report

1) Requests approved by BSO since last meeting:

Non-responsive

2) New requests approved by committee via electronic review:

a) *None*

3) New requests

Non-responsive

RML Biosafety Committee Meeting
July 19, 2018
Biosafety Officer/Responsible Official Report

Non-responsive

- 6) **Other Issues –**
 - a) *None*

RML Institutional Bio-Safety Committee Minutes

Meeting Date: 08/15/2019

Meeting Time: 1:05 PM **Adjourned:** 2:15 PM

Building A Library, Room A320

Members:

	P	A		P	A		P	A
Sue Priola, Chair	<input checked="" type="checkbox"/>	<input type="checkbox"/>	(b)(6)	<input type="checkbox"/>	<input checked="" type="checkbox"/>	(b)(6)	<input checked="" type="checkbox"/>	<input type="checkbox"/>
(b)(6)	<input checked="" type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input checked="" type="checkbox"/>		<input type="checkbox"/>	<input checked="" type="checkbox"/>
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(P=present; A=absent)

Guests (b)(6)

Minutes: Meeting minutes from 6/20/19 meeting

approved **not-approved**

Old Business: Summarized discussion not resolved at last meeting

Item 1:	<p>Minutes from 6/20/19</p> <p><u>Action:</u> Meeting minutes for 6/20/19 were unanimously approved with the following minor modification:</p> <div style="border: 1px solid black; padding: 5px; margin-top: 5px;"> Non-responsive </div>
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New Business: Summarized discussion of new items the committee addresses

Item 1:	<u>Registration of Material (Potentially) Infectious for Humans, Plants, or Animals</u>
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	<p>(Amend)</p> <ul style="list-style-type: none">▪ (b)(6)▪ PRD#18-90 Amend: Filoviridae▪ (b)(6) presented the risk assessment. The amendment is to add work with Mengla virus (MLAV) and animal work with bats. The (b)(6) lab has already obtained CDC DSAT approval for work with Filoviruses in bats and SOPs for this work have already been developed and used in the BSL-4 with other agents. Mengla virus genetic material was identified in the bat liver samples from Mengla County China and the sequence was determined by next-gen sequencing. This sequence data has been published. At the genomic level, MLAV shares 39, 41 and 54% nucleotide sequence identity with LLOV, Ebola virus and Marburg virus, respectively. The sequence was then commercially synthesized by (b)(3):Public Law 107-188 collaborators. They will provide the Mengla virus full length plasmid and helper plasmids so that the (b)(6) lab can generate the virus via reverse genetics. Mengla virus uses the same entry receptor and demonstrated a similar cell tropism as the other filoviruses▪ Animal studies with bats were proposed. Animal studies are approved at ABSL-4.▪ Work with Mengla virus is approved at BSL-4/ABSL-4.▪ The committee discussed the dual-use potential of these experiments. The committee agreed that there were no dual-use concerns with the proposal. <p><u>Action:</u> The committee approved (b)(6) (abstained) PRD#18-90 Amend as written.</p>
<p>Item 2:</p>	<p>Non-responsive</p>

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Item 3:	

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Item 8:	
Item 9:	

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Item 10:	

Non-responsive

Non-responsive

Other issues	▪ None
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Next Meeting:

- Date: 9/19/19
- Place: Library conference room
- Time: 1:00 PM

RML Biosafety Committee Meeting
August 15, 2019
Biosafety Officer/Responsible Official Report

1) Requests approved by BSO since last meeting:

a) *None*

2) New requests approved by committee via electronic review:

Non-responsive

3) New requests

Non-responsive

RML Biosafety Committee Meeting
August 15, 2019
Biosafety Officer/Responsible Official Report

Non-responsive

RML Biosafety Committee Meeting
August 15, 2019
Biosafety Officer/Responsible Official Report

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