FactSheet Dual Use Research of Concern (DURC)

All US institutions that accept federal funding from any agency are required to develop, implement, and monitor a DURC program to make sure that researchers are in compliance with the federal policy. True dual use research is rare and has been identified in a relatively few number of US laboratories thus far.

Dual Use Research of Concern (DURC) is defined in the US Government policy statement as "life sciences research 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."

The following agents and toxins as well as categories of experimentation fall under the DURC.

The Fifteen Agents and Toxins

1.	Avian influenza virus (highly pathogenic)	9.	Marburg virus
2.	*Bacillus anthracis*	10.	Reconstructed 1918 Influenza virus
3.	Botulinum neurotoxin - no exempt quantities	11.	Rinderpest virus
4.	*Burkholderia mallei*	12.	Toxin-producing strains of *Clostridium botulinum*
5.	*Burkholderia pseudomallei*	13.	Variola major virus
6.	Ebola virus	14.	Variola minor virus
7.	Foot-and-mouth disease virus	15.	*Yersinia pestis*
8.	*Francisella tularensis*		

The Seven Categories of Experiments

1. Enhances the harmful consequences of 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.
7. Generates or reconstitutes an eradicated or extinct agent or toxin listed above.

What I need to know...

- The Office of EH&S will develop and implement the DURC program in conjunction with the USC Institutional Biosafety Committee.
- Participation in DURC is facilitated through the BUA process with the IBC.

USC's DURC Program

Principal investigators at USC will find compliance support by registering their project with the USC Institutional Biosafety Committee (IBC). This is accomplished by completing a Biological Use Authorization (BUA) form on iStar. The BUA form contains the pertinent questions to identify the agents involved with DURC. If the questions are answered appropriately, the review of the project for possible DURC use will proceed quickly and smoothly. USC's responsibility whether or not DURC is instituted:

1. TRAINING for PIs and researchers that there are restrictions on the types of research that may be performed under DURC.
2. COMMITTEE must be set up to review projects that may involve DURC.
3. RESPONSIBLE PARTY identified to ensure compliance and liaise with the funding agencies.

References

DURC https://osp.od.nih.gov/biotechnology/dual-use-research-of-concern/

DURC policy http://www.phe.gov/s3/dualuse/Documents/durc-policy.pdf

DURC companion guide
http://www.phe.gov/s3/dualuse/Documents/durc-companion-guide.pdf

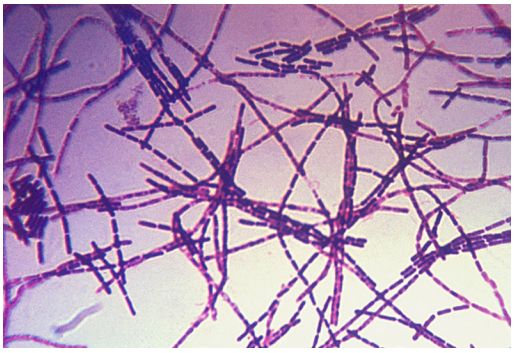
USC Environmental Health & Safety

University Park Campus
3434 South Grand Ave, CAL 120
Los Angeles, CA 90089-2815

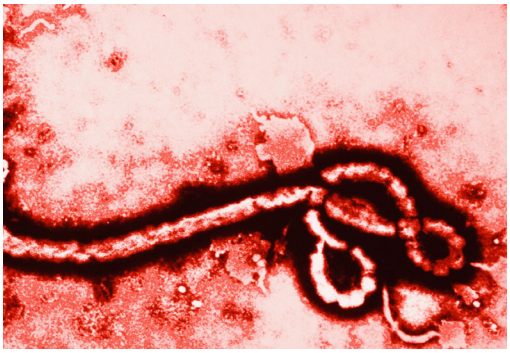
Health Sciences Campus
2001 N Soto St, SBA 329
Los Angeles, CA 90032

323.442.2200
biosafety@usc.edu
http://ehs.usc.edu

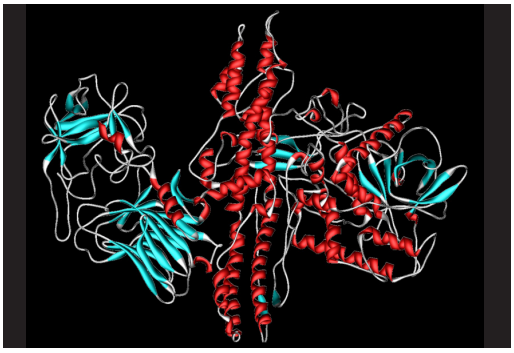
08/2018



Bacillus anthracis



Ebola virus



Botulinum toxin

Institutional Review Process Flow Chart

Process for Institutional Review of Life Sciences Research within the Scope of the Policy

PI notifies the IRE as soon as:

- PI's research involves any of the agents listed in Policy Sec. 6.2.1
- PI's research with one or more of the above agents also produces or can be reasonably anticipated to produce one or more of the effects listed in Policy Sec. 6.2.2; or
- PI's research that meets the criteria in Policy Sec. 6.2 may meet the definition of DURC.

(Policy Sec. 7.1.A; *CG* Sec.B)

If YES to any

If YES

Institution identifies whether USG funding agency has notified the institution that the research is DURC under the *March 2012 DURC Policy* (Policy Sec. 7.2.B)

If NO

IRE verifies that the research involves any of the listed agents, reviews PI's assessment, and makes final determination of the applicability of the list of experimental effects (Policy Sec. 6.2 and 7.2.B.i – ii; *CG* Sec. C)

If NO

If YES to both

Institution notifies appropriate USG funding agency of outcome within 30 calendar days (Policy Sec. 7.2.B.iv)

If YES or NO

IRE conducts a risk assessment to determine whether the research meets the definition of DURC (Policy Sec. 4.C and 7.2.B.iii; *CG* Sec. C)

If NO

If YES

The research requires oversight under the Policy: IRE considers the previously identified risks and the anticipated benefits in order to develop a draft risk mitigation plan (Policy Sec. 7.2.B.v; *CG* Sec. C and D)

Institution works with the USG funding agency to complete the draft risk mitigation plan within 90 calendar days of the IRE's determination that the research is DURC (Policy Sec. 7.2.B.v – vi; *CG* Sec. D)

USG funding agency finalizes the risk mitigation plan within 60 calendar days of receipt of the draft plan (Policy Sec. 7.2.B.vi)

Institution implements approved risk mitigation plan and provides ongoing oversight of DURC (Policy Sec. 7.2.B.vii – ix; *CG* Sec. E)

PI conducts and/or communicates research according to risk mitigation plan (Policy Sec. 7.1; *CG* Sec. F)

Key

- PI
- Institutional Review Entity
- Institution
- USG Funding Agency

CG: Companion Guide