From: Bridbord, Ken (NIH/FIC) [E]
Sent: Wed, 16 May 2012 17:50:27 -0400
To: Jessup, Christine (NIH/FIC) [E]
Subject: FW: NIH DURC Inventory Workshop
Attachments: USG interim DURO policy workshop (NIH) 5-17-2012.pptx

------ Forwarded Message
From: "Viggiani, Christopher (NIH/OD) [C]"
<(b) (6)
Date: Wed, 16 May 2012 17:40:53 -0400
To: "Eichacker, Peter (NIH/CC/CCMD) [E]"
<(b) (6) "Nakamura, Richard (NIH/CSR) [E]"
<(b) (6) "Bridbord, Ken (NIH/FIC) [E]"
(b) (6) "Goldrosen, Martin
(NIH/NCCAM) [E]" <(b) (6) "Gaston, Marilyn
(NIH/NCI) [E]" <(b) (6) "Briggs, Josephine
(NIH/NCCAM) [E]" <(b) (6) "Fisher, Richard
(NIH/NEI) [E]" <(b) (6) "Scholes, Derek
(NIH/NHGRI) [E]" <(b) (6) "Roth, Carl
(NIH/NHLBI) [E]" <(b) (6) "Reed, Kathie
(NIH/NIA) [E]" <(b) (6) "Dixon, Dennis M.
(NIH/NIAID) [E]" <(b) (6) "Moen, Laura
(NIH/NIAMS) [E]" <(b) (6) "Rowe, Mona
(NIH/NICHD) [E]" <(b) (6) "Weiss, Susan
(NIH/NIDA) [E]" <(b) (6) "Cyr, Janet
(NIH/NIDCD) [E]" <(b) (6) "Farishian, Richard
(NIH/NIDDK) [E]" <(b) (6)
"Schrader, Bill (NIH/NIEHS) [E]" <(b) (6)
"Mastin, Pat (NIH/NIEHS) [E]" <(b) (6) "Blome,
Juliana (NIH/NIGMS) [E]" <(b) (6) "Bertuzzi,

Stefano (NIH/NIMH) [E]" < (b) (6) "Sy, Francisco (NIH/NIMHD) [E]" < (b) (6) "Jett, David (NIH/NINDS) [E]" < (b) (6) "Grason, John (NIH/NINR) [E]" < (b) (6) "Weis, Brenda (NIH/OD) [E]" < (b) (6) "Grieder, Franziska (NIH/OD) [E]" < (b) (6) "Byrnes, Edmond (NIH/OD) [E]" < (b) (6) "Benson, Dennis (NIH/NLM/NCBI) [E]" < (b) (6) "Angerer, Robert (NIH/NIDCR) [E]" < (b) (6) "Hanning, Brenda (NIH/NICHD) [E]" < (b) (6) "Basaric, Sanja (NIH/NHGRI) [E]" < (b) (6) "Sina, Barbara (NIH/FIC) [E]" < (b) (6) "Jessup, Christine (NIH/FIC) [C]" (b) (6) "Davis, Frank (NIH/OD) [E]" (b) (6) "Groesch, Mary (NIH/OD) [E]" < (b) (6) "Harris, Kathryn (NIH/OD) [C]" < (b) (6) "Lev, Ori (NIH/OD) [C]" < (b) (6) "Luetkemeier, Erin (NIH/OD) [E]" < (b) (6) "Mistry, Allison (NIH/OD) [E]" < (b) (6) "Nightingale, Stuart (NIH/OD) [C]" < (b) (6) "O'Reilly, Marina (NIH/OD) [E]" < (b) (6) "Paine, Taunton (NIH/OD) [C]" < (b) (6) "Shipp, Allan (NIH/OD) [E]" < (b) (6) "Stagno, Jason (NIH/NCI) [F]" < (b) (6) "Viggiani, Christopher (NIH/OD) [C]" < (b) (6) "Sastre, Antonio (NIH/NIBIB) [E]" < (b) (6) "Finnegan, Sean (NIH/OD) [C]" < (b) (6) "Buchanan, Holly (NIH/NIDA) [E]" < (b) (6) "Dowling, Gayathri J (NIH/NIDA) [E]" < (b) (6) "Somerman, Martha

(NIH/NIDCR) [E]" <(b) (6) "Wehr, Elizabeth (NIH/NICHD) [E]" <(b) (6) "Antman, Melissa (NIH/NHLBI) [E]" <(b) (6) "Garcia, Isabel (NIH/NIDCR) [E]" <(b) (6) "Rapp, Barbara (NIH/NLM) [E]" <(b) (6) "Florance, Valerie (NIH/NLM) [E]" <(b) (6) "Adams, Amy B. (NIH/NIDCR) [E]" <(b) (6)
Subject: NIH DURC Inventory Workshop

Dear colleagues,

We look forward to your participation in the NIH DURC Inventory workshop on **Thursday, May, 17, 2012**. Attached please find the PowerPoint slides for tomorrow's workshop. The dial-in information is: 1-888-552-2815; passcode: 811533#

As a reminder, we will be asking each IC to report the results of their initial inventory, including:

- The number of grants or contracts involving any of the 15 agents/toxins.
- The number of grants or contracts involving any of the 15 agents/toxins AND those that are likely to involve any of the 7 effects/categories of experiments.
- A brief overview of your IC's approach to collecting the DURC inventory.
- Any challenges or outstanding issues encountered during this inventory process.

To meet the reporting deadline we ask that each IC report its final inventory (Step 1 and Step 2 of the process) to OSP by **noon on Friday, May 18**.

Thank you.

Christopher Viggiani, Ph.D.
Health Science Policy Analyst
Contractor
Office of Biotechnology Activities
Office of Science Policy
Office of the Director
(b) (6)
(b) (6)

------ End of Forwarded Message

The USG Interim Policy for Oversight of Federally-Funded Life Sciences DURC: Implementation of the Inventory and Reporting Requirements

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An Intra-agency Workshop Hosted byThe NIH Office of Science PolicyMay 17, 20121:00 – 2:30 pm

Today's Agenda

- **Quick recap of the USG Interim Policy and task at handInventory60-day reporting requirementsScope of the policy and definitionsIC ReportsInitial inventory reportsOverview of IC's approachChallenges and outstanding questionsNext stepsIC final reports to OSP by noon, May 183rd workshop to discuss 90-day reporting requirements**

Today's Workshop: Completing NIH DURC Inventory Report

1. **Within 60 days of issuance of this Interim Policy (i.e., by May 27)Aggregate number of current and proposed unclassified, intramural, and extramural research projects identified that include work with:One or more of the 15 agents and toxins One or more of the 15 agents and toxins and produces, aims to produce, or are reasonably anticipated to produce one or more of the7 effects listedWithin 90 days of issuance of this Interim Policy (i.e., by June 26), the following results of actions taken in response to inventory findings:Number of unclassified current and proposed DURC projects Number of current projects identified as DURC through initial proposals vice progress reportsSummary of risks and proposed mitigation measures and number of projects to which each mitigation tool would be applied. Report the number of projects by agent and/or toxin plus the category of experiment.**

Requires additional Feder

Step 1: Identification of research involving any of the 15 agents or toxins listed

1. Avian influenza virus (highly pathogenic)Bacillus anthracisBotulinum neurotoxinBurkholderia malleiBurkholderia pseudomalleiEbola virusFoot-and-mouth disease virusFrancisella tularensisMarburg virusReconstructed 1918 Influenza virusRinderpest virusToxin-producing strains of Clostridium botulinumVariola major virusVariola minor virusYersinia pestis

Step 2: Identification of research that produces, aims to produce, or is reasonably anticipated to produce any of the listed effects

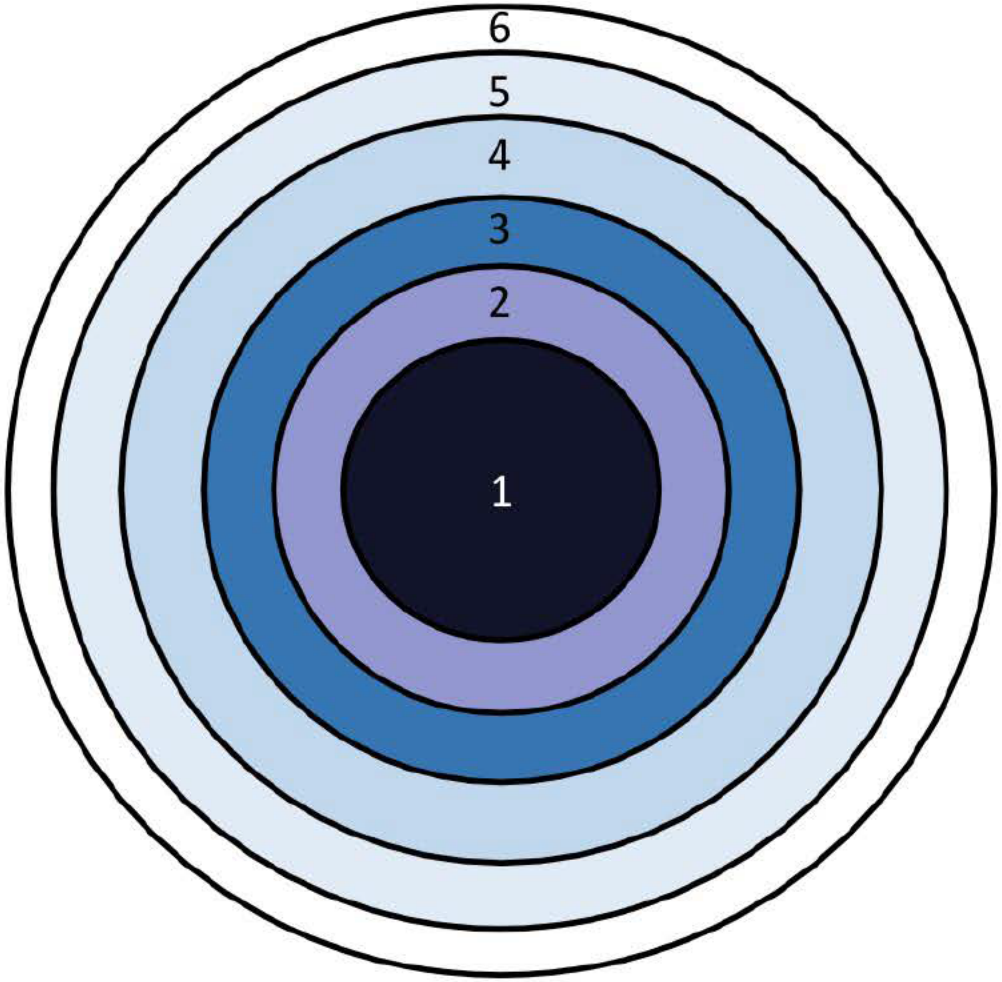
1. **Enhances the harmful consequences of the agent or toxin; Disrupts immunity or the effectiveness of an immunization against the agent or toxin without clinical and/or agricultural justification;Confers to the agent or toxin resistance to clinically and/or agriculturally useful prophylactic or therapeutic interventions against that agent or toxin or facilitates their ability to evade detection methodologies;Increases the stability, transmissibility, or the ability to disseminate the agent or toxin; Alters the host range or tropism of the agent or toxin; Enhances the susceptibility of a host population to the agent or toxin; orGenerates or reconstitutes an eradicated or extinct agent or toxin listed in Section III.1**

Step 3: Determination of whether the research is DURC

Is it Dual Use Research of Concern? Based on current understanding, can the research be reasonably anticipated to provide knowledge, information, products, or technologies that could be directly misapplied to pose a significant threat with broad potential consequences to public health and safety, agricultural crops and other plants, animals, the environment, materiel, or national security?

Scope of the USG Policy for DURC

"...review will focus on research that involves one or more of the agents or toxins listed in Section (III.1)"



Interpretations:Directly utilizes any of the 15 listed agents or toxinsIncludes the utilization of a toxin at a level that is not covered under the SAP (e.g., de minimus quantity of Botulinum toxin)Includes the utilization any of the 15 agents or toxins in attenuated forms that are not covered under the SAPAlso includes the use of genes from any of the 15 listed agents/toxinsAlso includes in silico (e.g. modeling experiments, bioinformatics approaches) involving the biology of the 15 agents/toxins.Also includes experiments related to the public health impact of any of the 15 agents/toxins (e.g. modeling the effects of a toxin in the milk supply, developing new methods to deliver a vaccine to a listed agent, developing surveillance mechanisms for a listed agent)

Note: This concept is more accurately conveyed as a Venn diagram but for simplicity we have shown the different interpretations as "layers."

Draft Inventory Template
Tab 1 – Basic Info

Instructions. In this Workbook please find four worksheets that are accessed by clicking on the tabs in the lower left labeled "Basic Info," "DURC Inventory," and "Risks and Strategies," and "Summary." For the May 17th Workshop please fill out the information requested in Tab 1 and Tab 2.

This table is for internal NIH use only. *For this Tab - Basic Info, please complete the table below. The grants and contracts listed here should be only those that are relevant to the DURC oversight policy (i.e., only those that involve any of the 15 agents or toxins covered by the DURC policy). Grants and contracts will be anaomized and given a unique identifyer by NIH OSP staff. The information in this chart will not be shared or reported as part of the DURC inventory.*

Unique Identifyer	Grant #	Contract #	Project Funding			Title	Principal Investigator	Institute or Center	Abstract
			Does the grant or contract receive funding from another institute, center, department, or agency?	Which other institute, center, department or agency?	Which funder is responsible for reporting this grant or contract as part of its DURC inventory?				
ABCD-1	ExampleGrant #NIH-1								
ABCD-2	ExampleGrant #NIH-2								
ABCD-3	ExampleGrant #NIH-3								

Draft Inventory Template
Tab 2 – DURC Inventory

Instructions. In this Workbook please find four worksheets that are accessed by clicking on the tabs in the lower left labeled "Basic Info," "DURC Inventory," and "Risks and Strategies," and "Summary." For the May 17th Workshop please fill out the information requested in Tab 1 and Tab 2.

For this Tab - DURC Inventory. List the Grant or Contract # (the information will be anonymized and given a unique identifyer).

Step 1: *Indicate which of the 15 agents/toxins are involved in each grant by inserting the number "1" in the appropriate cell. If a grant or contract utilizes more than one agent/toxin, indicate this on a separate row. See Example below.*

Step 2: *Indicate which of the 7 categories of experiments/potential consequences are likely to be associated with each agent/toxin by inserting a "1" in the appropriate cell. You can choose more than one experiment/consequence for each agent/toxin. See Example below.*

Step3: *Indicate whether the experiments involving each agent meet the definition for "Dual Use Research of Concern" by inserting a "1" in the column for Yes or No. Identify when the research was identified as DURC and briefly describe the rationale for deciding whether a project was or was not DURC.*

NOTE: ONLY STEP 1 AND STEP 2 NEED TO BE COMPLETED FOR THE MAY 17TH MEETING.

Institute or Center	Unique Identifyer	Agent(s)/Toxin(s)														
		Avian influenza (high path)	Bacillus anthracis	Botulinum neurotoxin	Burkholderia mallei	Burkholderia pseudomallei	Ebola virus	Foot-and-mouth disease virus	Francisella tularenis	Marburg virus	Reconstructed 1918 influenza virus	Rinderpest virus	Clostridium botulinum, toxin-producing strains	Variola major virus	Varioloa minor virus	Yersinia pestis
NIH	ABCD-1			1												
NIH	ABCD-1												1			
NIH	ABCD-2			1												
NIH	ABCD-2		1													
NIH	ABCD-3	1														

Draft Inventory Template
Tab 2 Continued – DURC Inventory

Categories of Experiments/Potential Effects

1-Enhances the harmful consequences of the agent or toxin;
2-Disrupts immunity or the effectiveness of an immunization against the agent or toxin without clinical or agricultural justification;
3-Confers to the agent or toxin resistance to clinically or agriculturally useful prophylactic or therapeutic interventions against that agent or toxin or facilitates their ability to evade detection methodologies;
4-Increases the stability, transmissibility, or the ability to disseminate the agent or toxin;
5-Alters the host range or tropism of the agent or toxin;
6-Enhances the susceptibility of a host population to the agent or toxin; or
7-Generates or reconstitutes an eradicated or extinct agent or toxin listed in Section (III.1) above.

DURC and related information is not being reported until the 90-day time point

Dept. or Agency	Unique Identifyer	Categories of Experiments/Effects							DURC?		If DURC:		
		1	2	3	4	5	6	7	Yes	No	When was DURC Identified?	If "other" indicate which stage DURC was identified	Rationale for Deciding that a project meets the DURC definition
NIH	ABCD-1		1							1			
NIH	ABCD-1		1			1		1	1				
NIH	ABCD-2												
NIH	ABCD-2												
NIH	ABCD-3			1						1			

Draft Inventory Template
Tab 3 – Risks and Strategies

Information related to DURC risks and mitigation strategies is not being reported until the 90-day time point

Instructions. In this Workbook please find four worksheets that are accessed by clicking on the tabs in the lower left labeled "Basic Info," "DURC Inventory," and "Risks and Strategies," and "Summary." For the May 17th Workshop please fill out the information requested in Tab 1 and Tab 2.

For this Tab - Risks and Strategies, describe the specific risks associated with the DURC.

Describe the proposed risk mitigation strategies identified to manage the risks associated with the DURC.

Where appropriate, indicate whether NIH has worked with any agencies or departments that are co-funding a DURC project to develop a harmonized risk mitigation strategy.

Unique Identifyer	IF DURC:		
	Specific Risks/Risk Categories	Proposed Risk Mitigation Strategies	If a grant or contract received funding from multiple agencies, have the agencies worked together to develop harmonized risk mitigation strategies?

Next Steps

- **Finalize Inventory ReportsIC final reports to OSP by noon, May 183rd IC Inventory Workshop90-day reporting requirementsDURC determinationCommunication with researchers and institutionsCategories of riskRisk mitigation strategies**

From: Bridbord, Ken (NIH/FIC) [E]
Sent: Mon, 14 May 2012 13:40:57 -0400
To: Jessup, Christine (NIH/FIC) [E];Sina, Barbara (NIH/FIC) [E]
Subject: FW: NIH DURC Inventory
Attachments: DURC Inventory Tables-NIH DRAFT.XLSX, FAQs on Implementation of USG Policy Inventory and Reporting Req 5-11-12.docx

------ Forwarded Message
From: "Patterson, Amy (NIH/OD) [E]" <(b) (6)
Date: Fri, 11 May 2012 19:47:22 -0400
To: "Eichacker, Peter (NIH/CC/CCMD) [E]"
<(b) (6) "Nakamura, Richard (NIH/CSR) [E]"
<(b) (6) "Bridbord, Ken (NIH/FIC) [E]"
<(b) (6)>, "Goldrosen, Martin
(NIH/NCCAM) [E]" <(b) (6) "Gaston, Marilyn
(NIH/NCI) [E]" <(b) (6) "Briggs, Josephine
(NIH/NCCAM) [E]" <(b) (6) "Fisher, Richard
(NIH/NEI) [E]" <(b) (6) "Scholes, Derek
(NIH/NHGRI) [E]" <(b) (6) "Roth, Carl
(NIH/NHLBI) [E]" <(b) (6) "Reed, Kathie
(NIH/NIA) [E]" <(b) (6) "Dixon, Dennis M.
(NIH/NIAID) [E]" (b) (6)>, "Moen, Laura
(NIH/NIAMS) [E]" <(b) (6) "Rowe, Mona
(NIH/NICHD) [E]" <(b) (6) "Weiss, Susan
(NIH/NIDA) [E]" <(b) (6) "Cyr, Janet
(NIH/NIDCD) [E]" <(b) (6) "Farishian, Richard
(NIH/NIDDK) [E]" <(b) (6)
"Schrader, Bill (NIH/NIEHS) [E]" <(b) (6)
"Mastin, Pat (NIH/NIEHS) [E]" <(b) (6) "Blome,
Juliana (NIH/NIGMS) [E]" <(b) (6) "Bertuzzi,

Stefano (NIH/NIMH) [E]" <(b) (6) "Sy, Francisco (NIH/NIMHD) [E]" <(b) (6) "Jett, David (NIH/NINDS) [E]" <(b) (6) "Grason, John (NIH/NINR) [E]" <(b) (6) "Weis, Brenda (NIH/OD) [E]" <(b) (6) "Grieder, Franziska (NIH/OD) [E]" <(b) (6) "Byrnes, Edmond (NIH/OD) [E]" <(b) (6) "Benson, Dennis (NIH/NLM/NCBI) [E]" <(b) (6) "Angerer, Robert (NIH/NIDCR) [E]" <(b) (6) "Hanning, Brenda (NIH/NICHD) [E]" <(b) (6) "Basaric, Sanja (NIH/NHGRI) [E]" <(b) (6) "Sina, Barbara (NIH/FIC) [E]" <(b) (6) "Jessup, Christine (NIH/FIC) [C]" <(b) (6)>, "Davis, Frank (NIH/OD) [E]" (b) (6)>, "Groesch, Mary (NIH/OD) [E]" <(b) (6)>, "Harris, Kathryn (NIH/OD) [C]" <(b) (6) "Lev, Ori (NIH/OD) [C]" <(b) (6) "Luetkemeier, Erin (NIH/OD) [E]" <(b) (6) "Mistry, Allison (NIH/OD) [E]" <(b) (6) "Nightingale, Stuart (NIH/OD) [C]" <(b) (6) "O'Reilly, Marina (NIH/OD) [E]" <(b) (6) "Paine, Taunton (NIH/OD) [C]" <(b) (6) "Shipp, Allan (NIH/OD) [E]" <(b) (6) "Stagno, Jason (NIH/NCI) [F]" <(b) (6) "Viggiani, Christopher (NIH/OD) [C]" <(b) (6)>

Cc: "Finnegan, Sean (NIH/OD) [C]" <(b) (6)

Subject: NIH DURC Inventory

<<DURC Inventory Tables-NIH DRAFT.XLSX>> <<FAQs

on Implementation of USG Policy Inventory and Reporting Req 5-11-12.docx>>

Dear Colleagues,

Thank you for your participation in Wednesday's (May 9) DURC Inventory Workshop. As promised during our discussion, I have attached the following items:

- **FAQs** – identified during the our call as well those encountered by other Departments and Agencies.

- **Excel spreadsheets** – for conducting the DURC inventory, updated as per our discussion. Note that the workbook has four Tabs – Basic Info, DURC Inventory, Risks and Strategies, and Summary.

Homework assignment: In preparation for that call, please review your IC's research portfolio and complete Tab 1 (Basic Info) and the first two steps listed in Tab 2 (DURC Inventory) in the attached spreadsheets (i.e. identify projects involving the 15 agents/toxins and the 7 categories of experiments). You do **NOT** need to determine if projects meet the DURC definition or develop risk mitigation strategies at this time. These items will be reported for 90-day deadline in June.

On the May 17 teleconference each IC point of contact will be asked to report:

- The number of grants or contracts involving any of the 15 agents/toxins.

- The number of grants or contracts involving any of the 15 agents/toxins AND those that are likely to involve any of the 7 effects/categories of experiments.

- A brief overview of your IC's approach to collecting the DURC inventory.

- Any challenges or outstanding issues encountered during this inventory process.

A slide deck and agenda will be circulated in advance of the meeting.

Thanks again for your help in conducting this inventory. We look forward to talking with you next week.

Amy

Amy P. Patterson, M.D.

Associate Director for Science Policy, NIH

------ End of Forwarded Message

Instructions. In this Workbook please find four worksheets that are accessed by clicking on the tabs in the lower left labeled "Basic Info," "DURC Inventory," and "Risks and Strategies," and "Summary." For the May 17th Workshop please fill out the information requested in Tab 1 and Tab 2.

This table is for internal NIH use only. *For this Tab - Basic Info, please complete the table below. The grants and contracts listed here should be only those that are relevant to the DURC oversight policy (i.e., only those that involve any of the 15 agents or toxins covered by the DURC policy). Grants and contracts will be anaomized and given a unique identifyer by NIH OSP staff. The information in this chart will not be shared or reported as part of the DURC inventory.*

Unique Identifyer	Grant #	Contract #	Project Funding			Title	Principal Investigator	Institute or Center	Abstract
			Does the grant or contract receive funding from another institute, center, department, or agency?	Which other institute, center, department or agency?	Which funder is responsible for reporting this grant or contract as part of its DURC inventory?				
ABCD-1	ExampleGrant #NIH-1								
ABCD-2	ExampleGrant #NIH-2								
ABCD-3	ExampleGrant #NIH-3								

Instructions. In this Workbook please find four worksheets that are accessed by clicking on the tabs in the lower left labeled "Basic Info," "DURC Inventory," and "Risks and Strategies," and "Summary." For the May 17th Workshop please fill out the information requested in Tab 1 and Tab 2.

For this Tab - DURC Inventory. List the Grant or Contract # (the information will be ananomized and given a unique identifyer).

Step 1: *Indicate which of the 15 agents/toxins are involved in each grant by inserting the number "1" in the appropriate cell. If a grant or contract utilizes more than one agent/toxin, indicate this on a separate row. See Example below.*

Step 2: *Indicate which of the 7 categories of experiments/potential consequences are likely to be associated with each agent/toxin by inserting a "1" in the appropriate cell. You can choose more than one experiment/consequence for each agent/toxin. See Example below.*

Step3: *Indicate whether the experiments involving each agent meet the definition for "Dual Use Research of Concern" by inserting a "1" in the column for Yes or No. Identify when the research was identified as DURC and briefly describe the rationale for deciding whether a project was or was not DURC.*

NOTE: ONLY STEP 1 AND STEP 2 NEED TO BE COMPLETED FOR THE MAY 17TH MEETING.

Categories of Experiments/Potential Effects
1-Enhances the harmful consequences of the agent or toxin;
2-Disrupts immunity or the effectiveness of an immunization against the agent or toxin without clinical or agricultural justification;
3-Confers to the agent or toxin resistance to clinically or agriculturally useful prophylactic or therapeutic interventions against that agent or toxin or facilitates their ability to evade detection methodologies;
4-Increases the stability, transmissibility, or the ability to disseminate the agent or toxin;
5-Alters the host range or tropism of the agent or toxin;
6-Enhances the susceptibility of a host population to the agent or toxin; or
7-Generates or reconstitutes an eradicated or extinct agent or toxin listed in Section (III.1) above.

Institute or Center	Unique Identifyer	Agent(s)/Toxin(s)															Categories of Experiments/Effects							DURC?		If DURC:		
		Avian influenza (high path)	Bacillus anthracis	Botulinum neurotoxin	Burkholderia mallei	Burkholderia pseudomallei	Ebola virus	Foot-and-mouth disease virus	Francisella tularenis	Marburg virus	Reconstructed 1918 Influenza virus	Rinderpest virus	Clostridium botulinum, toxin-producing strains	Variola major virus	Varioloa minor virus	Yersinia pestis	1	2	3	4	5	6	7	Yes	No	When was DURC Identified?	If "other" indicate which stage DURC was identified	Rationale for Deciding that a project meets the DURC definition
NIH	ABCD-1			1														1							1			
NIH	ABCD-1												1					1			1		1	1				
NIH	ABCD-2			1																								
NIH	ABCD-2		1																									
NIH	ABCD-3	1																	1						1			
		1	1	2	0	0	0	0	0	0	0	0	1	0	0	0	0	2	1	0	1	0	1	1	2			

Instructions. In this Workbook please find four worksheets that are accessed by clicking on the tabs in the lower left labeled "Basic Info," "DURC Inventory," and "Risks and Strategies," and "Summary." For the May 17th Workshop please fill out the information requested in Tab 1 and Tab 2.

For this Tab - Risks and Strategies, describe the specific risks associated with the DURC.

Describe the proposed risk mitigation strategies identified to manage the risks associated with the DURC.

Where appropriate, indicate whether NIH has worked with any agencies or departments that are co-funding a DURC project to develop a harmonized risk mitigation strategy.

Unique Identifyer	IF DURC:		
	Specific Risks/Risk Categories	Proposed Risk Mitigation Strategies	If a grant or contract received funding from multiple agencies, have the agencies worked together to develop harmonized risk mitigation strategies?

For NIH OSP use only. NIH will compile the requested information and report aggregate numbers of grants and contracts meeting the required criteria below. By Day 90 NIH will also report a summary of risks, mitigation measures already in place that address those risks, any additional mitigation measures that have been proposed or implemented, and number of projects to which each mitigation measure would be applied.

	Report by Day 60		Report by Day 90		
Department or Agency	**Number of Grants or Contracts Using Any of the 15 Agents**	**Number of Grants or Contracts Conducting Experiments that Use Any of the 15 Agents AND Meet any of the 7 Criteria**	**Number of Grants or Contracts Containing DURC**		
			Total DURC Cases	**DURC Identified at Initial Proposal Stage**	**DURC Identified at Progress Report Stage**
NIH					

Draft FAQs
Implementation of the Inventory and Reporting Requirements
of the USG Policy for Oversight of Life Sciences DURC

Questions involving the scope of the oversight.

Q1. The first criterion for determining whether research is subject to DURC oversight is if the research involves one of the 15 listed agents or toxins, which are all Select Agents. Botulinum neurotoxin is listed, and it is not regulated as a Select Agent if the amount under the control of a PI does not exceed at any time 0.5 mg. Is research using quantities of Botulinum neurotoxin that are not subject to regulation by the Select Agent Rule also exempt from the DURC oversight policy?

A1: No. Any research involving Botulinum toxin should be considered for its potential to result in any of the 7 listed effects. The intent of the DURC policy is different from, albeit complementary to, that of the Select Agent Rule. The focus of the DURC policy is information, technologies and other products of research that could be misused for harmful purposes. Research on botulinum toxin, for example, could potentially yield information that would have dual use potential, regardless of the amount of toxin used in the experiment. Therefore, there is no exemption under the DURC oversight policy for small quantities of any toxin on the list.

Q2. Does research that involves an attenuated version of one of the microorganisms listed in this Policy still need to be considered for its dual use research potential?

A2: No. The oversight Policy applies to microorganisms that are subject to the Select Agent Rule. Therefore, research using an attenuated strain that is not subject to the Select Agent Rule should not be included in this DURC inventory.

Q3. The oversight Policy applies to research that "involves" one of the listed agents or toxins. Does the Policy apply to research utilizing genes from any of the microorganisms or *in silico* experiments (e.g. modeling, bioinformatics) involving any of the listed agents or toxins?

A3: No. The oversight Policy applies to microorganisms that are subject to the Select Agent Rule. Experiments utilizing genes from any of the microorganisms, or *in silico* experiments involving any of the agents or toxins are not to be considered at this time.

Q4. The Policy requires departments and agencies to identify "research projects" that meet the listed criteria and may be considered DURC. What is being counted and reported as a research project?

A4. The departments and agencies are to identify and report the number of grants and contracts that meet the requested criteria. It is understood that there may be sub-projects within a given grant or contract.

Q5. The policy requires the reporting of projects that are identified as DURC during the project's "initial proposal" stage? What is meant by "initial proposal"?

A5. Initial proposals are research applications that have undergone scientific peer review and are intended to be funded.

Questions involving the identification, reporting and oversight of research covered by this Policy

Q6. Are there any pre-existing data-searching mechanisms that may assist in identifying projects that fall within the scope of the USG policy for oversight of DURC?

A6. Yes, through the use of key words, IMPACT2 IMPAC II or NIH RePORTer can be used as the first pass at identifying projects that fall within the scope of the USG policy; however, both have limitations, e.g., lack of inclusion of P51 grants, including only funded research and including only publicly available grant information. Going forward, grants could be coded when entered into a system such as IMPACT2 IMPAC II or NIH RePORTer, to later allow for the future search of certain key terms. NIAID has a unique system where projects are coded for the listed agents and toxins before they are deposited into their database. Such a system may be useful for other ICs in the future. In the meantime, existing databases of active and pending awards can be searched for the relevant agents and toxins.

Q7. How does reporting work for research that is funded by multiple Federal agencies? Should each funding agency report the work?

A7: No. If each agency were to report the same research, there would be double counting that would skew the data. In cases of multiple federal funding agencies, the primary awarding entity is responsible for reporting projects that are co-funded. However, all institutes, centers, departments, or agencies that fund research involving any of the 15 agents or toxins should list that grant or contract in Tab 1 of the inventory spreadsheet and fill out the appropriate columns regarding Project Funding. In these instances, co-funding entities should communicate to confirm which funder is responsible for fulfilling the reporting requirements. However, if NIH is one of the funding agencies, the NIH would be willing to report that research on behalf of the other agency or agencies, after appropriate consultation.

Q8. How should risk mitigation strategies be developed for DURC that is funded by multiple Federal agencies?

A8: Departments and agencies that are co-funding DURC should work together to develop risk mitigation strategies to ensure consistent, harmonized oversight of DURC. It would also be helpful to designate a lead agency for reporting on the research. Since it may not be evident that other funding agencies are involved, Program Officers from a funding agency that has identified research as needing DURC oversight should check with the research institution whether any other federal agencies are funding the research.

Q9. What should be provided in the abstract section on Tab 1 of the DURC inventory spreadsheet?

A9. A link to the abstract provided in the grant would be appropriate here. It is not necessary to copy and paste the entire abstract. This information is for internal use only and is being collected to provide background on the scope of the research, as it may not be evident in the title of the project alone.

Q10. Should agency staff contact Principal Investigators to report that their proposed or ongoing research has been determined to be DURC?

A10. For interagency discussion

Questions involving the 7 categories of experiments/potential effects

Q11. If a project is identified that includes experiments that result in (or are likely to result in) any of the listed 7 effects, is that project automatically considered DURC?

A11. No, a project may result in one or more of the 7 listed effects and still not be considered DURC. Projects that are likely to result in the 7 listed effects must then be considered for whether they meet the definition of DURC (i.e. – "life sciences research that, based on current understanding, can be reasonably anticipated to provide knowledge, information, products, or technologies that could be directly misapplied to pose a significant threat with broad potential consequences to public health and safety, agricultural crops and other plants, animals, the environment, materiel, or national security.")

Q12. In the first category of experiment/potential effect, what is meant by "enhance the harmful consequences" of an agent or toxin?

A12. "Harmful consequences" refers to the ability of a biological agent or toxin to critically alter normal biological functions, inflict damage on public health resources, materiel, and public safety. This would include augmenting properties such as virulence, infectivity, stability, transmissibility, or the ability of the biological agent or toxin to be disseminated.

Q13. The first effect is "enhances the harmful consequences of the agent or toxin." If an experiment starts with an attenuated strain of one of the listed agents and is anticipated to generate a strain that is more pathogenic than the starting strain but less pathogenic than the wild type strain, is that considered a "hit" for this effect?

A13: No. Experiments that generate strains that are less pathogenic than, or equal in pathogenicity to the wild type are not considered to enhance the harmful consequences of an agent or toxin. It is important to note, however, that although an experiment may not fit this particular effect, it still needs to be evaluated for the applicability of the other six effects listed for criterion 2.

Q14. In the second category of experiment/potential effect, what is meant by "disrupt immunity or the effectiveness of an immunization?"

A14. Immunity encompasses all aspects of host immunity (e.g., active, adaptive, adoptive, passive, innate, and immune modulators). Immunization refers to the active or passive induction of immunity through inoculation (e.g., natural inoculation or vaccination) with an immunizing agent or with antibodies; this includes antitoxins and toxoids. For instance, rendering an immunization ineffective could make a host population vulnerable to the pathogenic consequences of a microbe from which the host population would have otherwise been protected or for which protection, such as a vaccine, was available.

Q15. The second listed effect is "disrupts immunity or the effectiveness of an immunization against the agent or toxin without clinical and/or agriculture justification." Does this apply to experimental vaccines, or only licensed or approved vaccines?

A15: If the research aims to test a vaccine against various challenges and reveals some vulnerabilities, with little to no implications for existing, licensed vaccines, the research would not be considered to meet criterion 2. However, if the experimental vaccine falls into a class of extant, licensed vaccines, then the disruption of effectiveness could have important implications for the entire class of vaccines. In that case, the work should be considered as meeting at least one effect in the second criterion and should therefore be evaluated for the applicability of the third criterion (DURC potential).

Q16. In the third category of experiment/potential effect, what is meant by "clinically or agriculturally useful prophylactic or therapeutic interventions?"

A16. This includes first- or second-line prevention and treatment measures or alternative therapeutics used with special populations (e.g., pregnant women and pediatric patients) in the form of vaccines, antibiotics, antivirals, antiparasitics, antibodies, herbicides, fungicides, algaecides, insecticides, etc. "Agriculture" encompasses all methods of production and management of livestock, crops, vegetation, and soil. Therefore, useful prophylaxes and therapeutics would include herbicides, fungicides, algaecides, insecticides, rodenticides, etc. The main concept is that anything that might compromise the ability to detect, treat, or prevent disease or illness (human or agricultural) caused by biological agents or toxins could result in a significant public health and/or economic burden.

Q17. What is meant by the fourth category of experiment/potential effect?

A17. The rationale for this category is that increasing an agent's stability, transmissibility, or ability to disseminate could facilitate the purposeful malevolent use of a biological agent or toxin and increase the rate or ease by which an agent could spread, impeding attempts to contain disease outbreak. Stability is the ability of a biological agent to remain viable when exposed to various environmental factors, including temperature, relative humidity, atmospheric pollution, and sunlight. Stability also includes persistence in a host. Transmissibility is the ease with which an agent spreads from host to host or from vector to host (e.g., via arthropod vectors). Dissemination is the process by which infectious diseases or toxins are dispersed. The same routes of entry pertinent to the natural spread of diseases are also relevant when their etiologic agents are delivered intentionally (e.g., inhalation of biological agent disseminated as an aerosol or ingestion of a biological agent disseminated through a water supply).

Q18. In the fifth category of experiment/listed effect, what is meant by altering the "host range or tropism?"

A18. Host range is the number of different species or populations that can become infected by a biological agent, causing disease in the host or allowing the host to become a carrier. Tropism is the specificity of a biological agent or toxin for a particular host tissue or cell.

Q19. What is meant by the sixth category of experiment/potential effect?

A19. Information about rendering host populations more susceptible to the pathogenic consequences of an agent or toxin could be used to compromise immune responses and enable the acquisition and spread of disease on an epidemic scale. Of note, the distinction should be made that research applicable to this category would not alter the susceptibility of an individual host or research cohort but rather that of a host population. A host population is a collection of organisms that constitutes a specific group or occurs in a specified habitat. In the context of the criteria, this phrase implies that the misapplication of the knowledge, products, or technologies derived from the research has the potential to broadly impact a population of host organisms.

Q20. What types of agents are being referred to in the seventh category of experiment/potential effect?

A20. This category refers to eradicated and novel agents. An eradicated agent is a biological agent that has been exterminated through surveillance and containment resulting in the permanent reduction to zero of the worldwide incidence in the transmission of the agent and the infection/disease it causes; intervention measures are no longer needed. Eradicated agents are thought to no longer exist in circulation in plants, animals, or the environment. A novel agent is one that has not existed previously and is considered unique based on biological or other properties and traits (e.g., genotype and phenotype).

<u>Questions involving determining whether research meets the definition of DURC</u>

Q21. DURC oversight is required for research that meets three criteria—i.e., it involves a listed agent, produces one of the listed effects, and meets the definition of DURC. For the last step, determining whether research meets the definition of DURC, what if the research generates information that could be misapplied only if it was combined with additional extant information, e.g., information that is already publicly available? Is this DURC?

A21: For interagency discussion

Q22. Is research considered DURC if only in a successive phase of funding it will likely generate information that could be misused for harmful purposes?

A22: For interagency discussion

Q23. What criteria should be used to identify if something is "reasonably anticipated" to be DURC?

A23. The identification of DURC is ultimately a judgment call, and the decision should be as informed as possible. The knowledge and expertise from IC program officers and scientific staff can be used to evaluate the standards in the field and if the proposed research could meet this requirement as well as the other components that are required for the determination of DURC.

From: Bridbord, Ken (NIH/FIC) [E]
Sent: Fri, 4 May 2012 11:58:03 -0400
To: Jessup, Christine (NIH/FIC) [E];Bader, Farah (NIH/FIC) [C]
Cc: Sina, Barbara (NIH/FIC) [E];Bridbord, Ken (NIH/FIC) [E]
Subject: Re: NIH DURC policy

Christine, thanks. Ken

On 5/4/12 8:07 AM, "Jessup, Christine (NIH/FIC) [C]" <(b) (6) wrote:

Thanks Farah. I noted the May 9th workshop on my calendar and will participate.

Christine

From: Bader, Farah (NIH/FIC) [C]
Sent: Thursday, May 03, 2012 5:03 PM
To: Sina, Barbara (NIH/FIC) [E]; Jessup, Christine (NIH/FIC) [C]; Bridbord, Ken (NIH/FIC) [E]
Subject: NIH DURC policy

Dear all,

Ken requested that we have representation on the NIH DURC Inventory committee and recommended that both of you be involved. We are required to have FIC POCs regardless of whether we have projects with dual use. Please see attached document for details for the next meetings.

Kind Regards,

Farah Nikhath Bader, M.P.H
Public Health Analyst
Contractor
Division of International Training & Research (DITR)
Fogarty International Center (FIC)
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From: Bridbord, Ken (NIH/FIC) [E]
Sent: Wed, 11 Apr 2012 16:56:25 -0400
To: Rosenthal, Josh P. (NIH/FIC) [E];Jessup, Christine (NIH/FIC) [E];Sina, Barbara (NIH/FIC) [E];Katz, Flora (NIH/FIC) [E];Bader, Farah (NIH/FIC) [C]
Subject: FW: Policy on Dual Use Research of Concern (DURC)
Attachments: Fwd: New USG Policy for Dual Use Research, Memo to ICs re new USG Dual Use policy.pdf, United_States_Government_Policy_for_Oversight_of_DURC_FINAL_version_032812.pdf, AgentResults--ICs Other Than NIAID.XLSX

------ Forwarded Message
From: "Rockey, Sally (NIH/OD) [E]" <(b) (6)
Date: Wed, 11 Apr 2012 16:35:57 -0400
To: EPMC Principals <(b) (6)
Cc: "Patterson, Amy (NIH/OD) [E]" <(b) (6)
"Groesch, Mary (NIH/OD) [E]"
<(b) (6) "Shipp, Allan (NIH/OD) [E]" <(b) (6)
Subject: Policy on Dual Use Research of Concern (DURC)

Last Friday, OSP sent the attached message to the IC Directors regarding a new policy about Dual User Research of Concern (DURC) research. We are working with OSP on the implementation of this policy for the extramural community.

As you'll see in the attached message, by Friday April 13 ICs were requested to identify whether they fund and/or conduct research involving any of the 15 agents or toxins listed in the attached Policy. OSP and OER will then work with those ICs to implement the policy.

To help with this initial question, eRA has developed the attached spreadsheet showing when a Program Officer has answered "Yes" to the PO Checklist question "Are DHHS/USDA Select Agents or Toxins used in the Project? If Yes, indicate which." When a PO has provided explanatory text, that is available in column J of the spreadsheet. For the majority of NIH ICs, this is a required PO checklist question only for competing grants. Note, this spreadsheet is only as accurate as the information entered by POs and only includes grants for those ICs that are using the PO Checklist in IMPACII. (NIAID grants are not included since they have already begun working on this). Further, a "yes" answer to this question does not automatically mean the grant meets the scope of the focus of the potential DURC policy. Note that not all select agents and toxins are included in the policy so the list may include information that is not relevant. However, it may help you as a starting point.

Sally J. Rockey, Ph.D.
NIH Deputy Director for Extramural Research
OD/NIH/DHHS
One Center Drive
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Bethesda, MD 20892
(b) (6) (BLDG. 1)
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------ End of Forwarded Message

From: Rockey, Sally (NIH/OD) [E]
Sent: Mon, 9 Apr 2012 11:33:27 +0000
To: Zuk, Dorit (NIH/OD) [E];Hann, Della (NIH/OD) [E];Ellis, Joe (NIH/OD) [E];Mills, Sherry (NIH/OD) [E];Bulls, Michelle (NIH/OD) [E];Schaffer, Walter (NIH/OD) [E]
Subject: Fwd: New USG Policy for Dual Use Research
Attachments: Memo to ICs re new USG Dual Use policy.pdf, United_States_Government_Policy_for_Oversight_of_DURC_FINAL_version_032812.pdf

Begin forwarded message:

From: "Patterson, Amy (NIH/OD) [E]" <(b) (6)
To: "(b) (6) ((b) (6) < (b) (6)
Cc: "McGarey, Barbara (NIH/OD) [E]" <(b) (6) "Burklow, John (NIH/OD) [E]" <(b) (6) "Rockey, Sally (NIH/OD) [E]" <(b) (6) "White, Pat (NIH/OD) [E]" <(b) (6) "Barros, Colleen (NIH/OD) [E]" <(b) (6) "Shapiro, Neil (NIH/OD) [E]" <(b) (6) "Hudson, Kathy (NIH/OD) [E]" <(b) (6) "Collins, Francis (NIH/OD) [E]" <(b) (6) "Gottesman, Michael (NIH/OD) [E]" <(b) (6)v>, "Anderson, James (NIH/OD) [E]" <(b) (6) "Tabak, Lawrence (NIH/OD) [E]" <(b) (6) "Groesch, Mary (NIH/OD) [E]" <(b) (6)>, "Shipp, Allan (NIH/OD) [E]" <(b) (6) "Finnegan, Sean (NIH/OD) [C]" <(b) (6)
Subject: New USG Policy for Dual Use Research

Dear Colleagues,

As Francis and Tony mentioned this at this week's IC Director's meeting, the White House has just issued the United States Government Policy for Oversight of Life Sciences Dual Use Research of Concern. Please find attached both the new policy as well a memo regarding how we will coordinate NIH's implementation of the reporting requirements mandated under this policy. Our office will work closely with your staff to answer any questions.

Regards,

Amy

Amy P. Patterson, M.D.
Associate Director for Science Policy
Office of the Director
National Institutes of Health
telephone: (b) (6)
facsimile: (b) (6)
e-mail: (b) (6)

TO: IC Directors

FROM: Associate Director for Science Policy

SUBJECT: Implementation of New USG Policy for Oversight of Life Sciences Dual Use Research of Concern

As many of you are aware, on March 29, 2012, White House National Security Staff issued a new policy for oversight of life sciences dual use research of concern (attached). The Policy establishes regular review of federally-funded or -conducted research with certain high-consequence pathogens and toxins for its potential to be dual use research of concern (DURC) in order to minimize the risk of misuse of the knowledge, information, products, or technologies provided by such research. For the purpose of the Policy, DURC is life sciences research that, based on current understanding, can be reasonably anticipated to provide knowledge, information, products, or technologies that could be directly misapplied to pose a significant threat with broad potential consequences to public health and safety, agricultural crops and other plants, animals, the environment, materiel, or national security.

As an agency that conducts and funds life sciences research, NIH is required to:

1. Conduct a review ("Inventory") to identify all current or proposed, unclassified intramural or extramural, life sciences research grants and contracts that fall within the scope of Section III. This review will include, at a minimum, initial proposals and any progress reports.
2. Determine which, if any, of the projects identified in Section (IV.1.a) meet the definition of DURC in Section (II.1) of this document.
3. Assess the risks and benefits of such projects, including how research methodologies may generate risks and/or whether open access to the knowledge, information, products, or technologies generates risk.
4. Based on the risk assessment, in collaboration with the institution or researcher, develop a risk mitigation plan to apply any necessary and appropriate risk mitigation measures.
    - For DURC that is being considered for funding, departments and agencies will assess whether to incorporate risk mitigation measures into the terms of award of the grant, contract, or agreement.
    - For currently funded DURC, funding departments and agencies will consider modifying the grant, contract, or agreement to incorporate risk mitigation measures. If such modifications are not possible or desirable, departments and agencies will seek voluntary implementation of mitigation measures by the institution.
    - Possible elements of a risk mitigation plan are discussed in the Policy.

Certain aspects of the inventory must be reported to the Assistant to the President for Homeland Security and Counterterrorism within 60 days of issuance of this Policy (i.e., end of May).

The OD/Office of Science Policy (OSP) will be the NIH lead for the initial implementation of the Policy. OSP will coordinate the inventory exercise required under the Policy, including providing guidance to ICs on the Policy, identification of DURC and the risks associated with it, and the development of risk mitigation plans.

Toward this end, please indicate to OSP (Sean Finnegan, (b) (6) by April 13 whether your IC funds and/or conducts research involving any of the 15 agents or toxins listed in Section III.1 of the attached Policy. If so, please also identify a POC for your IC for implementation of the Policy. The POC should be someone who is sufficiently senior to have ready access to IC leadership to discuss the policy implications of the inventory and risk mitigation plans. *Please note that all ICs need to respond to OSP, even if your IC does not conduct or plan to conduct such research.*

OSP will convene the POCs in the course of the next 1-2 weeks to discuss the Policy and the next steps. Please do not hesitate to contact me if you have any questions about the Policy or its implementation.

Amy P. Patterson, M.D.

Attachment:
United States Government Policy for Oversight of
Life Sciences Dual Use Research of Concern

United States Government Policy for Oversight of
Life Sciences Dual Use Research of Concern

Section I: Purpose and Principles

1) The purpose of this Policy is to establish regular review of United States Government funded or conducted research with certain high-consequence pathogens and toxins for its potential to be dual use research of concern (DURC) in order to: (a) mitigate risks where appropriate; and (b) collect information needed to inform the development of an updated policy, as needed, for the oversight of DURC. The fundamental aim of this oversight is to preserve the benefits of life sciences research while minimizing the risk of misuse of the knowledge, information, products, or technologies provided by such research.
2) This Policy complements existing United States Government regulations and policies governing the possession and handling of pathogens and toxins. Currently, the Select Agent Regulations ensure appropriate oversight of biosafety and biosecurity of the possession and handling of pathogens and toxins that have the potential to pose a severe threat to human, animal, or plant health, or to animal and plant products. In addition, recommendations from Federal advisory bodies such as the National Science Advisory Board for Biosecurity (NSABB) have helped inform United States Government policies for identifying and managing DURC. This Policy will be updated, as needed, following domestic dialogue, engagement with our international partners, and input from interested communities including scientists, national security officials, and global health specialists.
3) The following principles guide implementation of this Policy:
    a) Life sciences research is essential to the scientific advances that underpin improvements in the health and safety of the public, agricultural crops and other plants, animals, the environment, materiel, and national security. Despite its value and benefits, some research may provide knowledge, information, products, or technologies that could be misused for harmful purposes.
    b) Accordingly, some degree of Federal and institutional oversight of DURC is critical to reducing the risks to public health and safety, agricultural crops and other plants, animals, the environment, materiel, and national security.
    c) Measures that mitigate the risks of DURC should be applied, where appropriate, in a manner that minimizes, to the extent possible, adverse impact on legitimate research, is commensurate with the risk, includes flexible approaches that leverage existing processes, and endeavors to preserve and foster the benefits of research.
    d) The United States Government will facilitate the sharing of the results and products of life sciences research conducted or funded by United States Government agencies, and honor United States Government obligations within relevant international frameworks and agreements, while taking into account United States' national security interests.
    e) In executing this Policy, the United States Government will abide by and enforce all relevant Presidential Directives and Executive Orders, all applicable laws and regulations, and support the implementation of legally binding treaties, commitments, and United Nations Security Council resolutions prohibiting the development and use of biological agents as weapons.

Section II: Definitions

1) For the purpose of this Policy, DURC is life sciences research that, based on current understanding, can be reasonably anticipated to provide knowledge, information, products, or technologies that could be directly misapplied to pose a significant threat with broad potential consequences to public

health and safety, agricultural crops and other plants, animals, the environment, materiel, or national security[1].

2) "Life sciences" pertains to living organisms (e.g., microbes, human beings, animals, and plants) and their products, including all disciplines and methodologies of biology such as aerobiology, agricultural science, plant science, animal science, bioinformatics, genomics, proteomics, synthetic biology, environmental science, public health, modeling, engineering of living systems, and all applications of the biological sciences. The term is meant to encompass the diverse approaches for understanding life at the level of ecosystems, organisms, organs, tissues, cells, and molecules.
3) Extramural research is that which is funded by a department or agency under a grant, contract, cooperative agreement, or other agreement and not conducted directly by the department or agency.
4) Intramural research is that which is directly conducted by a department or agency.

Section III: Scope

Under this Policy, review will focus on research that involves one or more of the agents or toxins listed in Section (III.1) below, which pose the greatest risk of deliberate misuse with most significant potential for mass casualties or devastating effects to the economy, critical infrastructure, or public confidence, and produces, aims to produce, or is reasonably anticipated to produce one or more of the effects listed in Section (III.2) below:

1) Agents and toxins[2]:
   a) Avian influenza virus (highly pathogenic)
   b) *Bacillus anthracis*
   c) Botulinum neurotoxin
   d) *Burkholderia mallei*
   e) *Burkholderia pseudomallei*
   f) Ebola virus
   g) Foot-and-mouth disease virus
   h) *Francisella tularensis*
   i) Marburg virus
   j) Reconstructed 1918 Influenza virus
   k) Rinderpest virus
   l) Toxin-producing strains of *Clostridium botulinum*
   m) Variola major virus
   n) Variola minor virus
   o) *Yersinia pestis*
2) Categories of experiments:
   a) Enhances the harmful consequences of the agent or toxin;
   b) Disrupts immunity or the effectiveness of an immunization against the agent or toxin without clinical or agricultural justification;
   c) Confers to the agent or toxin resistance to clinically or agriculturally useful prophylactic or therapeutic interventions against that agent or toxin or facilitates their ability to evade detection methodologies;
   d) Increases the stability, transmissibility, or the ability to disseminate the agent or toxin;
   e) Alters the host range or tropism of the agent or toxin;

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[1] This definition of DURC is derived from the NSABB definition, but is modified for purposes of this Policy.

[2] These agents and toxins are regulated by the Select Agent Program under Federal Law (7 C.F.R. part 331, 9 C.F.R. part 121, and 42 C.F.R. part 73), and have the potential to pose a severe threat to human, animal, or plant health, or to animal and plant products.

f) Enhances the susceptibility of a host population to the agent or toxin; or
g) Generates or reconstitutes an eradicated or extinct agent or toxin listed in Section (III.1) above.

Section IV: Department and Agency Responsibilities

1) Federal departments and agencies that conduct or fund life sciences research should implement the following actions:
   a) Conduct a review to identify all current or proposed, unclassified intramural or extramural, life sciences research projects that fall within the scope of Section III. This review will include, at a minimum, initial proposals and any progress reports.
   b) Determine which, if any, of the projects identified in Section (IV.1.a) meet the definition of DURC in Section (II.1) of this document.
   c) Assess the risks and benefits of such projects, including how research methodologies may generate risks and/or whether open access to the knowledge, information, products, or technologies generates risk.
   d) Based on the risk assessment, in collaboration with the institution or researcher, develop a risk mitigation plan to apply any necessary and appropriate risk mitigation measures. In addition:
      i) For DURC that is proposed and not yet funded, departments and agencies will assess whether to incorporate risk mitigation measures in the grant, contract, or agreement.
      ii) For currently funded DURC, funding departments and agencies will consider modifying the grant, contract, or agreement to incorporate risk mitigation measures. If such modifications are not possible or desirable, departments and agencies will seek voluntary implementation of mitigation measures by the institution.
   e) A risk mitigation plan may include, but not be limited to, the following risk mitigation measures:
      i) Modifying the design or conduct of the research.
      ii) Applying specific or enhanced biosecurity or biosafety measures.
      iii) Evaluating existing evidence of medical countermeasures (MCM) efficacy, or conducting experiments to determine MCM efficacy against agents or toxins resulting from DURC, and where effective MCM exist, including that information in publications.
      iv) Referring the institution to available DURC educational tools such as: http://oba.od.nih.gov/biosecurity/biosecurity.html
      v) Regularly reviewing, at the institutional level, emerging research findings for additional DURC.
      vi) Requesting that institutions notify funding departments or agencies if additional DURC is identified, and propose modifications to the risk mitigation plan, as needed.
      vii) Determining the venue and mode of communication (addressing content, timing, and possibly the extent of distribution of the information) to communicate the research responsibly.
      viii) Reviewing annual progress reports from Principal Investigators to determine if DURC results have been generated, and if so, flagging them for institutional attention and applying potential mitigation measures as described above, as necessary.
      ix) If the risks posed by the research cannot be adequately mitigated with the measures above, Federal departments and agencies will determine whether it is appropriate to:
         (a) Request voluntary redaction of the research publications or communications [3];
         (b) Classify the research:
            (i) In accordance with National Security Decision Directive/NSDD-189, departments and agencies will make classification determinations within

[3] Actions taken to restrict the publication of technology may have implications under export control laws and regulations (e.g., 15 CFR parts 730-774 and 22 CFR parts 120-130).

the scope of their classification authorities and appropriate classification guidelines or may consult with other departments and agencies to make these determinations.

(ii) Departments and agencies may consider whether to refer classified research to another department or agency for funding.

(c) Not provide or terminate research funding.

2) Federal departments and agencies are requested to report the following to the Assistant to the President for Homeland Security and Counterterrorism:
   a) Within 60 days of issuance of this Policy, the following results of the review conducted in response to Section (IV.1.a):
      i) Aggregate number of current and proposed unclassified, intramural, and extramural research projects identified that include work with one or more of the agents and toxins in Section (III.1).
      ii) Aggregate number of current and proposed unclassified, intramural, and extramural research projects that include work with one or more of the agents and toxins in Section (III.1) and produces, aims to produce, or are reasonably anticipated to produce one or more of the effects listed in Section (III.2).
   b) Within 90 days of issuance of this Policy, the following results of the review conducted in response to Sections (IV.1. b. c. and d):
      i) Number of unclassified current and proposed DURC projects.[4]
      ii) Number of current projects identified as DURC through initial proposals versus progress reports.[5]
      iii) Summary of risks, mitigation measures already in place that address those risks, any additional mitigation measures that have been proposed or implemented, and number of projects to which each mitigation measure would be applied.
3) Following completion of the reporting requirements in Section (IV.2), Federal departments and agencies are requested to submit periodic reports on items in Section (IV.2.a. and b) biannually.
4) Federal departments and agencies should implement Section IV in accordance with their relevant and applicable authorities, regulations, and statutes.
5) For additional guidance on how to conduct the risk assessment identified in Section (IV. 1.c), departments and agencies may refer to the "Proposed Framework for the Oversight of Dual Use Life Sciences Research: Strategies for Minimizing the Potential Misuse of Research Information," which identifies useful assessment tools and is available at: http://oba.od.nih.gov/biosecurity/biosecurity_documents.html .

Section V: Consultation

As necessary and appropriate, the United States Government will continue to consult with the NSABB (in compliance with provisions of the Federal Advisory Committee Act) or convene the Countering Biological Threats Interagency Policy Committee for guidance on matters relating to the review and conduct of DURC and the mitigation of DURC risks.

[4,5] Report the number of projects by agent and/or toxin plus the category of experiment.

TO: IC Directors

FROM: Associate Director for Science Policy

SUBJECT: Implementation of New USG Policy for Oversight of Life Sciences Dual Use Research of Concern

As many of you are aware, on March 29, 2012, White House National Security Staff issued a new policy for oversight of life sciences dual use research of concern (attached). The Policy establishes regular review of federally-funded or -conducted research with certain high-consequence pathogens and toxins for its potential to be dual use research of concern (DURC) in order to minimize the risk of misuse of the knowledge, information, products, or technologies provided by such research. For the purpose of the Policy, DURC is life sciences research that, based on current understanding, can be reasonably anticipated to provide knowledge, information, products, or technologies that could be directly misapplied to pose a significant threat with broad potential consequences to public health and safety, agricultural crops and other plants, animals, the environment, materiel, or national security.

As an agency that conducts and funds life sciences research, NIH is required to:

1. Conduct a review ("Inventory") to identify all current or proposed, unclassified intramural or extramural, life sciences research grants and contracts that fall within the scope of Section III. This review will include, at a minimum, initial proposals and any progress reports.
2. Determine which, if any, of the projects identified in Section (IV.1.a) meet the definition of DURC in Section (II.1) of this document.
3. Assess the risks and benefits of such projects, including how research methodologies may generate risks and/or whether open access to the knowledge, information, products, or technologies generates risk.
4. Based on the risk assessment, in collaboration with the institution or researcher, develop a risk mitigation plan to apply any necessary and appropriate risk mitigation measures.
    - For DURC that is being considered for funding, departments and agencies will assess whether to incorporate risk mitigation measures into the terms of award of the grant, contract, or agreement.
    - For currently funded DURC, funding departments and agencies will consider modifying the grant, contract, or agreement to incorporate risk mitigation measures. If such modifications are not possible or desirable, departments and agencies will seek voluntary implementation of mitigation measures by the institution.
    - Possible elements of a risk mitigation plan are discussed in the Policy.

Certain aspects of the inventory must be reported to the Assistant to the President for Homeland Security and Counterterrorism within 60 days of issuance of this Policy (i.e., end of May).

The OD/Office of Science Policy (OSP) will be the NIH lead for the initial implementation of the Policy. OSP will coordinate the inventory exercise required under the Policy, including providing guidance to ICs on the Policy, identification of DURC and the risks associated with it, and the development of risk mitigation plans.

Toward this end, please indicate to OSP (Sean Finnegan, (b) (6) by April 13 whether your IC funds and/or conducts research involving any of the 15 agents or toxins listed in Section III.1 of the attached Policy. If so, please also identify a POC for your IC for implementation of the Policy. The POC should be someone who is sufficiently senior to have ready access to IC leadership to discuss the policy implications of the inventory and risk mitigation plans. *Please note that all ICs need to respond to OSP, even if your IC does not conduct or plan to conduct such research.*

OSP will convene the POCs in the course of the next 1-2 weeks to discuss the Policy and the next steps. Please do not hesitate to contact me if you have any questions about the Policy or its implementation.

Amy P. Patterson, M.D.

Attachment:
United States Government Policy for Oversight of
Life Sciences Dual Use Research of Concern

United States Government Policy for Oversight of
Life Sciences Dual Use Research of Concern

Section I: Purpose and Principles

1) The purpose of this Policy is to establish regular review of United States Government funded or conducted research with certain high-consequence pathogens and toxins for its potential to be dual use research of concern (DURC) in order to: (a) mitigate risks where appropriate; and (b) collect information needed to inform the development of an updated policy, as needed, for the oversight of DURC. The fundamental aim of this oversight is to preserve the benefits of life sciences research while minimizing the risk of misuse of the knowledge, information, products, or technologies provided by such research.
2) This Policy complements existing United States Government regulations and policies governing the possession and handling of pathogens and toxins. Currently, the Select Agent Regulations ensure appropriate oversight of biosafety and biosecurity of the possession and handling of pathogens and toxins that have the potential to pose a severe threat to human, animal, or plant health, or to animal and plant products. In addition, recommendations from Federal advisory bodies such as the National Science Advisory Board for Biosecurity (NSABB) have helped inform United States Government policies for identifying and managing DURC. This Policy will be updated, as needed, following domestic dialogue, engagement with our international partners, and input from interested communities including scientists, national security officials, and global health specialists.
3) The following principles guide implementation of this Policy:
    a) Life sciences research is essential to the scientific advances that underpin improvements in the health and safety of the public, agricultural crops and other plants, animals, the environment, materiel, and national security. Despite its value and benefits, some research may provide knowledge, information, products, or technologies that could be misused for harmful purposes.
    b) Accordingly, some degree of Federal and institutional oversight of DURC is critical to reducing the risks to public health and safety, agricultural crops and other plants, animals, the environment, materiel, and national security.
    c) Measures that mitigate the risks of DURC should be applied, where appropriate, in a manner that minimizes, to the extent possible, adverse impact on legitimate research, is commensurate with the risk, includes flexible approaches that leverage existing processes, and endeavors to preserve and foster the benefits of research.
    d) The United States Government will facilitate the sharing of the results and products of life sciences research conducted or funded by United States Government agencies, and honor United States Government obligations within relevant international frameworks and agreements, while taking into account United States' national security interests.
    e) In executing this Policy, the United States Government will abide by and enforce all relevant Presidential Directives and Executive Orders, all applicable laws and regulations, and support the implementation of legally binding treaties, commitments, and United Nations Security Council resolutions prohibiting the development and use of biological agents as weapons.

Section II: Definitions

1) For the purpose of this Policy, DURC is life sciences research that, based on current understanding, can be reasonably anticipated to provide knowledge, information, products, or technologies that could be directly misapplied to pose a significant threat with broad potential consequences to public

health and safety, agricultural crops and other plants, animals, the environment, materiel, or national security[1].

2) "Life sciences" pertains to living organisms (e.g., microbes, human beings, animals, and plants) and their products, including all disciplines and methodologies of biology such as aerobiology, agricultural science, plant science, animal science, bioinformatics, genomics, proteomics, synthetic biology, environmental science, public health, modeling, engineering of living systems, and all applications of the biological sciences. The term is meant to encompass the diverse approaches for understanding life at the level of ecosystems, organisms, organs, tissues, cells, and molecules.
3) Extramural research is that which is funded by a department or agency under a grant, contract, cooperative agreement, or other agreement and not conducted directly by the department or agency.
4) Intramural research is that which is directly conducted by a department or agency.

Section III: Scope

Under this Policy, review will focus on research that involves one or more of the agents or toxins listed in Section (III.1) below, which pose the greatest risk of deliberate misuse with most significant potential for mass casualties or devastating effects to the economy, critical infrastructure, or public confidence, and produces, aims to produce, or is reasonably anticipated to produce one or more of the effects listed in Section (III.2) below:

1) Agents and toxins[2]:
   a) Avian influenza virus (highly pathogenic)
   b) *Bacillus anthracis*
   c) Botulinum neurotoxin
   d) *Burkholderia mallei*
   e) *Burkholderia pseudomallei*
   f) Ebola virus
   g) Foot-and-mouth disease virus
   h) *Francisella tularensis*
   i) Marburg virus
   j) Reconstructed 1918 Influenza virus
   k) Rinderpest virus
   l) Toxin-producing strains of *Clostridium botulinum*
   m) Variola major virus
   n) Variola minor virus
   o) *Yersinia pestis*
2) Categories of experiments:
   a) Enhances the harmful consequences of the agent or toxin;
   b) Disrupts immunity or the effectiveness of an immunization against the agent or toxin without clinical or agricultural justification;
   c) Confers to the agent or toxin resistance to clinically or agriculturally useful prophylactic or therapeutic interventions against that agent or toxin or facilitates their ability to evade detection methodologies;
   d) Increases the stability, transmissibility, or the ability to disseminate the agent or toxin;
   e) Alters the host range or tropism of the agent or toxin;

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[1] This definition of DURC is derived from the NSABB definition, but is modified for purposes of this Policy.

[2] These agents and toxins are regulated by the Select Agent Program under Federal Law (7 C.F.R. part 331, 9 C.F.R. part 121, and 42 C.F.R. part 73), and have the potential to pose a severe threat to human, animal, or plant health, or to animal and plant products.

f) Enhances the susceptibility of a host population to the agent or toxin; or
g) Generates or reconstitutes an eradicated or extinct agent or toxin listed in Section (III.1) above.

Section IV: Department and Agency Responsibilities

1) Federal departments and agencies that conduct or fund life sciences research should implement the following actions:
   a) Conduct a review to identify all current or proposed, unclassified intramural or extramural, life sciences research projects that fall within the scope of Section III. This review will include, at a minimum, initial proposals and any progress reports.
   b) Determine which, if any, of the projects identified in Section (IV.1.a) meet the definition of DURC in Section (II.1) of this document.
   c) Assess the risks and benefits of such projects, including how research methodologies may generate risks and/or whether open access to the knowledge, information, products, or technologies generates risk.
   d) Based on the risk assessment, in collaboration with the institution or researcher, develop a risk mitigation plan to apply any necessary and appropriate risk mitigation measures. In addition:
      i) For DURC that is proposed and not yet funded, departments and agencies will assess whether to incorporate risk mitigation measures in the grant, contract, or agreement.
      ii) For currently funded DURC, funding departments and agencies will consider modifying the grant, contract, or agreement to incorporate risk mitigation measures. If such modifications are not possible or desirable, departments and agencies will seek voluntary implementation of mitigation measures by the institution.
   e) A risk mitigation plan may include, but not be limited to, the following risk mitigation measures:
      i) Modifying the design or conduct of the research.
      ii) Applying specific or enhanced biosecurity or biosafety measures.
      iii) Evaluating existing evidence of medical countermeasures (MCM) efficacy, or conducting experiments to determine MCM efficacy against agents or toxins resulting from DURC, and where effective MCM exist, including that information in publications.
      iv) Referring the institution to available DURC educational tools such as: http://oba.od.nih.gov/biosecurity/biosecurity.html
      v) Regularly reviewing, at the institutional level, emerging research findings for additional DURC.
      vi) Requesting that institutions notify funding departments or agencies if additional DURC is identified, and propose modifications to the risk mitigation plan, as needed.
      vii) Determining the venue and mode of communication (addressing content, timing, and possibly the extent of distribution of the information) to communicate the research responsibly.
      viii) Reviewing annual progress reports from Principal Investigators to determine if DURC results have been generated, and if so, flagging them for institutional attention and applying potential mitigation measures as described above, as necessary.
      ix) If the risks posed by the research cannot be adequately mitigated with the measures above, Federal departments and agencies will determine whether it is appropriate to:
         (a) Request voluntary redaction of the research publications or communications [3];
         (b) Classify the research:
            (i) In accordance with National Security Decision Directive/NSDD-189, departments and agencies will make classification determinations within

[3] Actions taken to restrict the publication of technology may have implications under export control laws and regulations (e.g., 15 CFR parts 730-774 and 22 CFR parts 120-130).

the scope of their classification authorities and appropriate classification guidelines or may consult with other departments and agencies to make these determinations.

(ii) Departments and agencies may consider whether to refer classified research to another department or agency for funding.

(c) Not provide or terminate research funding.

2) Federal departments and agencies are requested to report the following to the Assistant to the President for Homeland Security and Counterterrorism:
   a) Within 60 days of issuance of this Policy, the following results of the review conducted in response to Section (IV.1.a):
      i) Aggregate number of current and proposed unclassified, intramural, and extramural research projects identified that include work with one or more of the agents and toxins in Section (III.1).
      ii) Aggregate number of current and proposed unclassified, intramural, and extramural research projects that include work with one or more of the agents and toxins in Section (III.1) and produces, aims to produce, or are reasonably anticipated to produce one or more of the effects listed in Section (III.2).
   b) Within 90 days of issuance of this Policy, the following results of the review conducted in response to Sections (IV.1. b. c. and d):
      i) Number of unclassified current and proposed DURC projects.[4]
      ii) Number of current projects identified as DURC through initial proposals versus progress reports.[5]
      iii) Summary of risks, mitigation measures already in place that address those risks, any additional mitigation measures that have been proposed or implemented, and number of projects to which each mitigation measure would be applied.
3) Following completion of the reporting requirements in Section (IV.2), Federal departments and agencies are requested to submit periodic reports on items in Section (IV.2.a. and b) biannually.
4) Federal departments and agencies should implement Section IV in accordance with their relevant and applicable authorities, regulations, and statutes.
5) For additional guidance on how to conduct the risk assessment identified in Section (IV. 1.c), departments and agencies may refer to the "Proposed Framework for the Oversight of Dual Use Life Sciences Research: Strategies for Minimizing the Potential Misuse of Research Information," which identifies useful assessment tools and is available at: http://oba.od.nih.gov/biosecurity/biosecurity_documents.html .

Section V: Consultation

As necessary and appropriate, the United States Government will continue to consult with the NSABB (in compliance with provisions of the Federal Advisory Committee Act) or convene the Countering Biological Threats Interagency Policy Committee for guidance on matters relating to the review and conduct of DURC and the mitigation of DURC risks.

[4,5] Report the number of projects by agent and/or toxin plus the category of experiment.

ADMIN_PHS_ORG_CODE	APPL_TYPE_CODE	GRANT_NUM	FY	DESCRIP	TRANS_LAST_NAME	INTCLPRV_GRANT_PI_PI_LAST_NAME || INTCLPRV_GRANT_PI_PI_FIRST_NAME	ORG_NAME	GIR_CODE	GIR_EXPLAN_TEXT	HUMAN_CLASS_CODE	[illegible]	PROJECT_PERIOD_START_DATE	PROJECT_PERIOD_END_DATE	BUDGET_START_DATE	PROJECT_PERIOD_END_DATE	AWD_NOTICE_ISSUED_DATE
AA	1	[illegible]	2010	Are DHHS/USDA Select Agents or Toxins used in this project? If YES, indicate which...	[illegible]	[illegible]	NATIONAL DEVELOPMENT & RES INSTITUTES	Y		[illegible]	D	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
AA	[illegible]	[illegible]	[illegible]	Are DHHS/USDA Select Agents or Toxins used in this project? If YES, indicate which...	[illegible]	[illegible]	[illegible]	Y	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
AA	1	[illegible]	2009	Are DHHS/USDA Select Agents or Toxins used in this project? If YES, indicate which...	[illegible]	[illegible]	UNIVERSITY OF CALIFORNIA SAN DIEGO	Y		[illegible]	D	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
AA	[illegible]	[illegible]	[illegible]	Are DHHS/USDA Select Agents or Toxins used in this project? If YES, indicate which...	[illegible]	[illegible]	[illegible]	Y	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
AA	1	[illegible]	2010	Are DHHS/USDA Select Agents or Toxins used in this project? If YES, indicate which...	[illegible]	[illegible]	CHILDREN'S HOSPITAL OF PHILADELPHIA	Y	[illegible]	[illegible]	D	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
[illegible]	[illegible]	[illegible]	[illegible]	Are DHHS/USDA Select Agents or Toxins used in this project? If YES, indicate which...	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]

From: Bader, Farah (NIH/FIC) [C]
Sent: Thu, 3 May 2012 17:02:33 -0400
To: Sina, Barbara (NIH/FIC) [E];Jessup, Christine (NIH/FIC) [E];Bridbord, Ken (NIH/FIC) [E]
Subject: NIH DURC policy
Attachments: NIH DURC Inventory.rtf

Dear all,

Ken requested that we have representation on the NIH DURC Inventory committee and recommended that both of you be involved. We are required to have FIC POCs regardless of whether we have projects with dual use. Please see attached document for details for the next meetings.

Kind Regards,

Farah Nikhath Bader, M.P.H
Public Health Analyst
Contractor
Division of International Training & Research (DITR)
Fogarty International Center (FIC)
National Institute of Health (NIH)
31 Center Drive
Building 31, Room B2C39
Bethesda, Maryland 20892
Ph: (b) (6)
E-mail: (b) (6)

Subject:	NIH DURC Inventory
Location:	1-877-919-1590; pass: 414701#
Start:	Wed 5/9/2012 1:00 PM
End:	Wed 5/9/2012 3:00 PM
Show Time As:	Tentative
Recurrence:	(none)
Meeting Status:	Not yet responded
Organizer:	Patterson, Amy (NIH/OD) [E]
Required Attendees:	Eichacker, Peter (NIH/CC/CCMD) [E]; Nakamura, Richard (NIH/CSR) [E]; Bridbord, Ken (NIH/FIC) [E]; Goldrosen, Martin (NIH/NCCAM) [E]; Gaston, Marilyn (NIH/NCI) [E]; Briggs, Josephine (NIH/NCCAM) [E]; Fisher, Richard (NIH/NEI) [E]; Scholes, Derek (NIH/NHGRI) [E]; Roth, Carl (NIH/NHLBI) [E]; Reed, Kathie (NIH/NIA) [E]; Dixon, Dennis M. (NIH/NIAID) [E]; Moen, Laura (NIH/NIAMS) [E]; Demsey, Anthony (NIH/NIBIB) [E]; Rowe, Mona (NIH/NICHD) [E]; Weiss, Susan (NIH/NIDA) [E]; Cyr, Janet (NIH/NIDCD) [E]; Somerman, Martha (NIH/NIDCR) [E]; Farishian, Richard (NIH/NIDDK) [E]; Schrader, Bill (NIH/NIEHS) [E]; Mastin, Pat (NIH/NIEHS) [E]; Blome, Juliana (NIH/NIGMS) [E]; Bertuzzi, Stefano (NIH/NIMH) [E]; Sy, Francisco (NIH/NIMHD) [E]; Jett, David (NIH/NINDS) [E]; Grason, John (NIH/NINR) [E]; Humphreys, Betsy (NIH/NLM) [E]; Weis, Brenda (NIH/OD) [E]; Grieder, Franziska (NIH/OD) [E]

USG interim DURO policy worksh...

Dear Colleagues:

In order to fulfill the agency's responsibilities under the New USG Policy for Oversight of Life Sciences Dual Use Research of Concern (DURC), the Office of Science Policy will host a tele-workshop for all IC Point-of-Contacts (POC) on Wednesday, May 9, 2012, 1:00 – 3:00 pm. This will be the first of two teleconferences in advance of the 60-day deadline (i.e., May 27) for the NIH to submit its inventory of "all current or proposed, unclassified intramural or extramural, life sciences research grants and contracts that fall within the scope" of the USG policy.

POCs from *all* IC are asked to participate in these workshops. Although most of the Institutes responded to last month's initial survey that their organization was not currently sponsoring DURC projects, the new policy stipulates that reporting of dual-use research falling under Sections III and IV occur every six months. Therefore, we encourage POCs from across NIH be informed on the requirements of the inventory should future projects of DURC appear in their extramural and/or intramural portfolios. ICs may elect to have two POCs participate in the discussions (i.e., one assigned to intramural review, the other to extramural).

Expected outcomes for next week's discussion include:

- To develop a common understanding among the NIH ICs regarding how to identify research projects that fall within the scope of the draft USG interim policy for oversight of dual use research of concern
- How to identify DURC
- Challenges and lessons learned from Depts/Agencies inventories, discussion of specific cases
- Keeping track of results and reporting aggregate data
- Development of menu of risk mitigation strategies
- Communicating with researchers and research institutions
- How to address the issue in funding announcements

See the attached slide deck for an overview of Wednesday's topics; the agenda for the workshop can be found on slide #3.

Please contact me if you have any questions.

Sincerely,

Sean J. Finnegan
Assistant to Amy Patterson, M.D.
Office of Science Policy
Office of the Director
National Institutes of Health
Rockledge 1, Room 750
6705 Rockledge Drive
Bethesda, MD 20892

Draft FAQs
Implementation of the Inventory and Reporting Requirements
of the USG Policy for Oversight of Life Sciences DURC

Questions involving the scope of the oversight.

Q1. The first criterion for determining whether research is subject to DURC oversight is if the research involves one of the 15 listed agents or toxins, which are all Select Agents. Botulinum neurotoxin is listed, and it is not regulated as a Select Agent if the amount under the control of a PI does not exceed at any time 0.5 mg. Is research using quantities of Botulinum neurotoxin that are not subject to regulation by the Select Agent Rule also exempt from the DURC oversight policy?

A1: No. Any research involving Botulinum toxin should be considered for its potential to result in any of the 7 listed effects. The intent of the DURC policy is different from, albeit complementary to, that of the Select Agent Rule. The focus of the DURC policy is information, technologies and other products of research that could be misused for harmful purposes. Research on botulinum toxin, for example, could potentially yield information that would have dual use potential, regardless of the amount of toxin used in the experiment. Therefore, there is no exemption under the DURC oversight policy for small quantities of any toxin on the list.

Q2. Does research that involves an attenuated version of one of the microorganisms listed in this Policy still need to be considered for its dual use research potential?

A2: No. The oversight Policy applies to microorganisms that are subject to the Select Agent Rule. Therefore, research using an attenuated strain that is not subject to the Select Agent Rule should not be included in this DURC inventory.

Q3. The oversight Policy applies to research that "involves" one of the listed agents or toxins. Does the Policy apply to research utilizing genes from any of the microorganisms or *in silico* experiments (e.g. modeling, bioinformatics) involving any of the listed agents or toxins?

A3: No. The oversight Policy applies to microorganisms that are subject to the Select Agent Rule. Experiments utilizing genes from any of the microorganisms, or *in silico* experiments involving any of the agents or toxins are not to be considered at this time.

Q4. The Policy requires departments and agencies to identify "research projects" that meet the listed criteria and may be considered DURC. What is being counted and reported as a research project?

A4. The departments and agencies are to identify and report the number of grants and contracts that meet the requested criteria. It is understood that there may be sub-projects within a given grant or contract.

Q5. The policy requires the reporting of projects that are identified as DURC during the project's "initial proposal" stage? What is meant by "initial proposal"?

A5. Initial proposals are research applications that have undergone scientific peer review and are intended to be funded.

Questions involving the identification, reporting and oversight of research covered by this Policy

Q6. Are there any pre-existing data-searching mechanisms that may assist in identifying projects that fall within the scope of the USG policy for oversight of DURC?

A6. Yes, through the use of key words, IMPACT2 IMPAC II or NIH RePORTer can be used as the first pass at identifying projects that fall within the scope of the USG policy; however, both have limitations, e.g., lack of inclusion of P51 grants, including only funded research and including only publicly available grant information. Going forward, grants could be coded when entered into a system such as IMPACT2 IMPAC II or NIH RePORTer, to later allow for the future search of certain key terms. NIAID has a unique system where projects are coded for the listed agents and toxins before they are deposited into their database. Such a system may be useful for other ICs in the future. In the meantime, existing databases of active and pending awards can be searched for the relevant agents and toxins.

Q7. How does reporting work for research that is funded by multiple Federal agencies? Should each funding agency report the work?

A7: No. If each agency were to report the same research, there would be double counting that would skew the data. In cases of multiple federal funding agencies, the primary awarding entity is responsible for reporting projects that are co-funded. However, all institutes, centers, departments, or agencies that fund research involving any of the 15 agents or toxins should list that grant or contract in Tab 1 of the inventory spreadsheet and fill out the appropriate columns regarding Project Funding. In these instances, co-funding entities should communicate to confirm which funder is responsible for fulfilling the reporting requirements. However, if NIH is one of the funding agencies, the NIH would be willing to report that research on behalf of the other agency or agencies, after appropriate consultation.

Q8. How should risk mitigation strategies be developed for DURC that is funded by multiple Federal agencies?

A8: Departments and agencies that are co-funding DURC should work together to develop risk mitigation strategies to ensure consistent, harmonized oversight of DURC. It would also be helpful to designate a lead agency for reporting on the research. Since it may not be evident that other funding agencies are involved, Program Officers from a funding agency that has identified research as needing DURC oversight should check with the research institution whether any other federal agencies are funding the research.

Q9. What should be provided in the abstract section on Tab 1 of the DURC inventory spreadsheet?

A9. A link to the abstract provided in the grant would be appropriate here. It is not necessary to copy and paste the entire abstract. This information is for internal use only and is being collected to provide background on the scope of the research, as it may not be evident in the title of the project alone.

Q10. Should agency staff contact Principal Investigators to report that their proposed or ongoing research has been determined to be DURC?

A10. For interagency discussion

Questions involving the 7 categories of experiments/potential effects

Q11. If a project is identified that includes experiments that result in (or are likely to result in) any of the listed 7 effects, is that project automatically considered DURC?

A11. No, a project may result in one or more of the 7 listed effects and still not be considered DURC. Projects that are likely to result in the 7 listed effects must then be considered for whether they meet the definition of DURC (i.e. – "life sciences research that, based on current understanding, can be reasonably anticipated to provide knowledge, information, products, or technologies that could be directly misapplied to pose a significant threat with broad potential consequences to public health and safety, agricultural crops and other plants, animals, the environment, materiel, or national security.")

Q12. In the first category of experiment/potential effect, what is meant by "enhance the harmful consequences" of an agent or toxin?

A12. "Harmful consequences" refers to the ability of a biological agent or toxin to critically alter normal biological functions, inflict damage on public health resources, materiel, and public safety. This would include augmenting properties such as virulence, infectivity, stability, transmissibility, or the ability of the biological agent or toxin to be disseminated.

Q13. The first effect is "enhances the harmful consequences of the agent or toxin." If an experiment starts with an attenuated strain of one of the listed agents and is anticipated to generate a strain that is more pathogenic than the starting strain but less pathogenic than the wild type strain, is that considered a "hit" for this effect?

A13: No. Experiments that generate strains that are less pathogenic than, or equal in pathogenicity to the wild type are not considered to enhance the harmful consequences of an agent or toxin. It is important to note, however, that although an experiment may not fit this particular effect, it still needs to be evaluated for the applicability of the other six effects listed for criterion 2.

Q14. In the second category of experiment/potential effect, what is meant by "disrupt immunity or the effectiveness of an immunization?"

A14. Immunity encompasses all aspects of host immunity (e.g., active, adaptive, adoptive, passive, innate, and immune modulators). Immunization refers to the active or passive induction of immunity through inoculation (e.g., natural inoculation or vaccination) with an immunizing agent or with antibodies; this includes antitoxins and toxoids. For instance, rendering an immunization ineffective could make a host population vulnerable to the pathogenic consequences of a microbe from which the host population would have otherwise been protected or for which protection, such as a vaccine, was available.

Q15. The second listed effect is "disrupts immunity or the effectiveness of an immunization against the agent or toxin without clinical and/or agriculture justification." Does this apply to experimental vaccines, or only licensed or approved vaccines?

A15: If the research aims to test a vaccine against various challenges and reveals some vulnerabilities, with little to no implications for existing, licensed vaccines, the research would not be considered to meet criterion 2. However, if the experimental vaccine falls into a class of extant, licensed vaccines, then the disruption of effectiveness could have important implications for the entire class of vaccines. In that case, the work should be considered as meeting at least one effect in the second criterion and should therefore be evaluated for the applicability of the third criterion (DURC potential).

Q16. In the third category of experiment/potential effect, what is meant by "clinically or agriculturally useful prophylactic or therapeutic interventions?"

A16. This includes first- or second-line prevention and treatment measures or alternative therapeutics used with special populations (e.g., pregnant women and pediatric patients) in the form of vaccines, antibiotics, antivirals, antiparasitics, antibodies, herbicides, fungicides, algaecides, insecticides, etc. "Agriculture" encompasses all methods of production and management of livestock, crops, vegetation, and soil. Therefore, useful prophylaxes and therapeutics would include herbicides, fungicides, algaecides, insecticides, rodenticides, etc. The main concept is that anything that might compromise the ability to detect, treat, or prevent disease or illness (human or agricultural) caused by biological agents or toxins could result in a significant public health and/or economic burden.

Q17. What is meant by the fourth category of experiment/potential effect?

A17. The rationale for this category is that increasing an agent's stability, transmissibility, or ability to disseminate could facilitate the purposeful malevolent use of a biological agent or toxin and increase the rate or ease by which an agent could spread, impeding attempts to contain disease outbreak. Stability is the ability of a biological agent to remain viable when exposed to various environmental factors, including temperature, relative humidity, atmospheric pollution, and sunlight. Stability also includes persistence in a host. Transmissibility is the ease with which an agent spreads from host to host or from vector to host (e.g., via arthropod vectors). Dissemination is the process by which infectious diseases or toxins are dispersed. The same routes of entry pertinent to the natural spread of diseases are also relevant when their etiologic agents are delivered intentionally (e.g., inhalation of biological agent disseminated as an aerosol or ingestion of a biological agent disseminated through a water supply).

Q18. In the fifth category of experiment/listed effect, what is meant by altering the "host range or tropism?"

A18. Host range is the number of different species or populations that can become infected by a biological agent, causing disease in the host or allowing the host to become a carrier. Tropism is the specificity of a biological agent or toxin for a particular host tissue or cell.

Q19. What is meant by the sixth category of experiment/potential effect?

A19. Information about rendering host populations more susceptible to the pathogenic consequences of an agent or toxin could be used to compromise immune responses and enable the acquisition and spread of disease on an epidemic scale. Of note, the distinction should be made that research applicable to this category would not alter the susceptibility of an individual host or research cohort but rather that of a host population. A host population is a collection of organisms that constitutes a specific group or occurs in a specified habitat. In the context of the criteria, this phrase implies that the misapplication of the knowledge, products, or technologies derived from the research has the potential to broadly impact a population of host organisms.

Q20. What types of agents are being referred to in the seventh category of experiment/potential effect?

A20. This category refers to eradicated and novel agents. An eradicated agent is a biological agent that has been exterminated through surveillance and containment resulting in the permanent reduction to zero of the worldwide incidence in the transmission of the agent and the infection/disease it causes; intervention measures are no longer needed. Eradicated agents are thought to no longer exist in circulation in plants, animals, or the environment. A novel agent is one that has not existed previously and is considered unique based on biological or other properties and traits (e.g., genotype and phenotype).

<u>Questions involving determining whether research meets the definition of DURC</u>

Q21. DURC oversight is required for research that meets three criteria—i.e., it involves a listed agent, produces one of the listed effects, and meets the definition of DURC. For the last step, determining whether research meets the definition of DURC, what if the research generates information that could be misapplied only if it was combined with additional extant information, e.g., information that is already publicly available? Is this DURC?

A21: For interagency discussion

Q22. Is research considered DURC if only in a successive phase of funding it will likely generate information that could be misused for harmful purposes?

A22: For interagency discussion

Q23. What criteria should be used to identify if something is "reasonably anticipated" to be DURC?

A23. The identification of DURC is ultimately a judgment call, and the decision should be as informed as possible. The knowledge and expertise from IC program officers and scientific staff can be used to evaluate the standards in the field and if the proposed research could meet this requirement as well as the other components that are required for the determination of DURC.

FIC DURC Inventory Process

Process of identifying FIC projects for DURC Inventory:

Sent to DIEPS for identification of relevant DIEPS projects (May 15). Identified relevant DITR projects as follows:

1. **Ran QVR search** using keyword search of Abstract, Summary Statement or Title with 15 Select Agents and Toxins as search terms combined by "OR" Boolean. Searched Awarded and Pending Council for FY 2011 and FY 2012 and with FIC as Primary.

   ...IC's = TW Primary/Admin Projects Only ... Project Status = AWARDED, PENDING COUNCIL ...Fy's = 2012, 2011... Abstract/Summ Stmt/Title/ for: Avian influenza//Bacillus anthracis//anthrax//Botulinum neurotoxin//Burkholderia mallei //Burkholderia pseudomallei//Ebola//Foot-and-mouth//Francisella tularensis//Marburg//1918 Influenza//influenza// Rinderpest//Clostridium botulinum//Variola Variola minor//Yersinia pestis//yersinia//pestis//clostridium//bacillus//botulinum//burkholderia//tularensis//variola, combined with 'Or' .....Extramural Grants, Intramurals, Contracts, include Extramural Grant Subprojects

2. Extramural **infectious disease program officers reviewed** the resulting project list (21 projects), and
   a. **omitted projects that were not relevant** [some "pending council" captured projects that were not discussed in review so they are not being considered for funding; the search terms identified some projects where part of a select agent name was captured, but the project was not related to the select agent/toxin itself (i.e., the word bacillus spp. or clostridium spp.).
   b. **omitted supplements** if parent award was represented
   c. **added projects** based on personal knowledge of activities in parent award or supplements (3 projects added)

      18 projects omitted; 3 retained; 3 added

- The number of grants or contracts involving any of the 15 agents/toxins.
  6
- The number of grants or contracts involving any of the 15 agents/toxins AND those that are likely to involve any of the 7 effects/categories of experiments.
  0
- A brief overview of your IC's approach to collecting the DURC inventory.
  Above
- Any challenges or outstanding issues encountered during this inventory process.
  Below

Issues and concerns:

- FIC supports a number of research training projects (D43s) that are linked to research grants in other ICs. Although the training award may not be DURC, the related research grant may be but would not be readily identified by FIC. How should research training grants and career development awards be handled in this process? Both policy and FAQs refer to "research projects".

- Need clarification on modeling studies. Last week's discussion led us to believe that modeling studies related to one of the agents/toxins should be captured in Step 1. But FAQ #3 contradicts this stating "*in silico* experiments involving any of the agents or toxins are not to be considered at this time."

  Modeling not to be included at this time based on

- Difficult to identify projects that we are "considering for funding" using QVR search. Several false positives.

- No way to readily search progress reports; relied on PO knowledge of projects.

Subject:	NIH DURC Inventory
Location:	1-877-919-1590; pass: 414701#
Start:	Wed 5/9/2012 1:00 PM
End:	Wed 5/9/2012 3:00 PM
Show Time As:	Tentative
Recurrence:	(none)
Meeting Status:	Not yet responded
Organizer:	Patterson, Amy (NIH/OD) [E]
Required Attendees:	Eichacker, Peter (NIH/CC/CCMD) [E]; Nakamura, Richard (NIH/CSR) [E]; Bridbord, Ken (NIH/FIC) [E]; Goldrosen, Martin (NIH/NCCAM) [E]; Gaston, Marilyn (NIH/NCI) [E]; Briggs, Josephine (NIH/NCCAM) [E]; Fisher, Richard (NIH/NEI) [E]; Scholes, Derek (NIH/NHGRI) [E]; Roth, Carl (NIH/NHLBI) [E]; Reed, Kathie (NIH/NIA) [E]; Dixon, Dennis M. (NIH/NIAID) [E]; Moen, Laura (NIH/NIAMS) [E]; Demsey, Anthony (NIH/NIBIB) [E]; Rowe, Mona (NIH/NICHD) [E]; Weiss, Susan (NIH/NIDA) [E]; Cyr, Janet (NIH/NIDCD) [E]; Somerman, Martha (NIH/NIDCR) [E]; Farishian, Richard (NIH/NIDDK) [E]; Schrader, Bill (NIH/NIEHS) [E]; Mastin, Pat (NIH/NIEHS) [E]; Blome, Juliana (NIH/NIGMS) [E]; Bertuzzi, Stefano (NIH/NIMH) [E]; Sy, Francisco (NIH/NIMHD) [E]; Jett, David (NIH/NINDS) [E]; Grason, John (NIH/NINR) [E]; Humphreys, Betsy (NIH/NLM) [E]; Weis, Brenda (NIH/OD) [E]; Grieder, Franziska (NIH/OD) [E]

USG interim DURO policy worksh...

Dear Colleagues:

In order to fulfill the agency's responsibilities under the New USG Policy for Oversight of Life Sciences Dual Use Research of Concern (DURC), the Office of Science Policy will host a tele-workshop for all IC Point-of-Contacts (POC) on Wednesday, May 9, 2012, 1:00 – 3:00 pm. This will be the first of two teleconferences in advance of the 60-day deadline (i.e., May 27) for the NIH to submit its inventory of "all current or proposed, unclassified intramural or extramural, life sciences research grants and contracts that fall within the scope" of the USG policy.

POCs from *all* IC are asked to participate in these workshops. Although most of the Institutes responded to last month's initial survey that their organization was not currently sponsoring DURC projects, the new policy stipulates that reporting of dual-use research falling under Sections III and IV occur every six months. Therefore, we encourage POCs from across NIH be informed on the requirements of the inventory should future projects of DURC appear in their extramural and/or intramural portfolios. ICs may elect to have two POCs participate in the discussions (i.e., one assigned to intramural review, the other to extramural).

Expected outcomes for next week's discussion include:

- To develop a common understanding among the NIH ICs regarding how to identify research projects that fall within the scope of the draft USG interim policy for oversight of dual use research of concern
- How to identify DURC
- Challenges and lessons learned from Depts/Agencies inventories, discussion of specific cases
- Keeping track of results and reporting aggregate data
- Development of menu of risk mitigation strategies
- Communicating with researchers and research institutions
- How to address the issue in funding announcements

See the attached slide deck for an overview of Wednesday's topics; the agenda for the workshop can be found on slide #3.

Please contact me if you have any questions.

Sincerely,

Sean J. Finnegan
Assistant to Amy Patterson, M.D.
Office of Science Policy
Office of the Director
National Institutes of Health
Rockledge 1, Room 750
6705 Rockledge Drive
Bethesda, MD 20892

The USG Interim Policy for Oversight of Federally-Funded Life Sciences DURC: Implementation of the Inventory and Reporting Requirements

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An Intra-agency Workshop Hosted byThe NIH Office of Science PolicyMay 9, 20121:00 – 3:00 pm

Today's Workshop

- **To develop a common understanding among the NIH ICs regarding how to identify research projects that fall within the scope of the draft USG interim policy for oversight of dual use research of concernFirst in a short series of meetings that will cover the following topics:How to identify DURC Challenges and lessons learned from Depts/Agencies inventories, discussion of specific casesKeeping track of results and reporting aggregate dataDevelopment of menu of risk mitigation strategiesCommunicating with researchers and research institutions How to address the issue in funding announcements**

Today's Agenda

- **Quick recap of the USG Interim Policy and task at handInventoryReporting requirementsStatus of ongoing inventory efforts and preliminary points to considerNIAID — Dennis DixonRecent updates from other D/As — Amy PattersonProposed tools for D/AsDURC ResourcesInventory templateA "menu" of approved risk mitigation strategiesNext steps**

USG Policy on Oversight of DURC

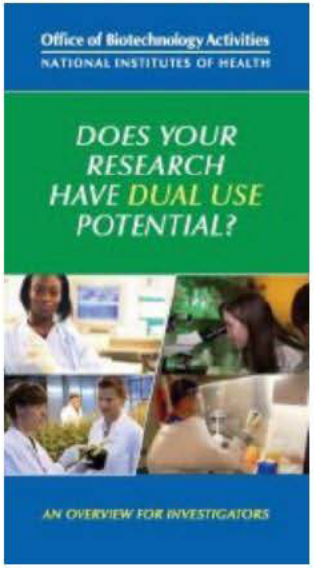
- **Issued by the Administration on March 29, 2012. Purpose: To establish regular review of USG funded or conducted research with certain high-consequence pathogens and toxins for its potential to be DURC in order to: mitigate risks where appropriate; and collect information needed to inform the development of an updated policy, as needed, for the oversight of DURC.**

What is "Dual Use Research of Concern (DURC)"?

- **As defined in the Interim Policy, DURC is:Life sciences research that, based on current understanding, can be reasonably anticipated to provide knowledge, information, products, or technologies that could be directly misapplied to pose a significant threat with broad potential consequences to public health and safety, agricultural crops and other plants, animals, the environment, materiel, or national security. Adapted from definition developed by the National Science Advisory Board for Biosecurity**

Resources for Identifying DURC

Educational Brochure



Educational Module in Slide Format

Video on NIH Website and YouTube

- [www.biosecurityboard.govNSABB report on Oversight Framework includes definition of DURC and tools for better understanding the definition and types of research that might be considered DURCDVD on dual us researchBrochure on dual use researchEducation module on DURCAlso: http://www.serceb.org/documents/SERCEBDual-UsePolicy.08.pdf]

Inventory

- **Conduct a review of our research portfolios to identify all current or proposed, unclassified intramural or extramural, life sciences research projects that fall within the scope of this policy. This review will include, at a minimum, initial proposals and any progress reports.Determine which, if any, of the projects meet the definition of DURC set forth in this policy. Assess the risks and benefits of such projects, including how research methodologies may generate risks and/or whether open access to the knowledge, information, products, or technologies generates risk.Based on the risk assessment, in collaboration with the institution and/or researcher, develop a risk mitigation plan to apply any necessary and appropriate risk mitigation measures.**

Scope of Interim Policy

- **Research that—Involves one or more of the 15 listed agents or toxins; andproduces, aims to produce, or is reasonably anticipated to produce one or more of the 7 listed effects——will be evaluated for DURC potential.**

Requires additional Feder

Rationale for Scope

- **Focused on a subset of biologic agents considered to present greatest risk of deliberate misuse with highest potential consequencesOffers a clearly defined list of agents such that research projects that need to be assessed for DURC potential can be readily identifiedInstitutions working with these 15 select agents have established biocontainment labs equipped with physical and other security measures in place as well as institutional biosafety oversightOnce experience with the oversight framework is gained and the effectiveness and impact are assessed, the scope may need to be adjusted**

Step 1: Identification of research involving any of the 15 agents or toxins listed

1. Avian influenza virus (highly pathogenic)Bacillus anthracisBotulinum neurotoxinBurkholderia malleiBurkholderia pseudomalleiEbola virusFoot-and-mouth disease virusFrancisella tularensisMarburg virusReconstructed 1918 Influenza virusRinderpest virusToxin-producing strains of Clostridium botulinumVariola major virusVariola minor virusYersinia pestis

Step 2: Identification of research that produces, aims to produce, or is reasonably anticipated to produce any of the listed effects

1. Enhances the harmful consequences of the agent or toxin; Disrupts immunity or the effectiveness of an immunization against the agent or toxin without clinical and/or agricultural justification;Confers to the agent or toxin resistance to clinically and/or agriculturally useful prophylactic or therapeutic interventions against that agent or toxin or facilitates their ability to evade detection methodologies;Increases the stability, transmissibility, or the ability to disseminate the agent or toxin; Alters the host range or tropism of the agent or toxin; Enhances the susceptibility of a host population to the agent or toxin; orGenerates or reconstitutes an eradicated or extinct agent or toxin listed in Section III.1

Step 3: Determination of whether the research is DURC

Is it Dual Use Research of Concern? Based on current understanding, can the research be reasonably anticipated to provide knowledge, information, products, or technologies that could be directly misapplied to pose a significant threat with broad potential consequences to public health and safety, agricultural crops and other plants, animals, the environment, materiel, or national security?

Reports

1. **Within 60 days of issuance of this Interim Policy (i.e., by May 27)Aggregate number of current and proposed unclassified, intramural, and extramural research projects identified that include work with:One or more of the 15 agents and toxins One or more of the 15 agents and toxins and produces, aims to produce, or are reasonably anticipated to produce one or more of the7 effects listedWithin 90 days of issuance of this Interim Policy (i.e., by June 26), the following results of actions taken in response to inventory findings:Number of unclassified current and proposed DURC projects Number of current projects identified as DURC through initial proposals vice progress reportsSummary of risks and proposed mitigation measures and number of projects to which each mitigation tool would be applied. Report the number of projects by agent and/or toxin plus the category of experiment.**

Draft Inventory TemplateTab 1 – Basic Info

Instructions. In this Workbook please find three worksheets that are accessed by clicking on the tabs in the lower left labeled "Basic Info," "DURC Inventory," and Risks and Strategies." Please fill out the information requested in ALL THREE worksheets.

This table is for internal Department and Agency use only. *For this Tab - Basic Info, please complete the table below. Grants and contracts will be anaomized and given a unique identifyer by NIH staff.*

Unique Identifyer	Grant or Contract #	Title	Principal Investigator	Institute or Center	Abstract
ABCD-1	ExampleGrant #NIH-1				
ABCD-2	ExampleGrant #NIH-2				
ABCD-3	ExampleGrant #NIH-3				

Draft Inventory TemplateTab 2 – DURC Inventory

Instructions. In this Workbook please find three worksheets that are accessed by clicking on the tabs in the lower left labeled "Basic Info," "DURC Inventory," and Risks and Strategies." Please fill out the information requested in ALL THREE worksheets.

For this Tab - DURC Inventory. List the Grant or Contract # (the information will be anonymized and given a unique identifyer).

Indicate which of the 15 agents/toxins are utilized in each grant by inserting the number "1" in the appropriate cell. If a grant or contract utilizes more than one agent/toxin, indicate this on a separate row. See Example below.

Indicate which of the 7 categories of experiments/potential consequences are likely to be associated with each agent/toxin by inserting a "1" in the appropriate cell. You can choose more than one experiment/consequence for each agent/toxin. See Example below.

Indicate whether the experiments being conducted with each agent meet the definition for "Dual Use Research of Concern" by inserting a "1" in the column for Yes or No. Briefly describe the rationale for this decision in the appropriate column.

Dept. or Agency	Unique Identifyer	Agent(s)/Toxin(s)														
		Avian influenza (high path)	Bacillus anthracis	Botulinum neurotoxin	Burkholderia mallei	Burkholderia pseudomallei	Ebola virus	Foot-and-mouth disease virus	Francisella tularenis	Marburg virus	Reconstructed 1918 Influenza virus	Rinderpest virus	Clostridium botulinum, toxin-producing strains	Variola major virus	Varioloa minor virus	Yersinia pestis
NIH	ABCD-1			1												
NIH	ABCD-1												1			
NIH	ABCD-2			1												
NIH	ABCD-2		1													
NIH	ABCD-3	1														
		1	1	2	0	0	0	0	0	0	0	0	1	0	0	0

(Tab 2 continued)

Categories of Experiments/Potential Consequences

1-Enhances the harmful consequences of the agent or toxin;
2-Disrupts immunity or the effectiveness of an immunization against the agent or toxin without clinical or agricultural justification;
3-Confers to the agent or toxin resistance to clinically or agriculturally useful prophylactic or therapeutic interventions against that agent or toxin or facilitates their ability to evade detection methodologies;
4-Increases the stability, transmissibility, or the ability to disseminate the agent or toxin;
5-Alters the host range or tropism of the agent or toxin;
6-Enhances the susceptibility of a host population to the agent or toxin; or
7-Generates or reconstitutes an eradicated or extinct agent or toxin listed in Section (III.1) above.

Dept. or Agency	Unique Identifyer
NIH	ABCD-1
NIH	ABCD-1
NIH	ABCD-2
NIH	ABCD-2
NIH	ABCD-3

...

Categories of Experiments							DURC?		If DURC:
1	2	3	4	5	6	7	Yes	No	Rationale for Decision
	1							1	
	1			1		1	1		
		1						1	
0	2	1	0	1	0	1	1	2	

Draft Inventory TemplateTab 3 – Risks and Strategies

left labeled "Basic Info," "DURC Inventory," and Risks and Strategies." Please fill out the information requested in ALL THREE worksheets.		
For this Tab - Risks and Strategies, describe the specific risks associated with the DURC.		
Describe the proposed risk mitigation strategies identified to manage the risks associated with the DURC.		
Unique Identifyer	**IF DURC:**	
	Specific Risks/Risk Categories	**Proposed Risk Mitigation Strategies**

Draft Inventory TemplateTab 4 – Summary

Department or Agency	Number of Grants or Contracts Using Any of the 15 Agents	Number of Grants or Contracts Conducting Experiments that Meet any of the 7 Criteria	Number of Grants or Contracts Containing DURC
NIH EXAMPLE	3	2	1

Toward a Common Understanding of Risk Categories and Mitigation Strategies

By analyzing our inventory results, the D/As can develop a common list of:Categories of risks associated with dual use research of concernRisk mitigation strategies that could be drawn from to address specific categories of risksSuch a list will need to be informed by a full understanding of the pros/cons, intended as well as unintended consequences Could serve as a "menu" of potential risk mitigation approachesAim to have a common understanding of what strategies would be appropriate for certain categories of riskWill need OGC evaluation of legal basis for any risk mitigation measures before they are implementedHelps to create a harmonized USG approach to oversight and therefore a more even playing field for researchersWill inform the development of longer term policy

Next Steps

- **Initiate inventoriesUse inventory templateThink about risk categories and risk mitigation strategiesOngoing workshops**

Workshop Series

- Session 1:Overview of USG interim policyDiscussion of how to approach identifying DURCSessions 2:Inventory progress reportQuestions, issues, challengesFinalize inventory report for 60-day deadlineSession 3:Review risk categories and risk mitigationsDiscuss 90-day reportSession 4:Review and finalize 90-day report

Source	15 select	Notes	Type	Actv	Project	PI Name(s) All	Abs	Admin IC	Title	
QVR Search	no		1	D43	TW009121-01	POLACK, FERNANDO P	Abs	TW	Pediatric respiratory diseases Translational Research Training Program-Arg	1D43TW009121-01
QVR Search	no	n/a	1	D43	TW009373-01	GRAY, GREGORY CHAR	Abs	TW	One Health Research Framework for the Prevention of Zoonotic Infections	1D43TW009373-01
QVR Search	no		1	D43	TW009379-01	NARDELL, EDWARD A.	Abs	TW	Innovative Interdisciplinary Approaches to Sustainable Airborne Infection C	1D43TW009379-01
QVR Search	no		1	K02	TW008771-01	IANNOTTI, LORA LYNN	Abs	TW	YOUNG CHILD NUTRITION, ANEMIA AND INFECTIOUS DISEASE IN HAITI	1K02TW008771-01
QVR Search	no		1	R01	TW009165-01	PASSOS, SARA T	Abs	TW	Immune response in leprosy patients.	1R01TW009165-01
QVR Search	yes		1	R01	TW009502-01	DASZAK, PETER	*Abs	TW	Comparative Spillover Dynamics of Avian HPAI	1R01TW009502-01
QVR Search	no		1	R03	TW008739-01	TURNER, DOUGLAS H.	Abs	TW	Folding RNA: Influenza	1R03TW008739-01
QVR Search	no		1	R03	TW009022-01	ADAMS, JOHN (contac	Abs	TW	Understanding protective immunity against Plasmodium vivax Duffy bindin	1R03TW009022-01
QVR Search	yes	not discusse	1	R03	TW009030-01	GETZ, WAYNE M	*Abs	TW	Transmission of zoonotic pathogens amc Bacillus anthracis	1R03TW009030-01
QVR Search	no		1	R03	TW009174-01	JIANG, XI	Abs	TW	Immune responses to Norovirus after natural infection in Vietnamese child	1R03TW009174-01
QVR Search	yes	not funded	2	D43	TW007387-07	CUMMINGS, DEREK (c	Abs	TW	Planning for avian influenza outbreaks in AI	2D43TW007387-07
QVR Search	yes		3	D43	TW007393-07S1	LESCANO, ANDRES G	Abs	TW	Peru Infectious Diseases Epidemiology R AI (not HPAI)	3D43TW007393-07S1
QVR Search	yes		3	R01	TW007869-05S5	XIAO, XIANGMING	Abs	TW	Ecology-Based Risk Assessment and Earl HPAI	3R01TW007869-05S5
QVR Search	no		5	D43	TW001038-13	HARRISON, LEE H.	Abs	TW	AIDS international Training and Research Program	5D43TW001038-13
QVR Search	no		5	D43	TW001038-14	HARRISON, LEE H.	Abs	TW	AIDS international Training and Research Program	5D43TW001038-14
QVR Search	yes		5	D43	TW007393-07	LESCANO, ANDRES G	Abs	TW	Peru Infectious Diseases Epidemiology R AI (not HPAI?)	5D43TW007393-07
QVR Search	no		5	R01	TW008126-04	ALI, SYED ASAD	Abs	TW	Burden of RSV and Influenza Virus in Children in Pakistan	5R01TW008126-04
QVR Search	no		5	R01	TW008246-04	CUMMINGS, DEREK	Abs	TW	Ecology of Infectious Diseases (EID)-Immune Landscapes of Human Influe	5R01TW008246-04
QVR Search	no		5	R03	TW008237-02	YAN, GUIYUN	Abs	TW	Insecticide Resistance in Anopheles minimus Mosquitoes	5R03TW008237-02
QVR Search	no		5	R03	TW008237-03	YAN, GUIYUN	Abs	TW	Insecticide Resistance in Anopheles minimus Mosquitoes	5R03TW008237-03
QVR Search	no		5	R03	TW008739-02	TURNER, DOUGLAS H.	Abs	TW	Folding RNA: Influenza	5R03TW008739-02
PO Added	yes		5	D43	TW008273-03	GONZALEZ, ARMANDO	Abs	TW	Veterinarian Training in Zoonotic Disease AI	
PO Added	yes		5	R01	TW005869-08	DASZAK, PETER	Abs	TW	The Ecology, Emergence and Pandemic I AI	
PO Added	yes		5	U01	TW006634-09	GERWICK, WILLIAM H	Abs	TW	ICBG: 'Training, Conservation and Drug I AI	

Source	15 select	Notes	Type	Actv	Project	PI Name(s) All	Abs	Admin IC	Title	HPAI	Note	
QVR Search	yes		1	R01	TW009502-01	DASZAK, PETER	*Abs	TW	Comparative Spillover Dynam	Yes	will not be	1R01TW009502-01
QVR Search	yes		3	R01	TW007869-05	XIAO, XIANGMING	Abs	TW	Ecology-Based Risk Assessme	yes		3R01TW007869-05
QVR Search	yes		5	D43	TW007393-07	LESCANO, ANDRES G	Abs	TW	Peru Infectious Diseases Epid	yes		5D43TW007393-07
PO Added	yes		5	D43	TW008273-03	GONZALEZ, ARMANDO	Abs	TW	Veterinarian Training in Zoon	yes		5D43TW008273-03
PO Added	yes		5	R01	TW005869-08	DASZAK, PETER	Abs	TW	The Ecology, Emergence and	yes		5R01TW005869-08
PO Added	yes		5	U01	TW006634-09	GERWICK, WILLIAM H	Abs	TW	ICBG: 'Training, Conservation	yes		5U01TW006634-09
QVR Search	yes		5	R03	TW008739-02	TURNER, DOUGLAS H.	Abs	TW	Folding RNA: Influenza	yes		5R03TW008739-02

QVR Custom Download	
Query Criteria	...IC's = TW Primary/Admin Projects Only ... Project Status = AWARDED, PENDING COUNCIL ...Fy's = 2012, 2011... Abstract/Summ Stmt/Title/ for: Avian influenza//Bacillus anthracis//anthrax//Botulinum neurotoxin//Burkholderia mallei //Burkholderia pseudomallei//Ebola//Foot-and-mouth//Francisella tularensis//Marburg//1918 Influenza//influenza// Rinderpest//Clostridium botulinum//Variola Variola minor//Yersinia pestis//yersinia//pestis//clostridium//bacillus//botulinum//burkholderia//tularensis//variola, combined with 'Or' .....Extramural Grants, Intramurals, Contracts, include Extramural Grant Subprojects
Sort Criteria	

Download Cols	Type,Actv,Project ,PI Name(s) All,Abs,Admin IC,Title

User	JESSUPC

Date&Time Run	{ts '2012-05-14 21:01:20'}

headerstyle	33.33%	1000	1,000	$1,000	1,000.00	Charsm	CharMed	www.msn.com		2010/01/05	2010/01/05 12:00:00 AM
HDR	PCT	INT	COMINT	CURR	COMDEC	TEXTSTD	TEXTBIG	HYPER	DATESTD		DATETM

Instructions. In this Workbook please find four worksheets that are accessed by clicking on the tabs in the lower left labeled "Basic Info," "DURC Inventory," and "Risks and Strategies," and "Summary." For the May 17th Workshop please fill out the information requested in Tab 1 and Tab 2.

This table is for internal NIH use only. *For this Tab - Basic Info, please complete the table below. The grants and contracts listed here should be only those that are relevant to the DURC oversight policy (i.e., only those that involve any of the 15 agents or toxins covered by the DURC policy). Grants and contracts will be anaomized and given a unique identifyer by NIH OSP staff. The information in this chart will not be shared or reported as part of the DURC inventory.*

Unique Identifyer	Grant #	Contract #	Project Funding			Title	Principal Investigator	Institute or Center	Abstract
			Does the grant or contract receive funding from another institute, center, department, or agency?	Which other institute, center, department or agency?	Which funder is responsible for reporting this grant or contract as part of its DURC inventory?				
ABCD-1	5R03TW008739-02		no (but NIGMS parent awar	NIGMS	FIC for this grant;NIGMS for pare	Folding RNA: Influ	TURNER, DOU	TW	Abs
ABCD-2	3R01TW007869-05		no			Ecology-Based Risl	XIAO, XIANGM	TW	Abs
ABCD-3	5D43TW007393-07		no			Peru Infectious Dis	LESCANO, AN[	TW	Abs
	5D43TW008273-03		no			Veterinarian Train	GONZALEZ, AR	TW	Abs
	5R01TW005869-08		no			The Ecology, Emer	DASZAK, PETEI	TW	Abs
	5U01TW006634-09		no			ICBG: 'Training, Co	GERWICK, WIL	TW	Abs

Instructions. In this Workbook please find four worksheets that are accessed by clicking on the tabs in the lower left labeled "Basic Info," "DURC Inventory," and "Risks and Strategies," and "Summary." For the May 17th Workshop please fill out the information requested in Tab 1 and Tab 2.

For this Tab - DURC Inventory. List the Grant or Contract # (the information will be ananomized and given a unique identifyer).

Step 1: *Indicate which of the 15 agents/toxins are involved in each grant by inserting the number "1" in the appropriate cell. If a grant or contract utilizes more than one agent/toxin, indicate this on a separate row. See Example below.*

Step 2: *Indicate which of the 7 categories of experiments/potential consequences are likely to be associated with each agent/toxin by inserting a "1" in the appropriate cell. You can choose more than one experiment/consequence for each agent/toxin. See Example below.*

Step3: *Indicate whether the experiments involving each agent meet the definition for "Dual Use Research of Concern" by inserting a "1" in the column for Yes or No. Identify when the research was identified as DURC and briefly describe the rationale for deciding whether a project was or was not DURC.*

NOTE: ONLY STEP 1 AND STEP 2 NEED TO BE COMPLETED FOR THE MAY 17TH MEETING.

Categories of Experiments/Potential Effects

1-Enhances the harmful consequences of the agent or toxin;
2-Disrupts immunity or the effectiveness of an immunization against the agent or toxin without clinical or agricultural justification;
3-Confers to the agent or toxin resistance to clinically or agriculturally useful prophylactic or therapeutic interventions against that agent or toxin or facilitates their ability to evade detection methodologies;
4-Increases the stability, transmissibility, or the ability to disseminate the agent or toxin;
5-Alters the host range or tropism of the agent or toxin;
6-Enhances the susceptibility of a host population to the agent or toxin; or
7-Generates or reconstitutes an eradicated or extinct agent or toxin listed in Section (III.1) above.

Institute or Center	Unique Identifyer	Agent(s)/Toxin(s)																Categories of Experiments/Effects							DURC?		If DURC:		
		Avian influenza (high path)	Bacillus anthracis	Botulinum neurotoxin	Burkholderia mallei	Burkholderia pseudomallei	Ebola virus	Foot-and-mouth disease virus	Francisella tularenis	Marburg virus	Reconstructed 1918 Influenza virus	Rinderpest virus	Clostridium botulinum, toxin-producing strains	Variola major virus	Varioloa minor virus	Yersinia pestis		1	2	3	4	5	6	7	Yes	No	When was DURC Identified?	If "other" indicate which stage DURC was identified	Rationale for Deciding that a project meets the DURC definition
TW	5R03TW00873	1																											
TW	3R01TW00786	1																											
TW	5D43TW00739	1																											
TW	5D43TW00827	1																											
TW	5R01TW00586	1																											
TW	5U01TW00663	1																											
		6	0	0	0	0	0	0	0	0	0	0	0	0	0	0		0	0	0	0	0	0	0	0	0			

Instructions. In this Workbook please find four worksheets that are accessed by clicking on the tabs in the lower left labeled "Basic Info," "DURC Inventory," and "Risks and Strategies," and "Summary." For the May 17th Workshop please fill out the information requested in Tab 1 and Tab 2.

For this Tab - Risks and Strategies, describe the specific risks associated with the DURC.

Describe the proposed risk mitigation strategies identified to manage the risks associated with the DURC.

Where appropriate, indicate whether NIH has worked with any agencies or departments that are co-funding a DURC project to develop a harmonized risk mitigation strategy.

Unique Identifyer	IF DURC:		
	Specific Risks/Risk Categories	Proposed Risk Mitigation Strategies	If a grant or contract received funding from multiple agencies, have the agencies worked together to develop harmonized risk mitigation strategies?

For NIH OSP use only. NIH will compile the requested information and report aggregate numbers of grants and contracts meeting the required criteria below. By Day 90 NIH will also report a summary of risks, mitigation measures already in place that address those risks, any additional mitigation measures that have been proposed or implemented, and number of projects to which each mitigation measure would be applied.

	Report by Day 60		Report by Day 90		
Department or Agency	**Number of Grants or Contracts Using Any of the 15 Agents**	**Number of Grants or Contracts Conducting Experiments that Use Any of the 15 Agents AND Meet any of the 7 Criteria**	**Number of Grants or Contracts Containing DURC**		
			Total DURC Cases	**DURC Identified at Initial Proposal Stage**	**DURC Identified at Progress Report Stage**
NIH					

Full list:
Avian influenza virus (highly pathogenic) ***Bacillus anthracis*** **Botulinum neurotoxin** ***Burkholderia mallei Burkholderia pseudomallei*** **Ebola virus Foot-and-mouth disease virus** ***Francisella tularensis*** **Marburg virus Reconstructed 1918 Influenza virus Rinderpest virus Toxin-producing strains of** ***Clostridium botulinum*** **Variola major virus Variola minor virus*****Yersinia pestis***

Without some terms, use "OR", search awarded
Avian influenza ***Bacillus anthracis*** **Botulinum neurotoxin** ***Burkholderia mallei Burkholderia pseudomallei*** **Ebola Foot-and-mouth** ***Francisella tularensis*** **Marburg 1918 Influenza Rinderpest** ***Clostridium botulinum*** **Variola Variola minor** ***Yersinia pestis***

Avian influenza// *Bacillus anthracis* //Botulinum neurotoxin //*Burkholderia mallei* //*Burkholderia pseudomallei* //Ebola Foot-and-mouth *Francisella tularensis* Marburg 1918 Influenza Rinderpest *Clostridium botulinum* Variola Variola minor *Yersinia pestis*

Awarded,Pending,Pending Award,Pending Council,To be Paid

Draft FAQs
Implementation of the Inventory and Reporting Requirements
of the USG Policy for Oversight of Life Sciences DURC

Questions involving the scope of the oversight.

Q1. The first criterion for determining whether research is subject to DURC oversight is if the research involves one of the 15 listed agents or toxins, which are all Select Agents. Botulinum neurotoxin is listed, and it is not regulated as a Select Agent if the amount under the control of a PI does not exceed at any time 0.5 mg. Is research using quantities of Botulinum neurotoxin that are not subject to regulation by the Select Agent Rule also exempt from the DURC oversight policy?

A1: No. Any research involving Botulinum toxin should be considered for its potential to result in any of the 7 listed effects. The intent of the DURC policy is different from, albeit complementary to, that of the Select Agent Rule. The focus of the DURC policy is information, technologies and other products of research that could be misused for harmful purposes. Research on botulinum toxin, for example, could potentially yield information that would have dual use potential, regardless of the amount of toxin used in the experiment. Therefore, there is no exemption under the DURC oversight policy for small quantities of any toxin on the list.

Q2. Does research that involves an attenuated version of one of the microorganisms listed in this Policy still need to be considered for its dual use research potential?

A2: No. The oversight Policy applies to microorganisms that are subject to the Select Agent Rule. Therefore, research using an attenuated strain that is not subject to the Select Agent Rule should not be included in this DURC inventory.

Q3. The oversight Policy applies to research that "involves" one of the listed agents or toxins. Does the Policy apply to research utilizing genes from any of the microorganisms or *in silico* experiments (e.g. modeling, bioinformatics) involving any of the listed agents or toxins?

A3: No. The oversight Policy applies to microorganisms that are subject to the Select Agent Rule. Experiments utilizing genes from any of the microorganisms, or *in silico* experiments involving any of the agents or toxins are not to be considered at this time.

Q4. The Policy requires departments and agencies to identify "research projects" that meet the listed criteria and may be considered DURC. What is being counted and reported as a research project?

A4. The departments and agencies are to identify and report the number of grants and contracts that meet the requested criteria. It is understood that there may be sub-projects within a given grant or contract.

Q5. The policy requires the reporting of projects that are identified as DURC during the project's "initial proposal" stage? What is meant by "initial proposal"?

A5. Initial proposals are research applications that have undergone scientific peer review and are intended to be funded.

Questions involving the identification, reporting and oversight of research covered by this Policy

Q6. Are there any pre-existing data-searching mechanisms that may assist in identifying projects that fall within the scope of the USG policy for oversight of DURC?

A6. Yes, through the use of key words, IMPACT2 IMPAC II or NIH RePORTer can be used as the first pass at identifying projects that fall within the scope of the USG policy; however, both have limitations, e.g., lack of inclusion of P51 grants, including only funded research and including only publicly available grant information. Going forward, grants could be coded when entered into a system such as IMPACT2 IMPAC II or NIH RePORTer, to later allow for the future search of certain key terms. NIAID has a unique system where projects are coded for the listed agents and toxins before they are deposited into their database. Such a system may be useful for other ICs in the future. In the meantime, existing databases of active and pending awards can be searched for the relevant agents and toxins.

Q7. How does reporting work for research that is funded by multiple Federal agencies? Should each funding agency report the work?

A7: No. If each agency were to report the same research, there would be double counting that would skew the data. In cases of multiple federal funding agencies, the primary awarding entity is responsible for reporting projects that are co-funded. However, all institutes, centers, departments, or agencies that fund research involving any of the 15 agents or toxins should list that grant or contract in Tab 1 of the inventory spreadsheet and fill out the appropriate columns regarding Project Funding. In these instances, co-funding entities should communicate to confirm which funder is responsible for fulfilling the reporting requirements. However, if NIH is one of the funding agencies, the NIH would be willing to report that research on behalf of the other agency or agencies, after appropriate consultation.

Q8. How should risk mitigation strategies be developed for DURC that is funded by multiple Federal agencies?

A8: Departments and agencies that are co-funding DURC should work together to develop risk mitigation strategies to ensure consistent, harmonized oversight of DURC. It would also be helpful to designate a lead agency for reporting on the research. Since it may not be evident that other funding agencies are involved, Program Officers from a funding agency that has identified research as needing DURC oversight should check with the research institution whether any other federal agencies are funding the research.

Q9. What should be provided in the abstract section on Tab 1 of the DURC inventory spreadsheet?

A9. A link to the abstract provided in the grant would be appropriate here. It is not necessary to copy and paste the entire abstract. This information is for internal use only and is being collected to provide background on the scope of the research, as it may not be evident in the title of the project alone.

Q10. Should agency staff contact Principal Investigators to report that their proposed or ongoing research has been determined to be DURC?

A10. For interagency discussion

Questions involving the 7 categories of experiments/potential effects

Q11. If a project is identified that includes experiments that result in (or are likely to result in) any of the listed 7 effects, is that project automatically considered DURC?

A11. No, a project may result in one or more of the 7 listed effects and still not be considered DURC. Projects that are likely to result in the 7 listed effects must then be considered for whether they meet the definition of DURC (i.e. – "life sciences research that, based on current understanding, can be reasonably anticipated to provide knowledge, information, products, or technologies that could be directly misapplied to pose a significant threat with broad potential consequences to public health and safety, agricultural crops and other plants, animals, the environment, materiel, or national security.")

Q12. In the first category of experiment/potential effect, what is meant by "enhance the harmful consequences" of an agent or toxin?

A12. "Harmful consequences" refers to the ability of a biological agent or toxin to critically alter normal biological functions, inflict damage on public health resources, materiel, and public safety. This would include augmenting properties such as virulence, infectivity, stability, transmissibility, or the ability of the biological agent or toxin to be disseminated.

Q13. The first effect is "enhances the harmful consequences of the agent or toxin." If an experiment starts with an attenuated strain of one of the listed agents and is anticipated to generate a strain that is more pathogenic than the starting strain but less pathogenic than the wild type strain, is that considered a "hit" for this effect?

A13: No. Experiments that generate strains that are less pathogenic than, or equal in pathogenicity to the wild type are not considered to enhance the harmful consequences of an agent or toxin. It is important to note, however, that although an experiment may not fit this particular effect, it still needs to be evaluated for the applicability of the other six effects listed for criterion 2.

Q14. In the second category of experiment/potential effect, what is meant by "disrupt immunity or the effectiveness of an immunization?"

A14. Immunity encompasses all aspects of host immunity (e.g., active, adaptive, adoptive, passive, innate, and immune modulators). Immunization refers to the active or passive induction of immunity through inoculation (e.g., natural inoculation or vaccination) with an immunizing agent or with antibodies; this includes antitoxins and toxoids. For instance, rendering an immunization ineffective could make a host population vulnerable to the pathogenic consequences of a microbe from which the host population would have otherwise been protected or for which protection, such as a vaccine, was available.

Q15. The second listed effect is "disrupts immunity or the effectiveness of an immunization against the agent or toxin without clinical and/or agriculture justification." Does this apply to experimental vaccines, or only licensed or approved vaccines?

A15: If the research aims to test a vaccine against various challenges and reveals some vulnerabilities, with little to no implications for existing, licensed vaccines, the research would not be considered to meet criterion 2. However, if the experimental vaccine falls into a class of extant, licensed vaccines, then the disruption of effectiveness could have important implications for the entire class of vaccines. In that case, the work should be considered as meeting at least one effect in the second criterion and should therefore be evaluated for the applicability of the third criterion (DURC potential).

Q16. In the third category of experiment/potential effect, what is meant by "clinically or agriculturally useful prophylactic or therapeutic interventions?"

A16. This includes first- or second-line prevention and treatment measures or alternative therapeutics used with special populations (e.g., pregnant women and pediatric patients) in the form of vaccines, antibiotics, antivirals, antiparasitics, antibodies, herbicides, fungicides, algaecides, insecticides, etc. "Agriculture" encompasses all methods of production and management of livestock, crops, vegetation, and soil. Therefore, useful prophylaxes and therapeutics would include herbicides, fungicides, algaecides, insecticides, rodenticides, etc. The main concept is that anything that might compromise the ability to detect, treat, or prevent disease or illness (human or agricultural) caused by biological agents or toxins could result in a significant public health and/or economic burden.

Q17. What is meant by the fourth category of experiment/potential effect?

A17. The rationale for this category is that increasing an agent's stability, transmissibility, or ability to disseminate could facilitate the purposeful malevolent use of a biological agent or toxin and increase the rate or ease by which an agent could spread, impeding attempts to contain disease outbreak. Stability is the ability of a biological agent to remain viable when exposed to various environmental factors, including temperature, relative humidity, atmospheric pollution, and sunlight. Stability also includes persistence in a host. Transmissibility is the ease with which an agent spreads from host to host or from vector to host (e.g., via arthropod vectors). Dissemination is the process by which infectious diseases or toxins are dispersed. The same routes of entry pertinent to the natural spread of diseases are also relevant when their etiologic agents are delivered intentionally (e.g., inhalation of biological agent disseminated as an aerosol or ingestion of a biological agent disseminated through a water supply).

Q18. In the fifth category of experiment/listed effect, what is meant by altering the "host range or tropism?"

A18. Host range is the number of different species or populations that can become infected by a biological agent, causing disease in the host or allowing the host to become a carrier. Tropism is the specificity of a biological agent or toxin for a particular host tissue or cell.

Q19. What is meant by the sixth category of experiment/potential effect?

A19. Information about rendering host populations more susceptible to the pathogenic consequences of an agent or toxin could be used to compromise immune responses and enable the acquisition and spread of disease on an epidemic scale. Of note, the distinction should be made that research applicable to this category would not alter the susceptibility of an individual host or research cohort but rather that of a host population. A host population is a collection of organisms that constitutes a specific group or occurs in a specified habitat. In the context of the criteria, this phrase implies that the misapplication of the knowledge, products, or technologies derived from the research has the potential to broadly impact a population of host organisms.

Q20. What types of agents are being referred to in the seventh category of experiment/potential effect?

A20. This category refers to eradicated and novel agents. An eradicated agent is a biological agent that has been exterminated through surveillance and containment resulting in the permanent reduction to zero of the worldwide incidence in the transmission of the agent and the infection/disease it causes; intervention measures are no longer needed. Eradicated agents are thought to no longer exist in circulation in plants, animals, or the environment. A novel agent is one that has not existed previously and is considered unique based on biological or other properties and traits (e.g., genotype and phenotype).

<u>Questions involving determining whether research meets the definition of DURC</u>

Q21. DURC oversight is required for research that meets three criteria—i.e., it involves a listed agent, produces one of the listed effects, and meets the definition of DURC. For the last step, determining whether research meets the definition of DURC, what if the research generates information that could be misapplied only if it was combined with additional extant information, e.g., information that is already publicly available? Is this DURC?

A21: For interagency discussion

Q22. Is research considered DURC if only in a successive phase of funding it will likely generate information that could be misused for harmful purposes?

A22: For interagency discussion

Q23. What criteria should be used to identify if something is "reasonably anticipated" to be DURC?

A23. The identification of DURC is ultimately a judgment call, and the decision should be as informed as possible. The knowledge and expertise from IC program officers and scientific staff can be used to evaluate the standards in the field and if the proposed research could meet this requirement as well as the other components that are required for the determination of DURC.

FIC DURC Inventory Process

Process of identifying FIC projects for DURC Inventory:

Sent to DIEPS for identification of relevant DIEPS projects (May 15). Identified relevant DITR projects as follows:

1. **Ran QVR search** using keyword search of Abstract, Summary Statement or Title with 15 Select Agents and Toxins as search terms combined by "OR" Boolean. Searched Awarded and Pending Council for FY 2011 and FY 2012 and with FIC as Primary.

   ...IC's = TW Primary/Admin Projects Only ... Project Status = AWARDED, PENDING COUNCIL ...Fy's = 2012, 2011... Abstract/Summ Stmt/Title/ for: Avian influenza//Bacillus anthracis//anthrax//Botulinum neurotoxin//Burkholderia mallei //Burkholderia pseudomallei//Ebola//Foot-and-mouth//Francisella tularensis//Marburg//1918 Influenza//influenza// Rinderpest//Clostridium botulinum//Variola Variola minor//Yersinia pestis//yersinia//pestis//clostridium//bacillus//botulinum//burkholderia//tularensis//variola, combined with 'Or' .....Extramural Grants, Intramurals, Contracts, include Extramural Grant Subprojects

2. Extramural **infectious disease program officers reviewed** the resulting project list (21 projects), and
   a. **omitted projects that were not relevant** [some "pending council" captured projects that were not discussed in review so they are not being considered for funding; the search terms identified some projects where part of a select agent name was captured, but the project was not related to the select agent/toxin itself (i.e., the word bacillus spp. or clostridium spp.).
   b. **omitted supplements** if parent award was represented
   c. **added projects** based on personal knowledge of activities in parent award or supplements (3 projects added)

      18 projects omitted; 3 retained; 3 added

- The number of grants or contracts involving any of the 15 agents/toxins.
  6
- The number of grants or contracts involving any of the 15 agents/toxins AND those that are likely to involve any of the 7 effects/categories of experiments.
  0
- A brief overview of your IC's approach to collecting the DURC inventory.
  Above
- Any challenges or outstanding issues encountered during this inventory process.
  Below

Issues and concerns:

- FIC supports a number of research training projects (D43s) that are linked to research grants in other ICs. Although the training award may not be DURC, the related research grant may be but would not be readily identified by FIC. How should research training grants and career development awards be handled in this process? Both policy and FAQs refer to "research projects".

- Need clarification on modeling studies. Last week's discussion led us to believe that modeling studies related to one of the agents/toxins should be captured in Step 1. But FAQ #3 contradicts this stating "*in silico* experiments involving any of the agents or toxins are not to be considered at this time."

  Modeling not to be included at this time based on

- Difficult to identify projects that we are "considering for funding" using QVR search. Several false positives.

- No way to readily search progress reports; relied on PO knowledge of projects.

Subject:	NIH DURC Inventory
Location:	1-877-919-1590; pass: 414701#
Start:	Wed 5/9/2012 1:00 PM
End:	Wed 5/9/2012 3:00 PM
Show Time As:	Tentative
Recurrence:	(none)
Meeting Status:	Not yet responded
Organizer:	Patterson, Amy (NIH/OD) [E]
Required Attendees:	Eichacker, Peter (NIH/CC/CCMD) [E]; Nakamura, Richard (NIH/CSR) [E]; Bridbord, Ken (NIH/FIC) [E]; Goldrosen, Martin (NIH/NCCAM) [E]; Gaston, Marilyn (NIH/NCI) [E]; Briggs, Josephine (NIH/NCCAM) [E]; Fisher, Richard (NIH/NEI) [E]; Scholes, Derek (NIH/NHGRI) [E]; Roth, Carl (NIH/NHLBI) [E]; Reed, Kathie (NIH/NIA) [E]; Dixon, Dennis M. (NIH/NIAID) [E]; Moen, Laura (NIH/NIAMS) [E]; Demsey, Anthony (NIH/NIBIB) [E]; Rowe, Mona (NIH/NICHD) [E]; Weiss, Susan (NIH/NIDA) [E]; Cyr, Janet (NIH/NIDCD) [E]; Somerman, Martha (NIH/NIDCR) [E]; Farishian, Richard (NIH/NIDDK) [E]; Schrader, Bill (NIH/NIEHS) [E]; Mastin, Pat (NIH/NIEHS) [E]; Blome, Juliana (NIH/NIGMS) [E]; Bertuzzi, Stefano (NIH/NIMH) [E]; Sy, Francisco (NIH/NIMHD) [E]; Jett, David (NIH/NINDS) [E]; Grason, John (NIH/NINR) [E]; Humphreys, Betsy (NIH/NLM) [E]; Weis, Brenda (NIH/OD) [E]; Grieder, Franziska (NIH/OD) [E]

USG interim DURO policy worksh...

Dear Colleagues:

In order to fulfill the agency's responsibilities under the New USG Policy for Oversight of Life Sciences Dual Use Research of Concern (DURC), the Office of Science Policy will host a tele-workshop for all IC Point-of-Contacts (POC) on Wednesday, May 9, 2012, 1:00 – 3:00 pm. This will be the first of two teleconferences in advance of the 60-day deadline (i.e., May 27) for the NIH to submit its inventory of "all current or proposed, unclassified intramural or extramural, life sciences research grants and contracts that fall within the scope" of the USG policy.

POCs from *all* IC are asked to participate in these workshops. Although most of the Institutes responded to last month's initial survey that their organization was not currently sponsoring DURC projects, the new policy stipulates that reporting of dual-use research falling under Sections III and IV occur every six months. Therefore, we encourage POCs from across NIH be informed on the requirements of the inventory should future projects of DURC appear in their extramural and/or intramural portfolios. ICs may elect to have two POCs participate in the discussions (i.e., one assigned to intramural review, the other to extramural).

Expected outcomes for next week's discussion include:

- To develop a common understanding among the NIH ICs regarding how to identify research projects that fall within the scope of the draft USG interim policy for oversight of dual use research of concern
- How to identify DURC
- Challenges and lessons learned from Depts/Agencies inventories, discussion of specific cases
- Keeping track of results and reporting aggregate data
- Development of menu of risk mitigation strategies
- Communicating with researchers and research institutions
- How to address the issue in funding announcements

See the attached slide deck for an overview of Wednesday's topics; the agenda for the workshop can be found on slide #3.

Please contact me if you have any questions.

Sincerely,

Sean J. Finnegan
Assistant to Amy Patterson, M.D.
Office of Science Policy
Office of the Director
National Institutes of Health
Rockledge 1, Room 750
6705 Rockledge Drive
Bethesda, MD 20892

The USG Interim Policy for Oversight of Federally-Funded Life Sciences DURC: Implementation of the Inventory and Reporting Requirements

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An Intra-agency Workshop Hosted byThe NIH Office of Science PolicyMay 9, 20121:00 – 3:00 pm

Today's Workshop

- **To develop a common understanding among the NIH ICs regarding how to identify research projects that fall within the scope of the draft USG interim policy for oversight of dual use research of concernFirst in a short series of meetings that will cover the following topics:How to identify DURC Challenges and lessons learned from Depts/Agencies inventories, discussion of specific casesKeeping track of results and reporting aggregate dataDevelopment of menu of risk mitigation strategiesCommunicating with researchers and research institutions How to address the issue in funding announcements**

Today's Agenda

- **Quick recap of the USG Interim Policy and task at handInventoryReporting requirementsStatus of ongoing inventory efforts and preliminary points to considerNIAID — Dennis DixonRecent updates from other D/As — Amy PattersonProposed tools for D/AsDURC ResourcesInventory templateA "menu" of approved risk mitigation strategiesNext steps**

USG Policy on Oversight of DURC

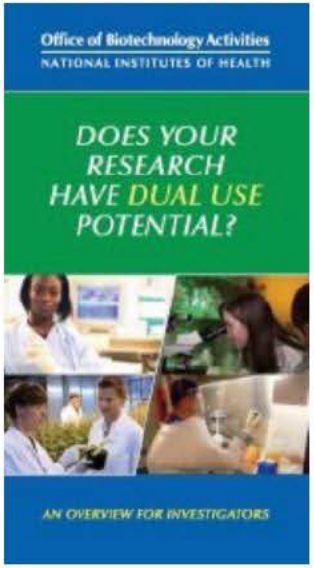
- **Issued by the Administration on March 29, 2012. Purpose: To establish regular review of USG funded or conducted research with certain high-consequence pathogens and toxins for its potential to be DURC in order to: mitigate risks where appropriate; and collect information needed to inform the development of an updated policy, as needed, for the oversight of DURC.**

What is "Dual Use Research of Concern (DURC)"?

- **As defined in the Interim Policy, DURC is:Life sciences research that, based on current understanding, can be reasonably anticipated to provide knowledge, information, products, or technologies that could be directly misapplied to pose a significant threat with broad potential consequences to public health and safety, agricultural crops and other plants, animals, the environment, materiel, or national security. Adapted from definition developed by the National Science Advisory Board for Biosecurity**

Resources for Identifying DURC

Educational Brochure



Educational Module in Slide Format

Video on NIH Website and YouTube

- [www.biosecurityboard.govNSABB report on Oversight Framework includes definition of DURC and tools for better understanding the definition and types of research that might be considered DURCDVD on dual us researchBrochure on dual use researchEducation module on DURCAlso: http://www.serceb.org/documents/SERCEBDual-UsePolicy.08.pdf]

Inventory

- **Conduct a review of our research portfolios to identify all current or proposed, unclassified intramural or extramural, life sciences research projects that fall within the scope of this policy. This review will include, at a minimum, initial proposals and any progress reports.Determine which, if any, of the projects meet the definition of DURC set forth in this policy. Assess the risks and benefits of such projects, including how research methodologies may generate risks and/or whether open access to the knowledge, information, products, or technologies generates risk.Based on the risk assessment, in collaboration with the institution and/or researcher, develop a risk mitigation plan to apply any necessary and appropriate risk mitigation measures.**

Scope of Interim Policy

- **Research that—Involves one or more of the 15 listed agents or toxins; andproduces, aims to produce, or is reasonably anticipated to produce one or more of the 7 listed effects——will be evaluated for DURC potential.**

Requires additional Feder

Rationale for Scope

- **Focused on a subset of biologic agents considered to present greatest risk of deliberate misuse with highest potential consequencesOffers a clearly defined list of agents such that research projects that need to be assessed for DURC potential can be readily identifiedInstitutions working with these 15 select agents have established biocontainment labs equipped with physical and other security measures in place as well as institutional biosafety oversightOnce experience with the oversight framework is gained and the effectiveness and impact are assessed, the scope may need to be adjusted**

Step 1: Identification of research involving any of the 15 agents or toxins listed

1. Avian influenza virus (highly pathogenic)Bacillus anthracisBotulinum neurotoxinBurkholderia malleiBurkholderia pseudomalleiEbola virusFoot-and-mouth disease virusFrancisella tularensisMarburg virusReconstructed 1918 Influenza virusRinderpest virusToxin-producing strains of Clostridium botulinumVariola major virusVariola minor virusYersinia pestis

Step 2: Identification of research that produces, aims to produce, or is reasonably anticipated to produce any of the listed effects

1. Enhances the harmful consequences of the agent or toxin; Disrupts immunity or the effectiveness of an immunization against the agent or toxin without clinical and/or agricultural justification;Confers to the agent or toxin resistance to clinically and/or agriculturally useful prophylactic or therapeutic interventions against that agent or toxin or facilitates their ability to evade detection methodologies;Increases the stability, transmissibility, or the ability to disseminate the agent or toxin; Alters the host range or tropism of the agent or toxin; Enhances the susceptibility of a host population to the agent or toxin; orGenerates or reconstitutes an eradicated or extinct agent or toxin listed in Section III.1

Step 3: Determination of whether the research is DURC

Is it Dual Use Research of Concern? Based on current understanding, can the research be reasonably anticipated to provide knowledge, information, products, or technologies that could be directly misapplied to pose a significant threat with broad potential consequences to public health and safety, agricultural crops and other plants, animals, the environment, materiel, or national security?

Reports

1. **Within 60 days of issuance of this Interim Policy (i.e., by May 27)Aggregate number of current and proposed unclassified, intramural, and extramural research projects identified that include work with:One or more of the 15 agents and toxins One or more of the 15 agents and toxins and produces, aims to produce, or are reasonably anticipated to produce one or more of the7 effects listedWithin 90 days of issuance of this Interim Policy (i.e., by June 26), the following results of actions taken in response to inventory findings:Number of unclassified current and proposed DURC projects Number of current projects identified as DURC through initial proposals vice progress reportsSummary of risks and proposed mitigation measures and number of projects to which each mitigation tool would be applied. Report the number of projects by agent and/or toxin plus the category of experiment.**

Draft Inventory TemplateTab 1 – Basic Info

Instructions. In this Workbook please find three worksheets that are accessed by clicking on the tabs in the lower left labeled "Basic Info," "DURC Inventory," and Risks and Strategies." Please fill out the information requested in ALL THREE worksheets.

This table is for internal Department and Agency use only. *For this Tab - Basic Info, please complete the table below. Grants and contracts will be anaomized and given a unique identifyer by NIH staff.*

Unique Identifyer	Grant or Contract #	Title	Principal Investigator	Institute or Center	Abstract
ABCD-1	ExampleGrant #NIH-1				
ABCD-2	ExampleGrant #NIH-2				
ABCD-3	ExampleGrant #NIH-3				

Draft Inventory TemplateTab 2 – DURC Inventory

Instructions. In this Workbook please find three worksheets that are accessed by clicking on the tabs in the lower left labeled "Basic Info," "DURC Inventory," and Risks and Strategies." Please fill out the information requested in ALL THREE worksheets.

For this Tab - DURC Inventory. List the Grant or Contract # (the information will be anonymized and given a unique identifyer).

Indicate which of the 15 agents/toxins are utilized in each grant by inserting the number "1" in the appropriate cell. If a grant or contract utilizes more than one agent/toxin, indicate this on a separate row. See Example below.

Indicate which of the 7 categories of experiments/potential consequences are likely to be associated with each agent/toxin by inserting a "1" in the appropriate cell. You can choose more than one experiment/consequence for each agent/toxin. See Example below.

Indicate whether the experiments being conducted with each agent meet the definition for "Dual Use Research of Concern" by inserting a "1" in the column for Yes or No. Briefly describe the rationale for this decision in the appropriate column.

Dept. or Agency	Unique Identifyer	Agent(s)/Toxin(s)														
		Avian influenza (high path)	Bacillus anthracis	Botulinum neurotoxin	Burkholderia mallei	Burkholderia pseudomallei	Ebola virus	Foot-and-mouth disease virus	Francisella tularenis	Marburg virus	Reconstructed 1918 Influenza virus	Rinderpest virus	Clostridium botulinum, toxin-producing strains	Variola major virus	Varioloa minor virus	Yersinia pestis
NIH	ABCD-1			1												
NIH	ABCD-1												1			
NIH	ABCD-2			1												
NIH	ABCD-2		1													
NIH	ABCD-3	1														
		1	1	2	0	0	0	0	0	0	0	0	1	0	0	0

(Tab 2 continued)

Categories of Experiments/Potential Consequences

1-Enhances the harmful consequences of the agent or toxin;
2-Disrupts immunity or the effectiveness of an immunization against the agent or toxin without clinical or agricultural justification;
3-Confers to the agent or toxin resistance to clinically or agriculturally useful prophylactic or therapeutic interventions against that agent or toxin or facilitates their ability to evade detection methodologies;
4-Increases the stability, transmissibility, or the ability to disseminate the agent or toxin;
5-Alters the host range or tropism of the agent or toxin;
6-Enhances the susceptibility of a host population to the agent or toxin; or
7-Generates or reconstitutes an eradicated or extinct agent or toxin listed in Section (III.1) above.

Dept. or Agency	Unique Identifyer
NIH	ABCD-1
NIH	ABCD-1
NIH	ABCD-2
NIH	ABCD-2
NIH	ABCD-3

...

Categories of Experiments							DURC?		If DURC:
1	2	3	4	5	6	7	Yes	No	Rationale for Decision
	1							1	
	1			1		1	1		
		1						1	
0	2	1	0	1	0	1	1	2	

Draft Inventory TemplateTab 3 – Risks and Strategies

left labeled "Basic Info," "DURC Inventory," and Risks and Strategies." Please fill out the information requested in ALL THREE worksheets.		
For this Tab - Risks and Strategies, describe the specific risks associated with the DURC.		
Describe the proposed risk mitigation strategies identified to manage the risks associated with the DURC.		
Unique Identifyer	**IF DURC:**	
	Specific Risks/Risk Categories	**Proposed Risk Mitigation Strategies**

Draft Inventory TemplateTab 4 – Summary

Department or Agency	Number of Grants or Contracts Using Any of the 15 Agents	Number of Grants or Contracts Conducting Experiments that Meet any of the 7 Criteria	Number of Grants or Contracts Containing DURC
NIH EXAMPLE	3	2	1

Toward a Common Understanding of Risk Categories and Mitigation Strategies

By analyzing our inventory results, the D/As can develop a common list of:Categories of risks associated with dual use research of concernRisk mitigation strategies that could be drawn from to address specific categories of risksSuch a list will need to be informed by a full understanding of the pros/cons, intended as well as unintended consequences Could serve as a "menu" of potential risk mitigation approachesAim to have a common understanding of what strategies would be appropriate for certain categories of riskWill need OGC evaluation of legal basis for any risk mitigation measures before they are implementedHelps to create a harmonized USG approach to oversight and therefore a more even playing field for researchersWill inform the development of longer term policy

Next Steps

- **Initiate inventoriesUse inventory templateThink about risk categories and risk mitigation strategiesOngoing workshops**

Workshop Series

- Session 1:Overview of USG interim policyDiscussion of how to approach identifying DURCSessions 2:Inventory progress reportQuestions, issues, challengesFinalize inventory report for 60-day deadlineSession 3:Review risk categories and risk mitigationsDiscuss 90-day reportSession 4:Review and finalize 90-day report

Source	15 select	Notes	Type	Actv	Project	PI Name(s) All	Abs	Admin IC	Title	
QVR Search	no		1	D43	TW009121-01	POLACK, FERNANDO P	Abs	TW	Pediatric respiratory diseases Translational Research Training Program-Arg	1D43TW009121-01
QVR Search	no	n/a	1	D43	TW009373-01	GRAY, GREGORY CHAR	Abs	TW	One Health Research Framework for the Prevention of Zoonotic Infections	1D43TW009373-01
QVR Search	no		1	D43	TW009379-01	NARDELL, EDWARD A.	Abs	TW	Innovative Interdisciplinary Approaches to Sustainable Airborne Infection C	1D43TW009379-01
QVR Search	no		1	K02	TW008771-01	IANNOTTI, LORA LYNN	Abs	TW	YOUNG CHILD NUTRITION, ANEMIA AND INFECTIOUS DISEASE IN HAITI	1K02TW008771-01
QVR Search	no		1	R01	TW009165-01	PASSOS, SARA T	Abs	TW	Immune response in leprosy patients.	1R01TW009165-01
QVR Search	yes		1	R01	TW009502-01	DASZAK, PETER	*Abs	TW	Comparative Spillover Dynamics of Avian HPAI	1R01TW009502-01
QVR Search	no		1	R03	TW008739-01	TURNER, DOUGLAS H.	Abs	TW	Folding RNA: Influenza	1R03TW008739-01
QVR Search	no		1	R03	TW009022-01	ADAMS, JOHN (contac	Abs	TW	Understanding protective immunity against Plasmodium vivax Duffy bindin	1R03TW009022-01
QVR Search	yes	not discusse	1	R03	TW009030-01	GETZ, WAYNE M	*Abs	TW	Transmission of zoonotic pathogens amc Bacillus anthracis	1R03TW009030-01
QVR Search	no		1	R03	TW009174-01	JIANG, XI	Abs	TW	Immune responses to Norovirus after natural infection in Vietnamese child	1R03TW009174-01
QVR Search	yes	not funded	2	D43	TW007387-07	CUMMINGS, DEREK (c	Abs	TW	Planning for avian influenza outbreaks in AI	2D43TW007387-07
QVR Search	yes		3	D43	TW007393-07S1	LESCANO, ANDRES G	Abs	TW	Peru Infectious Diseases Epidemiology R AI (not HPAI)	3D43TW007393-07S1
QVR Search	yes		3	R01	TW007869-05S5	XIAO, XIANGMING	Abs	TW	Ecology-Based Risk Assessment and Earl HPAI	3R01TW007869-05S5
QVR Search	no		5	D43	TW001038-13	HARRISON, LEE H.	Abs	TW	AIDS international Training and Research Program	5D43TW001038-13
QVR Search	no		5	D43	TW001038-14	HARRISON, LEE H.	Abs	TW	AIDS international Training and Research Program	5D43TW001038-14
QVR Search	yes		5	D43	TW007393-07	LESCANO, ANDRES G	Abs	TW	Peru Infectious Diseases Epidemiology R AI (not HPAI?)	5D43TW007393-07
QVR Search	no		5	R01	TW008126-04	ALI, SYED ASAD	Abs	TW	Burden of RSV and Influenza Virus in Children in Pakistan	5R01TW008126-04
QVR Search	no		5	R01	TW008246-04	CUMMINGS, DEREK	Abs	TW	Ecology of Infectious Diseases (EID)-Immune Landscapes of Human Influe	5R01TW008246-04
QVR Search	no		5	R03	TW008237-02	YAN, GUIYUN	Abs	TW	Insecticide Resistance in Anopheles minimus Mosquitoes	5R03TW008237-02
QVR Search	no		5	R03	TW008237-03	YAN, GUIYUN	Abs	TW	Insecticide Resistance in Anopheles minimus Mosquitoes	5R03TW008237-03
QVR Search	no		5	R03	TW008739-02	TURNER, DOUGLAS H.	Abs	TW	Folding RNA: Influenza	5R03TW008739-02
PO Added	yes		5	D43	TW008273-03	GONZALEZ, ARMANDO	Abs	TW	Veterinarian Training in Zoonotic Disease AI	
PO Added	yes		5	R01	TW005869-08	DASZAK, PETER	Abs	TW	The Ecology, Emergence and Pandemic I AI	
PO Added	yes		5	U01	TW006634-09	GERWICK, WILLIAM H	Abs	TW	ICBG: 'Training, Conservation and Drug I AI	

Source	15 select	Notes	Type	Actv	Project	PI Name(s) All	Abs	Admin IC	Title	HPAI	Note	
QVR Search	yes		1	R01	TW009502-01	DASZAK, PETER	*Abs	TW	Comparative Spillover Dynam	Yes	will not be	1R01TW009502-01
QVR Search	yes		3	R01	TW007869-05	XIAO, XIANGMING	Abs	TW	Ecology-Based Risk Assessme	yes		3R01TW007869-05
QVR Search	yes		5	D43	TW007393-07	LESCANO, ANDRES G	Abs	TW	Peru Infectious Diseases Epid	yes		5D43TW007393-07
PO Added	yes		5	D43	TW008273-03	GONZALEZ, ARMANDO	Abs	TW	Veterinarian Training in Zoon	yes		5D43TW008273-03
PO Added	yes		5	R01	TW005869-08	DASZAK, PETER	Abs	TW	The Ecology, Emergence and	yes		5R01TW005869-08
PO Added	yes		5	U01	TW006634-09	GERWICK, WILLIAM H	Abs	TW	ICBG: 'Training, Conservation	yes		5U01TW006634-09
QVR Search	yes		5	R03	TW008739-02	TURNER, DOUGLAS H.	Abs	TW	Folding RNA: Influenza	yes		5R03TW008739-02

QVR Custom Download	
Query Criteria	...IC's = TW Primary/Admin Projects Only ... Project Status = AWARDED, PENDING COUNCIL ...Fy's = 2012, 2011... Abstract/Summ Stmt/Title/ for: Avian influenza//Bacillus anthracis//anthrax//Botulinum neurotoxin//Burkholderia mallei //Burkholderia pseudomallei//Ebola//Foot-and-mouth//Francisella tularensis//Marburg//1918 Influenza//influenza// Rinderpest//Clostridium botulinum//Variola Variola minor//Yersinia pestis//yersinia//pestis//clostridium//bacillus//botulinum//burkholderia//tularensis//variola, combined with 'Or' .....Extramural Grants, Intramurals, Contracts, include Extramural Grant Subprojects
Sort Criteria	

Download Cols	Type,Actv,Project ,PI Name(s) All,Abs,Admin IC,Title

User	JESSUPC

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Instructions. In this Workbook please find four worksheets that are accessed by clicking on the tabs in the lower left labeled "Basic Info," "DURC Inventory," and "Risks and Strategies," and "Summary." For the May 17th Workshop please fill out the information requested in Tab 1 and Tab 2.

This table is for internal NIH use only. *For this Tab - Basic Info, please complete the table below. The grants and contracts listed here should be only those that are relevant to the DURC oversight policy (i.e., only those that involve any of the 15 agents or toxins covered by the DURC policy). Grants and contracts will be anaomized and given a unique identifyer by NIH OSP staff. The information in this chart will not be shared or reported as part of the DURC inventory.*

Unique Identifyer	Grant #	Contract #	Project Funding			Title	Principal Investigator	Institute or Center	Abstract
			Does the grant or contract receive funding from another institute, center, department, or agency?	Which other institute, center, department or agency?	Which funder is responsible for reporting this grant or contract as part of its DURC inventory?				
ABCD-1	5R03TW008739-02		no (but NIGMS parent awar	NIGMS	FIC for this grant;NIGMS for pare	Folding RNA: Influ	TURNER, DOU	TW	Abs
ABCD-2	3R01TW007869-05		no			Ecology-Based Risl	XIAO, XIANGM	TW	Abs
ABCD-3	5D43TW007393-07		no			Peru Infectious Dis	LESCANO, AN[	TW	Abs
	5D43TW008273-03		no			Veterinarian Train	GONZALEZ, AR	TW	Abs
	5R01TW005869-08		no			The Ecology, Emer	DASZAK, PETEI	TW	Abs
	5U01TW006634-09		no			ICBG: 'Training, Co	GERWICK, WIL	TW	Abs

Instructions. In this Workbook please find four worksheets that are accessed by clicking on the tabs in the lower left labeled "Basic Info," "DURC Inventory," and "Risks and Strategies," and "Summary." For the May 17th Workshop please fill out the information requested in Tab 1 and Tab 2.

For this Tab - DURC Inventory. List the Grant or Contract # (the information will be ananomized and given a unique identifyer).

Step 1: *Indicate which of the 15 agents/toxins are involved in each grant by inserting the number "1" in the appropriate cell. If a grant or contract utilizes more than one agent/toxin, indicate this on a separate row. See Example below.*

Step 2: *Indicate which of the 7 categories of experiments/potential consequences are likely to be associated with each agent/toxin by inserting a "1" in the appropriate cell. You can choose more than one experiment/consequence for each agent/toxin. See Example below.*

Step3: *Indicate whether the experiments involving each agent meet the definition for "Dual Use Research of Concern" by inserting a "1" in the column for Yes or No. Identify when the research was identified as DURC and briefly describe the rationale for deciding whether a project was or was not DURC.*

NOTE: ONLY STEP 1 AND STEP 2 NEED TO BE COMPLETED FOR THE MAY 17TH MEETING.

Categories of Experiments/Potential Effects

1-Enhances the harmful consequences of the agent or toxin;
2-Disrupts immunity or the effectiveness of an immunization against the agent or toxin without clinical or agricultural justification;
3-Confers to the agent or toxin resistance to clinically or agriculturally useful prophylactic or therapeutic interventions against that agent or toxin or facilitates their ability to evade detection methodologies;
4-Increases the stability, transmissibility, or the ability to disseminate the agent or toxin;
5-Alters the host range or tropism of the agent or toxin;
6-Enhances the susceptibility of a host population to the agent or toxin; or
7-Generates or reconstitutes an eradicated or extinct agent or toxin listed in Section (III.1) above.

Institute or Center	Unique Identifyer	Agent(s)/Toxin(s)																Categories of Experiments/Effects							DURC?		If DURC:		
		Avian influenza (high path)	Bacillus anthracis	Botulinum neurotoxin	Burkholderia mallei	Burkholderia pseudomallei	Ebola virus	Foot-and-mouth disease virus	Francisella tularenis	Marburg virus	Reconstructed 1918 Influenza virus	Rinderpest virus	Clostridium botulinum, toxin-producing strains	Variola major virus	Varioloa minor virus	Yersinia pestis		1	2	3	4	5	6	7	Yes	No	When was DURC Identified?	If "other" indicate which stage DURC was identified	Rationale for Deciding that a project meets the DURC definition
TW	5R03TW00873	1																											
TW	3R01TW00786	1																											
TW	5D43TW00739	1																											
TW	5D43TW00827	1																											
TW	5R01TW00586	1																											
TW	5U01TW00663	1																											
		6	0	0	0	0	0	0	0	0	0	0	0	0	0	0		0	0	0	0	0	0	0	0	0			

Instructions. In this Workbook please find four worksheets that are accessed by clicking on the tabs in the lower left labeled "Basic Info," "DURC Inventory," and "Risks and Strategies," and "Summary." For the May 17th Workshop please fill out the information requested in Tab 1 and Tab 2.

For this Tab - Risks and Strategies, describe the specific risks associated with the DURC.

Describe the proposed risk mitigation strategies identified to manage the risks associated with the DURC.

Where appropriate, indicate whether NIH has worked with any agencies or departments that are co-funding a DURC project to develop a harmonized risk mitigation strategy.

Unique Identifyer	IF DURC:		
	Specific Risks/Risk Categories	Proposed Risk Mitigation Strategies	If a grant or contract received funding from multiple agencies, have the agencies worked together to develop harmonized risk mitigation strategies?

For NIH OSP use only. NIH will compile the requested information and report aggregate numbers of grants and contracts meeting the required criteria below. By Day 90 NIH will also report a summary of risks, mitigation measures already in place that address those risks, any additional mitigation measures that have been proposed or implemented, and number of projects to which each mitigation measure would be applied.

	Report by Day 60		Report by Day 90		
Department or Agency	**Number of Grants or Contracts Using Any of the 15 Agents**	**Number of Grants or Contracts Conducting Experiments that Use Any of the 15 Agents AND Meet any of the 7 Criteria**	**Number of Grants or Contracts Containing DURC**		
			Total DURC Cases	**DURC Identified at Initial Proposal Stage**	**DURC Identified at Progress Report Stage**
NIH					

Full list:
Avian influenza virus (highly pathogenic) ***Bacillus anthracis*** **Botulinum neurotoxin** ***Burkholderia mallei Burkholderia pseudomallei*** **Ebola virus Foot-and-mouth disease virus** ***Francisella tularensis*** **Marburg virus Reconstructed 1918 Influenza virus Rinderpest virus Toxin-producing strains of** ***Clostridium botulinum*** **Variola major virus Variola minor virus*****Yersinia pestis***

Without some terms, use "OR", search awarded
Avian influenza ***Bacillus anthracis*** **Botulinum neurotoxin** ***Burkholderia mallei Burkholderia pseudomallei*** **Ebola Foot-and-mouth** ***Francisella tularensis*** **Marburg 1918 Influenza Rinderpest** ***Clostridium botulinum*** **Variola Variola minor** ***Yersinia pestis***

Avian influenza// *Bacillus anthracis* //Botulinum neurotoxin //*Burkholderia mallei* //*Burkholderia pseudomallei* //Ebola Foot-and-mouth *Francisella tularensis* Marburg 1918 Influenza Rinderpest *Clostridium botulinum* Variola Variola minor *Yersinia pestis*

Awarded,Pending,Pending Award,Pending Council,To be Paid

Jessup, Christine (NIH/FIC) [C]

From: Miller, Mark (NIH/FIC) [E]
Sent: Wednesday, May 16, 2012 10:11 PM
To: Jessup, Christine (NIH/FIC) [C]
Cc: Knobler, Stacey (NIH/FIC) [C]
Subject: Re: ACTION: DURC Inventory - Due COB Wednesday May 16

Hi Christine, we are not working in any of these areas.
Mark

On 5/15/12 7:03 AM, "Jessup, Christine (NIH/FIC) [C]" < (b) (6) wrote:

Mark,

I am representing FIC in the NIH Life Sciences Dual Use Research of Concern (DURC) inventory process. This is a multistep process to identify projects that meet the DURC definition in order to comply with the USG policy on oversight of DURC. I have attached some background slides on the policy and this inventory process.

To capture DIEPS activities, particularly those related to influenza, please list projects in the attached spreadsheet. At this stage in the inventory process, only information on the first two steps (listed below) is required. It is not necessary to determine whether a project meets the DURC definition at this time. Please complete Tab 1 and Tab 2 (Agents and Categories of Experiments/Effects only).

Please return the spreadsheet to me by COB Wednesday, May 16. If you identify no projects in Steps 1 and 2, please reply to this effect.

Step 1. Identify any projects that relate to the following select agents:

1. Avian influenza virus (highly pathogenic)
2. *Bacillus anthracis*
3. Botulinum neurotoxin
4. *Burkholderia mallei*
5. *Burkholderia pseudomallei*
6. Ebola virus
7. Foot-and-mouth disease virus
8. *Francisella tularensis*
9. Marburg virus
10. Reconstructed 1918 Influenza virus
11. Rinderpest virus
12. Toxin-producing strains of *Clostridium botulinum*
13. Variola major virus
14. Variola minor virus
15. *Yersinia pestis*

Step 2. Of the projects identified in Step 1, identify research that produces, aims to produce, or is reasonably anticipated to produce any of the listed effects:

1. Enhances the harmful consequences of the agent or toxin;

2. Disrupts immunity or the effectiveness of an immunization against the agent or toxin without clinical and/or agricultural justification;
3. Confers to the agent or toxin resistance to clinically and/or agriculturally useful prophylactic or therapeutic interventions against that agent or toxin or facilitates their ability to evade detection methodologies;
4. Increases the stability, transmissibility, or the ability to disseminate the agent or toxin;
5. Alters the host range or tropism of the agent or toxin;
6. Enhances the susceptibility of a host population to the agent or toxin; or
7. Generates or reconstitutes an eradicated or extinct agent or toxin listed above.

Please let me know if you have any questions.

Thank you,
Christine

Mark Miller, MD

Associate Director for Research
Director, Division of International Epidemiology and Population Studies
Fogarty International Center, National Institutes of Health

From: Jessup, Christine (NIH/FIC) [E]
Sent: Wed, 22 May 2013 14:02:23 +0000
To: Rosenthal, Josh P. (NIH/FIC) [E]
Subject: RE: Proposal for supplemental funding to 2R01 TW005869 (Daszak PI) for H7N9 ecology and predictive modeling.
Attachments: Unobligated balances on Fogarty grants R01 TW005869 & R56 TW009502

Josh,

I did get more information from Peter and the main issue generating what looks like a very large unobligated balance in our records is the result of a billing lag with several subcontractees with whom EHA has signed contracts and tangible obligations. One of the larger subcontracts is with ICDDR,B which has always billed EHA slowly for funds. In addition there are the subcontracts with UCLA, Oklahoma, Stanford, etc. After accounting for the subcontracts, EHA's records show a remaining balance of $86,000 which is budgeted in the awards.

I don't feel that this should be a barrier to providing a supplement to work on the H7N9, assuming we get the HHS funds (Danielle is sorting this out). Please let me know if you agree or have any other thoughts on this. I think it would be better to supplement the R56 than the R01 (they requested a supplement to the R01), and they would have to modify the scope a bit to stay within the $300k. I'll review the proposal again to identify the priority activities.

Christine

From: Rosenthal, Josh P. (NIH/FIC) [E]
Sent: Sunday, May 19, 2013 1:03 PM
To: Jessup, Christine (NIH/FIC) [E]
Subject: Fwd: Proposal for supplemental funding to 2R01 TW005869 (Daszak PI) for H7N9 ecology and predictive modeling.

Christine, I don't know if you have gotten more info and a plan n use of their carryover yet. But in the current fiscal climate it's difficult to entertain any kind of supplementary funding request if they have a large unspent balance. I am supportive of doing something on the h7 problem, but ...
J

Begin forwarded message:

From: Peter Daszak <(b) (6)
Date: May 18, 2013, 1:19:05 PM EDT
To: "'Jessup, Christine (NIH/FIC) [C]'" <(b) (6)
Cc: Aleksei Chmura <(b) (6) Tom Smith <(b) (6)
"(b) (6)' <(b) (6) "Megan Walsh" <(b) (6)
"Rosenthal, Josh P. (NIH/FIC) [E]" <(b) (6)
Subject: Proposal for supplemental funding to 2R01 TW005869 (Daszak PI) for H7N9 ecology and predictive modeling.

Dear Christine,

Please find attached a proposal signed by EcoHealth Alliance's AOR for supplemental funding entitled "Understanding the Ecology of H7N9 Avian Influenza".

We understand the fiscal constraints you are under at NIH and appreciate all your efforts to seek out potential resources for this work.

We believe that the proposed work is critical at this point to understanding why H7N9 is emerging as a new potential pandemic. This is particularly so in the light of a complete lack of ecological research on this virus. We have tried to highlight this in our brief proposal and would be happy to develop this further, either in response to any questions you or your colleagues have, or perhaps if possible via a briefing to Fogarty, or other interested parties (e.g. HHS).

We look forward to your response.

Cheers,

Peter

Peter Daszak
President

EcoHealth Alliance
460 West 34th Street – 17th floor
New York, NY 10001

(b) (6) (direct)
1.212.380.4465 (fax)
www.ecohealthalliance.org

EcoHealth Alliance integrates innovative science-based solutions and partnerships that increase capacity to achieve two interrelated goals: protecting global health by preventing the outbreak of emerging diseases and safeguarding ecosystems by promoting conservation.

From: Peter Daszak
Sent: Wed, 22 May 2013 03:43:07 +0000
To: Jessup, Christine (NIH/FIC) [E];Brown, Kasima (NIH/FIC) [E]
Cc: Aleksei Chmura;Megan Walsh;Winifred Zubin
Subject: Unobligated balances on Fogarty grants R01 TW005869 & R56 TW009502
Attachments: Summary of NIH BalancesR3.xlsx
Importance: High

Dear Christine,

Our Director of Finance, Winifred Zubin has gone through all the details of our Fogarty grants. Currently there are two open grants: RO1-TW005869 (EEID for Nipah virus in Bangladesh) and 1R56TW009502 which is the supplemental for Avian Influenza spillover. Here are our findings:

- First you should know that we have requested a no-cost extension for the R01 because the human survey work is still ongoing, so the expected end date is Summer 2014.

- From our financial records (attached excel file above), the combined remaining balances from these grants that we have not yet drawn down from NIH is $933,905. Of this amount $847,445 is already obligated by us to our sub-recipients, but not yet billed to us by them. These are real, tangible obligations because we have signed contracts on file with sub-contractees and they will already have spent most of these funds in advance, and will be billing us for this amount in full before the end of the project. Note that one of the large subcontractees is ICDDR,B. They receive just under 50% of the funds from this award, and have done substantial and high quality work scientifically (including 3 or 4 papers in the last few months). However, they are based in Bangladesh, in a government institution which has a very rigorous, but slow bureaucracy which means they always bill us slowly for funds. I hope you understand.

- The remainder is only $86,460 and is also obligated for salary, benefits and other costs, as budgeted in our proposals, which cover the period from now until the end of the grants.

- The final issue is the IRB which I forwarded to you yesterday afternoon.

The attached spreadsheet summarizes the grant balances and obligations. Please do not hesitate to email or phone me, and/or Winifred Zubin if you require any further information. Also, if you think that it is possible and advisable to draw down this obligated amount from the NIH system so that this doesn't cause any problems with our submission, please let us know if this is OK.

I look forward to hearing from you and hopefully getting this sorted out..

Cheers,

Peter

Peter Daszak
President

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EcoHealth Alliance integrates innovative science-based solutions and partnerships that increase capacity to achieve two interrelated goals: protecting global health by preventing the outbreak of emerging diseases and safeguarding ecosystems by promoting conservation.

From: Winifred Zubin
Sent: Tuesday, May 21, 2013 6:02 PM
To: Peter Daszak
Subject: Again, revised and updated: Response to NIH updated and revised

Peter –

I have prepared information on two of our open grants

RO1-TW005869 and supplements EID Nipah Bangladesh

1R56TW009502 AI Spillover

The combined remaining balances from these grants that we have not yet drawn down from NIH is $933,905
Of this amount $847,445 is not yet billed to us on sub recipient agreements, but obligated by us to them

The remaining $86,460 is salary, benefits and other costs, til end of grants,

Attached is a spreadsheet summarizing the grant balances and obligations.

Winifred Zubin
Director, Financial Operations

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Summary of Remaining Balances

		Grant Balance		Expenditure Obligations	
Grant	**RO1-TW005869 and supplements**				**EID Nipah Bangladesh**
	Balances remaining main grant	631,773			
	Balances attributed to remaining obligations on subcontracts not yet invoiced to us				
			Princeton	74,000	
			ICDDR,B	544,000	
	Other costs				
			various	13,773	
	supplement 05S2	1,090		1,090	
	supplement 08S1	32,151			
	Balances attributed to remaining obligations on subcontracts not yet invoiced to us				
			ICDDR,B	32,151	
	Total grant balance 5869			**665,014**	
Grant	**1R56TW009502**	**268,891**		**268,891**	**AI Spillover**
	Balances attributed to remaining obligations on subcontracts not yet invoiced to us				
			Stanford	38,029	
			Univ Oklahon	77,439	
			UCLA	78,874	
			ICDDR,B	35,103	
	Other costs			39,446	
	Total grant balance 9502			**268,891**	

Total grant balances	933,905
total contractual commitments	847,445
Balance for salary and expense	86,460

From: Brown, Kasima (NIH/FIC) [E]
Sent: Mon, 23 Jul 2012 08:42:41 -0400
To: 'Aleksei Chmura'
Cc: Jessup, Christine (NIH/FIC) [E];Brown, Kasima (NIH/FIC) [E]
Subject: RE: REQUESTED DOCUMENTS FOR 5R01TW005869 - 09 PI Name: DASZAK , PETER
Attachments: ACTION Public Access Compliance [5 R01 TW005869-09]
Importance: High

Good morning,

Just wanted to touch base with you regarding the IACUC and IRB approvals for the above mentioned award. Additionally, please provide an update regarding the ACTION email (attached) from the Program Officer.

Thank you,

Kasima Brown
Grants Management Specialist
FIC/OD/NIH

31 Center Drive
Building 31, Room B2C29
Bethesda, MD 20892-2220
Phone: (b) (6)
Fax: (301) 594-1211
(b) (6)

From: Aleksei Chmura [mailto (b) (6)
Sent: Thursday, June 28, 2012 2:38 PM
To: Brown, Kasima (NIH/FIC) [E]
Cc: Jessup, Christine (NIH/FIC) [E]
Subject: Re: REQUESTED DOCUMENTS FOR 5R01TW005869 - 09 PI Name: DASZAK , PETER

Kasima,

I am waiting on both and hesitate to promise 'by Monday', but very much hope to get them to you by (if not before) then.

We apologize for the delay on this and are urgently trying to get these back to you.

Many thanks,

-aleksei

Aleksei Chmura
Program Coordinator

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On 28 Jun 2012, at 14:32, Brown, Kasima (NIH/FIC) [E] wrote:

Thank you very much for your update Aleksei. Please submit the IACUC approval letter as soon as possible.

Do you also have the IRB approval for the project? I will need that documentation as well.

Thank you!

Kasima Brown
Grants Management Specialist
FIC/OD/NIH

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From: Aleksei Chmura [mailto: (b) (6)
Sent: Thursday, June 28, 2012 2:27 PM
To: Brown, Kasima (NIH/FIC) [E]
Subject: REQUESTED DOCUMENTS FOR 5R01TW005869 - 09 PI Name: DASZAK , PETER

Dear Kasima,

I am still waiting to hear back, but suspect that although we have the FWA and current IACUC with Tufts University, we are waiting on the annual and official award letter, which is only sent upon request and pertinent to this NIH award. Since we are on the cusp of US Holiday, I am afraid that this will end up taking another two weeks and do not want to promise receipt of these documents by next Monday. That said, we will do all we can to get these documents to you rapidly!

Please call me anytime ((b) (6)), if you have questions and we very much appreciate your patience.

Cheers,

-Aleksei

Aleksei Chmura
Program Coordinator
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From: Jessup, Christine (NIH/FIC) [E]
Sent: Mon, 9 Jul 2012 11:50:44 -0400
To: (b) (6)
Cc: (b) (6) Brown, Kasima (NIH/FIC) [E]
Subject: ACTION Public Access Compliance [5 R01 TW005869-09]

Dear Peter,

The NIH Public Access Policy ensures that the public has access to peer-reviewed publications arising from NIH funded research. The full text of these publications is to be made freely available in the PubMed Central database in a manner consistent with copyright law.

The following citations in your recent progress report do not include **PubMed Central IDs (PMCIDs),** which are required for you to demonstrate compliance with the policy:

8. Borer ET, Antonovics J, Kinkel LL, Hudson PJ, Daszak P, Ferrari MJ, Garrett KA, Parrish CR, Read AF & Rizzo DM. (2012). Bridging taxonomic and disciplinary divides in infectious disease. EcoHealth 8: 261-267.
9. Lo MK, *et al.* (2012) Characterization of Nipah Virus from Outbreaks in Bangladesh, 2008-2010. *Emerging Infectious Diseases* 18(2):248-255.
10. Epstein JH*, Zambriski JA, Rostal MK, Heard DJ, Daszak P. (2011) Comparison of Intravenous Medetomidine and Medetomidine/Ketamine for Immobilization of Free-Ranging Variable Flying Foxes (*Pteropus hypomelanus*). PLoS ONE 6(10): e25361. doi:10.1371/journal.pone.0025361
11. Pulliam JR, Epstein JH, Dushoff J, Rahman SA, Meehan G, Bunning M, HERG, Jamaluddin AA, Hyatt AD, Field HE, Dobson AP & Daszak P. Agricultural intensification, priming for persistence, and the emergence of Nipah virus: a lethal bat-borne zoonoses. *Journal of the Royal Society, Interface*. 2011. Doi:10.1098/rsif.2011.0223
12. AR. Sohayati, L. Hassan, S. H. Sharifah, K. Lazarus, C. M. Zaini, J. H. Epstein, N. Shamsyul Naim, H. E. Field, S. S. Arshad, J. Abdul Aziz and P. Daszak (2011). Evidence for Nipah virus recrudescence and serological patterns of captive Pteropus vampyrus. *Epidemiology and Infection*. 139, pp 1570-1579 doi:10.1017/S0950268811000550
13. Kim Halpin, Alex D. Hyatt, Rhys Fogarty, Deborah Middleton, John Bingham, Jonathan H. Epstein, Sohayati Abdul Rahman, Tom Hughes, Craig Smith, Hume E. Field, Peter Daszak and the Henipavirus Ecology Research Group. Pteropid Bats are Confirmed as the Reservoir Hosts of Henipaviruses: A Comprehensive Experimental Study of Virus Transmission. Am J Trop Med Hyg 2011 85:946-951; doi:10.4269/ajtmh.2011.10-0567
14. Smith CS, Epstein JH, Breed AC, Plowright RK, Olival KJ, de Jong C, Daszak P, Field HE. (2011). Satellite telemetry and long-range bat movements. PLoS One 6: e14696.

To comply with the policy, reply to all on this email and provide the PMCID at the end of each citation listed above. Here's help on locating the PMCID. Note that a PMCID is not the same as a PubMed ID (PMID).

- The PMCID is the *only* way to show compliance for a paper that was published more than three months ago.

- If a PMCID is not available because the paper is *in press* or was published within the last three months:
  - Indicate **"PMC Journal - In Process"** at the end of the citation if the journal will be submitting directly to PMC. (Check this list ofjournals or confirm your arrangements with these publishers to be sure.)
  - OR, provide an **NIHMSID** for a manuscript that is still in process in the NIH Manuscript Submission (NIHMS) system. (Be sure to complete the submission process promptly to obtain the PMCID!)

- If you believe the paper does not fall under the Policy, please provide a brief explanation.

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Thank you, and hope you had a pleasant July 4 holiday!

Christine

--
Christine Jessup, PhD
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