



Administrative Procedure Chapter 12, Research
Administrative Procedure: AP 12.503, Procedure for Institutional Oversight of Life
Sciences Dual Use Research of Concern
Effective Date: September 2015
Last Revision Date: N/A
Responsible Office: Vice President for Research and Innovation
Governing Board or Executive Policy: EP 12., Institutional Oversight of Life Sciences
Dual Use Research of Concern
Review Date: August 2018

I. PURPOSE:

Description of the procedures, considerations, and requirements associated with the dual use of research concern (DURC) at the University of Hawai'i (University).

II. DEFINITIONS:

- A. "Companion Guide" means the *Tools for the Identification, Assessment, Management, and Responsible Communication of Dual Use Research of Concern: A Companion Guide to the U.S. Government Policies for Oversight of Life Sciences Dual Use Research of Concern*, prepared by the National Institutes of Health (September 2014).
- B. "Deciding Official" (DO) means the University's Vice President for Research and Innovation, or designee, who shall have authority to make final decisions on appeals from Institutional Review Entity decisions.
- C. "Dual Use Research" (DUR) is research conducted for legitimate purposes that generates knowledge, information, technologies, and/or products that can be utilized for benevolent and malevolent purposes.
- D. "Dual Use Research of Concern" (DURC) means the life sciences 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.
- E. "DURC Policies" means the *United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern* (Policy for Institutional DURC Oversight) and the *United States Government Policy for Oversight of Life*

Sciences Dual Use Research of Concern (March 2012 DURC Policy), or as superseded by later federal policies.

- F. “Extramural research” means research that is funded by a source other than the University, such as by federal grants.
- G. The “Federal Select Agent Program” oversees the possession, use and transfer of biological select agents and toxins, which have the potential to pose a severe threat to public, animal or plant health or to animal or plant products.
- H. The “Institutional Animal Care and Use Committee” (IACUC) is established by the University to provide institutional oversight and evaluation of the animal care and use program and its components.
- I. The “Institutional Biosafety Committee” (IBC) is established by the University to provide institutional oversight of recombinant DNA research (rDNA) and infectious materials.
- J. “Institutional Contact for Dual Use Research” (ICDUR) means the University’s Assistant Vice Chancellor for Research Compliance, or designee, who shall serve as an internal resource for issues regarding compliance with and implementation of the requirements for DURC oversight. The ICDUR shall also serve as the liaison (as necessary) between the University and the relevant federal funding agency, and other University offices, including, but not limited to the Office of Export Controls, Office of Research Services, and University General Counsel.
- K. The “Institutional Review Board” (IRB) is established by the University to provide institutional oversight of research protocols involving human research participants.
- L. The “Institutional Review Entity” (IRE) is established by the University to execute the requirements of this policy. Refer to Section 7.2.B.i-7.2.B.v of the *Policy for Institutional DURC Oversight* for further guidance.
- M. “Intramural research” means research that is funded by the University for its own benefit.
- N. “Listed agents” means the agents and toxins in the most current list by the National Select Agent Program.¹
- O. “Life sciences” refers 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

¹ The select agents and toxins are regulated by the Federal Select Agent Program under 7 C.F.R. part 331, 9 C.F.R. part 121, and 42 C.F.R. part 73.

- 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.
- P. The “March 2012 DURC Policy” refers to the *United States Government Policy for Oversight of Life Sciences Dual Use Research of Concern*.
 - Q. The “National Science Advisory Board for Biosecurity” (NSABB) advises all federal departments and agencies with an interest in life sciences research. The NSABB recommends specific strategies for the efficient use and effective oversight of dual use life sciences research, as well as raises awareness about the issue within the scientific community. The NSABB considers both national security concerns and the needs of the research community when providing guidance and recommendations to the federal government.
 - R. The “Office of Biotechnology Activities” (OBA), now the “Program on Biosecurity and Biosafety Policy” (PBBP), promotes science, safety and ethics in the area of Biosafety and Biosecurity, including oversight of dual use research.
 - S. The “Office of Research Compliance” (ORC) is established by the University to assure the public that research conducted throughout the University system is performed responsibly.
 - T. The “Office of Research Services” (ORS) is established by the University to provide services to facilitate the stewardship of extramural funded activities.
 - U. The “Office of Science Technology Policy” (OSTP) advises the President and others within the Executive Office of the President on the effects of science and technology on domestic and international affairs.
 - V. The “Policy for Institutional DURC Oversight” means the *United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern*.
 - W. “Principal Investigators” (PIs) are the individual(s) designated by the University of Hawaii and the granting agency to have the appropriate level of authority and responsibility to direct the project.

III. ADMINISTRATIVE PROCEDURES:

- A. The DURC Policies focus on life sciences research that involves one or more of the agents or toxins identified in the most current list from the PBBP, the Federal Select Agent Program, and the March 2012 DURC Policy from the Public Health Emergency, which pose the greatest risk of deliberate misuse with the 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.B., below, will be evaluated for DURC potential.

- B. The administrative procedures that implement EP _____ are subject to periodic review and revision. Consequently, institutional members are advised to review the University website and apply the most current version of the administrative procedures attached to this policy.
- C. Categories of experiments. As part of the screening process described in Section IV, Principal Investigators are required to assess whether their study will:
1. Enhance 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. Confer 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. Alter 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 in Section (III.A.) above.
- D. Responsibilities of the Principal Investigators (PIs).
1. PIs will conduct early and ongoing screening of their research proposals to ensure that potential issues related to DURC are addressed at the earliest stage of the research process to avoid unnecessary delays in starting funded research, including:
 2. PIs will be responsible for reporting whether other agents or toxins not specified in Section III.A., has the potential for DURC through bioengineering technologies.
 3. PIs will immediately notify the University Office of Research Services that their research proposal raises potential DURC issues (Pre-award Notice).
 4. Work with the IRE to develop risk mitigation measures where appropriate. The criteria for developing a risk mitigation plan is contained in Section IV.B.5.
 5. Conduct DURC activities in accordance with the provisions in the risk mitigation plan.

6. Be knowledgeable about and comply with all institutional and federal policies and requirements for oversight of DURC.
 7. Ensure that laboratory personnel conducting life sciences research that falls within the scope of this policy (i.e., those under the supervision of laboratory leadership, including graduate students, postdoctoral fellows, research technicians, laboratory staff, and visiting scientists) have received education on DURC.
 8. Communicate DURC in a responsible manner. Communication of research and research findings is an essential activity for all researchers, and occurs throughout the research process, not simply at the point of publication. When researchers are planning to communicate DURC, it is their duty to ensure that it is done in a responsible manner, and in compliance with any risk mitigation plan stipulated by the IRE.
 9. Non-compliance with the policies and procedures set forth in EP ____ and AP _____, respectively, may subject PIs to review under the University's research and scholarly misconduct or University misconduct policies and procedures.
- E. Responsibilities of the IBC and IRE in conducting the Dual Use Review.
1. Purpose. The IRE is responsible for executing the requirements of the Review Criteria, below. The formal review process involves the IBC acting as a screening committee, followed by the IRE review process conducted in two stages.
 2. IBC Screening of Applications.
 - a. PIs will exercise good faith in determining whether any of the biological agents or toxins from the sources listed in Section III.A., above, are involved in the study.
 - b. If the answer is "yes," PIs will respond to each of the seven screening questions in Section III.B.
 3. Review by IRE.

If the answer to any of the screening questions is "yes," the IBC, IRB, or IACUC office will forward the research protocol to the IRE, which will review the proposal in two stages:

Stage 1: The IRE will establish a DUR Review Sub-Committee to conduct the preliminary assessment of the research and determine whether it falls under DURC or not. If the DUR Review Sub-Committee determines that the research falls under DURC, then the research will be referred to the full IRE Committee. If not, the DUR Review Sub-

Committee will determine any necessary management plan for the ongoing monitoring of the research project.

Stage 2: If a research project is considered as DURC, the full IRE Committee will conduct a review according to established criteria.

In the cases where a PI is conducting potential DURC at multiple institutions, each institution is responsible for reviewing these projects and if DURC is being conducted at the University, the IRE will develop and implement a risk mitigation plan, as appropriate.

4. Review Criteria. When research is identified by a PI as utilizing one of the agents or toxins from the sources listed in Section III.A., the IRE shall initiate an institutional oversight process that includes:
 - a. Verification that research utilizes one or more of the agents or toxins from the sources listed in Section III.A.;
 - b. Determination of whether the research produces, aims to produce, or is reasonably anticipated to produce one or more of the effects listed in IBC questionnaire;
 - c. Determination of whether the research meets the DURC definition (Section II) and is therefore DURC. If the IRE determines that the research in question does not fall within the scope of Section 6.2.2 of the *Policy for Institutional DURC Oversight*, or does not meet the definition of DURC, the research can continue without additional DURC oversight;
 - d. Assessment of the dual use risks and the benefits of the research;
 - e. Development of a risk mitigation plan for DURC, as necessary, following the criteria described in Section IV.B.5., below;
 - f. Implementation of the risk mitigation plan. After a risk mitigation plan is developed, the research must be conducted in accordance with that plan and must be periodically reviewed by the institution to determine if additional modifications to the risk mitigation plan are appropriate. For research that has been proposed but not yet initiated, the DURC component of the project should not be initiated until a risk mitigation plan is implemented;
 - g. Within thirty (30) calendar days of the institutional review of the research for DURC potential, the federal funding agency shall be notified of any research that falls within the scope of Section III.A, including whether it meets or does not meet the definition of DURC. For non-federally funded research, notification may be made to NIH (who may in turn notify the appropriate Federal funding agency, based upon the nature of the research);

- h. Within thirty (30) calendar days from the date the University determines the research to be DURC, the IRE shall notify the University ORS and provide a copy of the risk management plan.
 - i. Within ninety (90) calendar days from the time that the University determines the research to be DURC, provision of a copy of the risk mitigation plan to the funding agency for review – or for non-federally funded research, provision of the plan to NIH for review (or referral to the appropriate funding agency).
5. Risk mitigation plan criteria. A risk mitigation plan may include, but not be limited to, the following criteria:
- a. Modifying the design or conduct of the research.
 - b. Applying specific or enhanced biosecurity or biosafety measures.
 - c. 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.
 - d. Referring the University, PIs, and committee members to available DURC educational tools, including, but not limited to:
 - 1) Office of Biotechnology Activities:
<http://oba.od.nih.gov/biosecurity/biosecurity.html>
 - 2) *Companion Guide* (September 2014):
<http://www.phe.gov/s3/dualuse/Documents/durc-companion-guide.pdf>
 - 3) Biosafety, NIH Guidelines:
<http://osp.od.nih.gov/office-biotechnology-activities/biosafety/nih-guidelines>
 - 4) Select Agent Regulations:
<http://www.selectagents.gov/SelectAgentsandToxinsList.html>
 - e. Regularly reviewing, at the University level, emerging research findings related to DURC, including educational tools that may be revised by or superseded by future DURC resources.
 - f. Requesting that institutions notify funding departments or agencies if additional DURC is identified, and propose modifications to the risk mitigation plan, as needed.

- g. Determining the venue and mode of communication (addressing content, timing, and possibly the extent of distribution of the information) to communicate the research responsibly.
- h. IRE review of annual progress reports from PIs to determine if DURC results have been generated, and if so, flagging them for University attention and applying potential mitigation measures as described above, as necessary.
- i. 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:
 - 1. Request voluntary redaction of the research publications or communications;
 - a. Departments and agencies may consider whether to refer classified research to another department or agency for funding.
 - 2. Not provide or terminate research funding.²

Each research proposal that is categorized as DUR or DURC is different and poses unique issues related to the implications of the information, materials, or technologies that may result from the research. Therefore, it is not possible to develop a single review process that can be used for all cases. The NSABB has developed a toolkit for such reviews that provides guidance for a comprehensive process. The University's IRE will perform its review based on these guidelines.

F. IRE Membership.

- 1. The IRE shall consist of members of the IBC, with the addition of ad hoc members having sufficient breadth of expertise to assess the dual use potential of the range of relevant life sciences research conducted at the University, including, but not limited to members with experience in microbiology. Other faculty and staff with knowledge or expertise and/or non-affiliated institutional experts may also be considered and asked to contribute to the DURC assessments on a case-by-case basis
- 2. The Chair of the IBC, the scientific representatives from the scientific community, and safety specialist(s) will form the DUR sub-committee conducting the Stage 1 review.
- 3. The Chair of the IBC shall serve as Chair of the IRE.
- 4. The IRE shall consist of individuals who are not involved in the research project in question or have a direct financial interest, except to provide specific

² The University does not engage in classified research.

information requested by the review entity. The IBC Chair shall determine whether a conflict exists.

G. Meetings and Minutes.

1. The full IRE will hold regularly scheduled meetings at least once a quarter to review the status of DURC at the University, review the latest recommendations of NSABB or other advisory or regulatory bodies, and determine whether any modifications to the oversight program are required.
2. The IRE will maintain minutes of its deliberations and communicate its management recommendations for oversight to the PI and IBC in writing.
3. The IRE will develop a strategy to post the minutes of its meetings and decisions online in a manner that does not compromise security.

H. Meetings with PIs.

1. The DURC Review Sub-Committee will schedule meetings, as necessary, when the preliminary questionnaire in the IBC application indicates that a study might be subject to DURC review, or if the IBC refers a study that potentially has DURC issues.
2. The IRE will also review and advise the PI if their prescreening during the proposal development indicates there might be DUR issues.

I. Responsibilities of the Institutional Contact for Dual Use Research (ICDUR).

1. The University shall designate an ICDUR to serve as an internal resource for issues regarding compliance with and implementation of the requirements for the oversight of research that falls within the scope of Section III and/or meets the definition of DURC.
2. If questions arise regarding compliance with the DURC Policies, or when guidance is needed about identifying DURC or developing risk mitigation plans, the ICDUR serves as the liaison (as necessary) between the University and the relevant program officers at the federal funding agencies, or for non-federally funded research, between the University and NIH (or the appropriate federal funding agency to which NIH refers the University).
3. The ICDUR shall also serve as the liaison (as necessary) between other University offices, including, but not limited to the Office of Export Controls, ORS, and University General Counsel.

J. Consultation with the federal Funding Agency.

The University may consult with the federal department or agency that is funding the research in question for advice on matters related to DURC. Such consultations should involve the ICDUR. The funding agency program officers can provide guidance on DURC issues. Questions regarding non-federally funded research can be directed to the NIH or to the federal funding agency to which NIH refers the institution based on the nature of the research in question. Consultation with the funding agency is not mandatory or intended as a substitute for institutional dual use review or the reporting requirements (see Section IV.B.2., above). Such consultations may be appropriate when:

1. The IRE requires guidance on developing an adequate risk mitigation plan in cases where the potential risks are perceived as particularly high;
2. The IRE considers the only viable risk mitigation measure to be not conducting or not communicating the research in question;
3. The PI does not agree with the finding of the IRE and so the University would like to request outside advice;
4. The research in question represents a particularly complex case or appears to fall outside the current definition of DURC, but still seems to present significant concerns; or
5. Guidance is required to ensure a clear understanding of how the federal government interprets the definition of DURC and related terms.

K. University duties and responsibilities.

1. Provide education on DURC for individuals conducting life sciences research that falls within the scope of this Policy. The University shall maintain records of personal education on dual use research for three years.
2. Report instances of noncompliance with this Policy, as well as mitigation measures undertaken by the University to prevent recurrence of similar noncompliance, within thirty (30) calendar days to the federal funding agency or, for non-federally funded research, to NIH on behalf of all the University's federal funders.
3. Provide additional review and oversight when questions arise.
4. Appeals from IRE decisions.
 - a. Any PI seeking to challenge the IRE's decisions shall file a notice of appeal with the Chair of the IBC within thirty (30) calendar days of the IRE decision.
 - b. The PI shall have thirty (30) calendar days from the date of filing the notice of appeal to submit a written statement to the Deciding Official identifying

alleged points of error on the part of the IRE with supporting arguments and references to the record of the proceeding before the IRE.

- c. The PI shall have access to the record of the IRE proceeding subject to the reasonable conditions imposed by the Chair of the IBC (e.g., time, place, and manner). The PI may not introduce new information or evidence.
 - d. The University shall have thirty (30) calendar days to submit a written statement in response to the PI's written statement.
 - e. The University has the burden of proof in upholding the IRE decision as accurate and complete.
 - f. The standard of proof to overturn the IRE decision is by a preponderance of the evidence.
 - g. The Deciding Official shall render a decision within thirty (30) calendar days, together with recommendations as appropriate. The decision shall be final and binding on the PI and the University, and incorporated into the record of the proceeding. Copies of the decision shall be forwarded to the PI, the IRE, and to the University ORC.
 - h. The record on appeal shall be forwarded to the University ORC and maintained for a period of seven (7) years.
5. Provide annual formal assurances to NIH regarding the following:
- a. The University has written policies and procedures for conducting a DUR and DURC assessment.
 - b. In fostering a research environment that promotes the responsible conduct of research, the University shall provide education on DURC.
 - c. The University shall provide annual formal assurances.

IV. DELEGATIONS OF AUTHORITY:

There is no administrative procedure specific to delegation of authority.

V. CONTACT INFORMATION:

Office of the Vice President for Research and Innovation, telephone number: [\(808\) 956-4740](tel:8089564740); and email lgouveia@hawaii.edu may be contacted for information relating to this Executive Policy.

Office of Research Compliance, John Galland, Assistant Vice Chancellor for Research Compliance, telephone number: (808) 956-9585; and email jgalland@hawaii.edu

V. REFERENCES:

To assist the University and PIs in identifying, assessing, and appropriately managing DURC, the following resources are available:

A. Federal Regulatory and Policy Guidelines.

Federal Select Agent Program, (7 C.F.R. part 331, 9 C.F.R. part 121, and 42 C.F.R. part 73), see <http://www.selectagents.gov/index.html> and <http://www.selectagents.gov/Regulations.html>

United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern (Policy for Institutional DURC Oversight), see <http://www.phe.gov/s3/dualuse/Documents/oversight-durc.pdf>

United States Government Policy for Oversight of Life Sciences Dual Use Research of Concern (March 2012 DURC Policy), see <http://www.phe.gov/s3/dualuse/documents/us-policy-durc-032812.pdf>

National Institute of Health, Office of Science Policy, OBA Topics, see <http://osp.od.nih.gov/office-biotechnology-activities/biosafety/biosafety-guidance>

B. Guidance Documents for DURC Oversight.

The United States Government has developed a compendium of tools to assist investigators and research institutions in the implementation of DURC oversight outlined in the DURC Policies. These tools will aid in the understanding and identification of DURC, the risk assessment and development of risk mitigation plans and risk management processes, the responsible communication of DURC, and education on DURC. These tools include the following:

Tools for the Identification, Assessment, Management, and Responsible Communication of Dual Use Research of Concern: A Companion Guide to the United States Government Policies for Oversight of Life Sciences Dual Use Research of Concern, see <http://www.phe.gov/s3/dualuse/Documents/durc-companion-guide.pdf>

Implementation of the U.S. Government Policy for Institutional Oversight of Life Sciences DURC: Case Studies, see <http://www.phe.gov/s3/dualuse/Documents/12-case-studies-durc.pdf>

Training on the US Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern (DURC), see <http://www.phe.gov/s3/dualuse/Documents/durc-us-policy-trng.pdf>

Dual Use Research: A Dialogue (video), see <http://osp.od.nih.gov/office-biotechnology-activities/biosecurity/dual-use-research-of-concern/dialogue>

NIH Guidelines, see <http://osp.od.nih.gov/office-biotechnology-activities/biosafety/nih-guidelines>