

#### **DUAL USE RESEARCH OF CONCERN (DURC)**

Principal Investigator Registration Form

#### INSTRUCTIONS FOR ELECTRONIC SUBMITTAL

You must first complete and save this form as a **pdf** file. The completed form is required to be submitted to the Institutional Review Entity (IRE) as a supporting document via Research Navigator IBC. Basic demographic information is required to be entered into the Research Navigator IBC system. Anyone can complete the form but the PI is the only person who can submit. Follow the steps below to attach and submit your completed **pdf** form.

- **1.** Login to <u>atNYULMC</u>, pull up the Research Navigator application and select "I want to view my IBC Registrations" from the tabs displayed.
- 2. You will be required to login to the IBC module with your Kerberos ID and password. After you login, at your home screen, select the **New IBC Application** button which appears on the left side of the screen. Complete the following:
  - i. Project Title (TITLE MUST BEGIN WITH THE WORD "DURC")
  - ii. Sponsor
  - iii. Submission Department
  - iv. Principal Investigator
  - v. **Do Not enter Study Staff** you should have listed them on the DURC Registration Form
  - vi. Additional team members who have EDIT rights Add name of person completing form
  - vii. Building where DURC agent(s) will be used List all
  - viii. Room number where DURC agent(s) will be used List all
  - ix. Answer "No" to "Involves Human Genome Transfer"

You will then select **Continue** on the bottom right corner of the page and complete the following entries:

3. Answer "No" to all items on the Recombinant DNA page

You will then select **Continue** on the bottom right corner of the page and complete the following:

- **4.** Answer "No" to Section D.
- **5.** Indicate in Section E that the description of the proposed research can be found in the DURC Registration form.
- **6.** Skip Section F. You will be completing it (or have already completed it) as part of your IBC application.
- **7.** Answer "No" to Section G.

You will then select **Finish** on the bottom right corner of the page.

Attach the completed DURC Registration pdf file as a Supporting Document by selecting **Add Supporting Documents** under My Activities. Once you have successfully added the form, the PI can then submit the DURC Registration form by selecting **Submit**.





Dual use research of concern (DURC) is defined as a subset of life sciences research that, based on current understanding, can be reasonably anticipated to provide knowledge, information, products, or technologies that could be directly misused to pose a significant threat with broad consequences to public health and safety, agricultural crops and other plants, animals, the environment, or national security. The **United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern** (USG Policy) describes the policies, practices, and procedures required to ensure DURC is identified and risk mitigation measures are implemented at the institutional level (<a href="http://www.phe.gov/s3/dualuse/Documents/durc-policy.pdf">http://www.phe.gov/s3/dualuse/Documents/durc-policy.pdf</a>). The **NYU Policy on Identification and Oversight of Dual Use Research of Concern** (NYU DURC Policy) has been developed to establish compliance with the USG policy and requirements.

In accordance with the NYU DURC Policy, Principal Investigators (PI) must complete and submit this registration form to the NYU Institutional Review Entity (IRE) if undertaking research with any of the agents and toxins covered by the <u>USG Policy</u> and listed in Section 3.1a of this Registration Form. This form must be submitted before initiation of research and at least annually.

PIs are also required by the NYU DURC Policy to conduct on-going DURC assessments for all research involving agents and toxins listed in Section 3. of this form. If an on-going assessment determines that a DURC potential

exists, the PI must notify the Institutional Contact for Dual Use Research (ICDUR) as soon as possible. The PI must submit an updated registration form to the IRE, of when the last registration form was submitted.

Questions regarding this form or any aspect of DURC, may be directed to the Institutional Contact for Dual Use Research (ICDUR). Additional information regarding DURC may also be obtained by contacting the Environmental Health & Safety (EH&S) office at your institution.

NYU School of Medicine EH&S: 212-263-5159 or

http://central.nyumc.org/shared/redf/eh-s/Pages/Home.aspx

NYU Washington Sq EH&S: 212-998-1450 or

http://www.nyu.edu/life/safety-health-wellness/be-safe/environmental-health-and-safety.html

Last updated: 2-7-2018 Page 1 of 8





1. Principal I	nvestigator (PI)
Name	Required Field
(Last, First, MI):	
Department	Required Field
Mailing address	
Email:	Required Field
Phone:	
Fax:	
2. Person Co	mpleting This Document (If Not the PI)
2. Person Co Name (Last, First, MI):	mpleting This Document (If Not the PI)
Name	mpleting This Document (If Not the PI)
Name (Last, First, MI):	mpleting This Document (If Not the PI)
Name (Last, First, MI): Department	mpleting This Document (If Not the PI)
Name (Last, First, MI): Department Mailing address	mpleting This Document (If Not the PI)

Last updated: 2-7-2018 Page **2** of **8** 





#### 3. Agent and Project Information

<b>3.1a</b> Do you currently use <u>or</u> possess any of the agents or toxins listed below? (Check all that apply) *Note: For purposes of the USG Policy and this registration form, there are <b>no exempt quantities</b> of Botulinum neurotoxin.		
Avian influenza virus (highly pathogenic)	Botulinum neurotoxin (any quantity)*	
Bacillus anthracis	Burkholderia pseudomallei	
Burkholderia mallei	Foot-and-mouth disease virus	
☐ Ebola virus	☐ Marburg virus	
Francisella tularensis	Rinderpest virus	
Reconstructed 1918 influenza virus	☐ Variola major virus	
Toxin-producing strains of Clostridium botulinum	☐ Variola minor virus	
	Yersinia pestis	
<b>3.1b</b> Please identify any life sciences research you contact attenuated forms of one or more of the agents or to separate DURC form for each identified research process.	onduct at this institution that involves non- xins listed in Section 3.1a above (please use a	
attenuated forms of one or more of the agents or to	onduct at this institution that involves non- xins listed in Section 3.1a above (please use a roject).  for <u>all</u> researchers conducting research with any	
attenuated forms of one or more of the agents or to separate DURC form for each identified research properties. Submission of this form is required annually of the agents and toxins listed above. If your research	onduct at this institution that involves non- xins listed in Section 3.1a above (please use a roject).  for all researchers conducting research with any arch involves none of the agents or toxins above,  th any of the agents/toxins listed in 3.1a, please circibe the status of your research. If at any time in	
attenuated forms of one or more of the agents or to separate DURC form for each identified research properties. Note: Submission of this form is required annually of the agents and toxins listed above. If your research you are not required to submit this form.  If you possess but do not have active research with state that below (in the project title section) and destructed the future, you anticipate using one of the agents list the IRE before initiating your project.  Project Title (Required Field - if you do not yet list.)	onduct at this institution that involves non- exins listed in Section 3.1a above (please use a roject).  for all researchers conducting research with any earch involves none of the agents or toxins above,  th any of the agents/toxins listed in 3.1a, please excribe the status of your research. If at any time in ested in Section 3.1a above, you will need to notify	
attenuated forms of one or more of the agents or to separate DURC form for each identified research properties. Note: Submission of this form is required annually of the agents and toxins listed above. If your research you are not required to submit this form.  If you possess but do not have active research with state that below (in the project title section) and destructed the future, you anticipate using one of the agents list the IRE before initiating your project.	onduct at this institution that involves non- exins listed in Section 3.1a above (please use a roject).  for all researchers conducting research with any earch involves none of the agents or toxins above,  th any of the agents/toxins listed in 3.1a, please excribe the status of your research. If at any time in ested in Section 3.1a above, you will need to notify	

Last updated: 2-7-2018 Page **3** of **8** 





Chealth	
3.1c Project Description (Attach additional pages, if necessary):	
3.2 Type of Funding Source(s) for This Project	
Department/institutional funds Foundation	
☐ Federal funds ☐ Business /industry ☐ Other	
IF PROJECT IS SUPPORTED WITH FEDERAL FUNDS, NAME OF FUNDING AGENCY AND GRANT OR CONTRACT NUMBER:	
<b>,</b>	
3.3 IBC REGISTRATION	
HAVE YOU REGISTERED THIS RESEARCH PROJECT WITH THE IBC?	
YES	
No	
3.4 IBC Approval #:	
3.5 IBC Approval Date:	





#### 4. Laboratory Personnel

Please list below the names of all laboratory staff and personnel (i.e., those under the supervision of laboratory leadership, including graduate students, postdoctoral fellows, research technicians, and visiting scientists) conducting research with non-attenuated forms of one or more of the agents and toxins listed in Section 3.1a of this form. Continue on a separate page if necessary. The PI and all study staff are required to complete DURC training before initiating work with Section 3.1a listed materials. Training is available for Medical Center personnel in Focus. Washington Square personnel must contact NYU EH&S (ehs@nyu.edu) to obtain training. Attach copies of the DURC training certificates for each individual listed below and submit them with this form.

Name (Last)	Name (First)	Title/Role	Email	





#### 5. Assessment of Experimental Effects

PIs are required to conduct initial <u>and</u> ongoing assessments of research involving nonattenuated forms of any of the agents and toxins listed in Section 3.1a. <u>Note:</u> Submission of this form is required annually from <u>all</u> researchers conducting research with any of the agents and toxins listed in Section 3.1a of this form.

If at any time a PI determines their research has DURC potential, the PI must immediately submit an updated form to the IRE, regardless of when the last registration form was submitted.

1.	Enhances the harmful consequences of the agent or toxin
	a. No
	<b>b.</b> Yes (please describe below)
2.	Disrupts immunity or the effectiveness of an immunization against the agent or toxin without clinical or agricultural justification
	a. No
	<b>b.</b> Yes (please describe below)

Last updated: 2-7-2018 Page 6 of 8





stability,
S

Last updated: 2-7-2018 Page **7** of **8** 





6.	Enhances the susceptibility of a host population to the agent or toxin.
	a. No
	<b>b.</b> Yes (please describe below)
7.	Generates or reconstitutes an eradicated or extinct agent or toxin listed in Section 3.2 of this form.
	a. No
	<b>b.</b> Yes (please describe below)

Questions regarding this form or any aspect of DURC, may be directed to the Institutional Contact for Dual Use Research (ICDUR). Additional information regarding DURC may also be obtained by contacting the Environmental Health & Safety (EH&S) office at your institution.

NYU School of Medicine EH&S: 212-263-5159 or

http://central.nyumc.org/shared/redf/eh-s/Pages/Home.aspx

**NYU Washington Sq EH&S:** 212-998-1450 or

http://www.nyu.edu/life/safety-health-wellness/be-safe/environmental-health-and-safety.html

Last updated: 2-7-2018 Page 8 of 8