Dual Use Research of Concern
Institutional Review Entity (IRE)
Standard Operating Procedures

Contents

1 Institutional Review Entity

1.1 Policy

The Institutional Review Entity (IRE) application requirements (see procedure below) are applicable to all faculty, staff, students, and users of the facilities of this University who propose and conduct research involving biological agents and toxins, *regardless of source of funding.*

The SBU website for DURC provides links to the current IRE membership roster, meeting dates, submission deadlines, and links to institutional policies and procedures, and other information relevant to the compliant conduct of research at Stony Brook University (SBU).

This institution has an Institutional Review Entity (IRE) whose responsibilities include review of research involving biological agents and toxins. The IRE is in compliance with the requirements of the United States Government Policy for Oversight of Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential.

The IRE is administered by the Office of Research Compliance, within the Office of Research and Innovation. The institutional official responsible for oversight of the IRE is the Vice President for Research (VPR), who delegates this responsibility to the Assistant Vice President for Research Compliance.

1.2 Definitions

For the purpose of this policy, the following terms are defined:

"*Biological agents*" are any microorganism (including, but not limited to, bacteria, viruses, fungi, or protozoa), infectious material, or any naturally occurring, bioengineered, or synthesized component of any such microorganism or infectious material, capable of causing:
• Death, disease, or other biological malfunction in a human, an animal, a plant, or another living organism;
- Deterioration of food, water, equipment, supplies, or material of any kind; or
- Deleterious alteration of the environment.

"*Biosafety*" is the application of practices, controls, and containment infrastructure that reduces the risk of unintentional exposure to, contamination with, release of, or harm from pathogens, toxins, and other associated biological materials.

"*Biosecurity*" is the application of security measures designed to prevent the loss, theft, misuse, diversion, unauthorized possession or material introduction, or intentional release of pathogens, toxins, biological materials, and related information and/or technology.

"*Dual use research*" is research conducted for legitimate purposes that generates knowledge, information, technologies, and/or products that can be utilized for benevolent or harmful purposes.

"*Dual use research of concern (DURC)*" is life sciences research that, based on current understanding, can be reasonably anticipated to provide knowledge, information, products, or technologies that could be misapplied to do harm with no, or only minor, modification to pose a significant threat with potential consequences to public health and safety, agricultural crops and other plants, animals, the environment, materiel, or national security.

"Federal funding agency" is a federal department, agency, institute, center, or office that funds or sponsors intramural or extramural research at research institutions in the United States or internationally, with biological agents or toxins where the research is within Category 1 or Category 2 under this policy.

"*Institutional Contact for Dual Use Research (ICDUR)*" is the official designated by the research institution to serve as an internal resource for application of this Policy as well as the liaison (as necessary) between the institution and the relevant federal funding agency. The ICDUR for Stony Brook University is the AVP Research Compliance

"*Institutional review entity (IRE)*" is the entity established by the research institution to execute the institutional oversight responsibilities.

"*Life sciences*" is the study or use of living organisms, viruses, or their products, including all disciplines, methodologies, and applications of biology (including biotechnology, genomics, proteomics, bioinformatics, and pharmaceutical and biomedical research and techniques).

"*Pathogen with enhanced pandemic potential (PEPP)*" is a type of pathogen with pandemic potential (PPP) resulting from experiments that enhance a pathogen's transmissibility or virulence, or disrupt the effectiveness of pre-existing immunity, regardless of its progenitor agent, such that it may pose a significant threat to public health, the capacity of health systems to function, or national security. Wild-type pathogens that are circulating in or have been recovered from nature are not PEPPs but may be considered PPPs because of their pandemic potential. Experiments that enhance a pathogen's transmissibility (include those that enhance environmental stability of the pathogen or toxin or change the tropism or host range of the pathogen or toxin in a way that enables an increased ability to infect and transmit between humans, among others.)

"*Pathogen with pandemic potential (PPP)*" is a pathogen that is likely capable of wide and uncontrollable spread in a human population and would likely cause moderate to severe disease and/or mortality in humans. Pathogens with pandemic potential are often those with little to no pre-existing immunity in the human population.

"*Principal investigator*" (PI) is the senior/key person seeking or receiving federal research and development funding (i.e., extramural funding). This includes researchers at federal agency laboratories and facilities, as well as researchers at government-owned, contractor-operated laboratories and facilities (i.e., intramural researchers, whether or not federally employed). There may be more than one PI on a research grant or project within a single or multiple institution(s).

"*Reasonably anticipated*" describes an assessment of an outcome such that, generally, individuals with scientific expertise relevant to the research in question would expect this outcome to occur with a non-trivial likelihood. It does not require high confidence that the outcome will definitely occur but excludes experiments in which experts would anticipate the outcome to be technically possible, but highly unlikely.

"*Research institution*" is any academic institution, corporation, company, partnership, society, association, firm, sole proprietorship, government agency, or other legal entity that conducts life sciences research.

1.3 Submission of Application

Stony Brook University uses the MyResearch Safety electronic system for the IRE submission process. Submission via MyResearch Safety of an IRE application, completion of the "Safety" "smart" form, and grant application (if external funding exists or is being sought) is required for all experiments***.***

- First time submissions, continuing reviews/progress reports, amendments and annual continuing reviews/progress reports where significant changes to protocol detail or design are proposed (determined by the Office of Research Compliance (ORC) in consultation with the IRE Chair) will be reviewed at a convened meeting of the IRE consisting of a quorum of members. Action will be determined by a simple majority of votes. Board actions, which are uploaded in MyResearch Safety, may include:
  - Approved: accepted as submitted.
  - Modifications Required: consist of requiring additional information or investigator concurrence as to required changes and providing applicable uploaded revisions.
  - Deferral: consists of requiring substantive response from the investigator; response must come back to the committee for review at a convened meeting.
  - Disapproval: no revision to the study would permit the possibility of approval.

Once approved, an activity is valid, as written, for a maximum of one year. No changes may be made to the approved activity unless prior approval is first granted by the IRE. Following the review, the IRE Administrator will notify the Principal Investigator of the results of the IRE's review and approval.

Minor, administrative amendments to IRE-approved studies, and studies that are undergoing continuing review for the first or second time with no changes or only personnel changes, are administratively reviewed and an approval is issued by the Office of Research Compliance on

behalf of the IRE, pending confirmation from the Principal Investigator that Environmental Health and Safety (EHS) training requirements are met. Minor, non-administrative amendments are reviewed and approved by the IRE chair.

It is the PI's responsibility to maintain continued approval. Courtesy renewal e-reminders are sent in MyResearch Safety at three (3) months, and again at two (2) months before study expiration. During inspections the EHS Biological Safety Officer requires that the approval letter from the Institutional Review Committee (IRE) be posted. Thus, study team members are fully aware of the study expiration date. If the study approval expires, the activity must stop until approval is re-issued by the IRE.

The completion or termination of the study, is a change in activity and should be reported to the IRE via the electronic management system. A final report to the IRE allows it to close its files as well as provides information that may be used by the IRE in the evaluation and approval of related studies.

Any significant problems, or any significant research related accidents and illnesses relating to Category 1 and/or Category 2 Research

- Breaches in biosafety during the conduct of an activity
- Research that is not covered by an approved IRE protocol.
- Research previously approved by the IRE, that is conducted during a lapsed IRE approval.

Upon receipt of the above report, the IRE Chair and BSO will take any or all of the following actions, depending on the incident:

- Initiate steps to mitigate the incident.
- Initiate an investigation to obtain details of the incident.
- Notify and consult with appropriate SBU officials as deemed necessary.
- Where there have been overt exposures to biosafety level 2 or higher and/or potential exposures at biosafety level 3 or higher, the incident will be reported immediately to NIH/OSP.

The IRE Chair will report to the IRE on the matter either by special meeting or at the regular monthly meeting. The IRE may require an additional investigation, explanation, a corrective action plan, suspend and/or terminate IRE approval, and/or other actions deemed necessary given the known details of the incident.

The IRE will determine if the incident requires a report to OSP (via the Incident Reporting template [https://osp.od.nih.gov/biotechnology/nih-guidelines/]). The relevant chair and dean will be copied on this report. The IRE will consider the OSP Guidance on determining if incidents are reportable.

Reports to other agencies:

- Any incidents that include the use of **Biological Select Agents and Toxins** (BSAT) will be immediately reported by the Bio-Safety Officer to the BSAT Responsible Official (RO) in EHS. Coordination of reports to Center for Disease Control and other agencies for BSAT materials is the responsibility of the Responsible Official.

1.4 Category 1 and Category 2 Research

This policy expands the scope of research previously overseen by those policies. Category 1 research is subject to oversight by research institutions and federal funding agencies, and Category 2 research is subject to oversight by research institutions, federal funding agencies, and their federal department if applicable due to heightened potential for biosafety and biosecurity risks.

NOTE: Any research that meets the definition of both Category 1 and Category 2 research is designated as Category 2 research.

1.4.1 Category 1 Research

Category 1 research meets three criteria: (1) it involves one or more of the biological agents and toxins specified below; (2) it is reasonably anticipated to result, or does result, in one of the experimental outcomes specified below; and (3) based on current understanding, the research institution and/or federal funding agency assesses that the research constitutes DURC.

1.4.1.1 Biological Agents and Toxins within Scope of Category 1 Research

- All Select Agents and Toxins listed in 9 CFR 121.3–121.4, 42 CFR 73.3–73.4, and 7 CFR 331.3 and regulated by USDA and/or HHS.
- All Risk Group 4 pathogens listed in Appendix B of the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines)* - Classification of Human Etiologic Agents on the Basis of Hazard.
- A subset of Risk Group 3 pathogens listed in Appendix B of the *NIH Guidelines* - Classification of Human Etiologic Agents on the Basis of Hazard.
  NOTE: As of the time of release of this Policy, this subset consists of all RG3 pathogens except HIV, HTLV, SIV, Mtb (including mycobacterium bovis), Clade II of MPVX viruses unless containing nucleic acids coding for clade I MPVX virus virulence factors, vesicular stomatitis virus, Coccidioides immitis, C. posadasii, Histoplasma capsulatum, and H. capsulatum var. duboisii. This list may be updated in the Implementation Guidance on a periodic basis.
- For biological agents affecting humans that have not been assigned a Risk Group in the *NIH Guidelines*, refer to the current edition of Biosafety in Microbiological and Biomedical Laboratories (BMBL). In such cases, agents affecting humans that are recommended to be handled at Biosafety Level 3 (BSL-3) or Biosafety Level 4 (BSL-4) per the BMBL guidance are subject to this Policy.

- Biological agents added during future updates to the Implementation Guidance as specified in.

1.4.1.2 Category 1 Research Experimental Outcomes

Research within the scope of Category 1 are those experimental outcomes with a biological agent or toxin outlined in Section 4.1.1 that are reasonably anticipated to:

i Increase transmissibility of a pathogen within or between host species;
ii Increase the virulence of a pathogen or convey virulence to a non-pathogen;
iii Increase the toxicity of a known toxin or produce a novel toxin;
iv Increase the stability of a pathogen or toxin in the environment, or increase the ability to disseminate a pathogen or toxin;
v Alter the host range or tropism of a pathogen or toxin;
vi Decrease the ability for a human or veterinary pathogen or toxin to be detected using standard diagnostic or analytical methods;
vii Increase resistance of a pathogen or toxin to clinical and/or veterinary prophylactic or therapeutic interventions;
viii Alter a human or veterinary pathogen or toxin to disrupt the effectiveness of preexisting immunity, via immunization or natural infection, against the pathogen or toxin; or
ix Enhance the susceptibility of a host population to a pathogen or toxin.

1.4.1.3 Category 1 Risk Assessment

Based on current understanding, the research can be reasonably anticipated to provide, or does provide, knowledge, information, products, or technologies that could be misapplied to do harm with no — or only minor — modification to pose a significant threat with potential consequences to public health and safety, agricultural crops and other plants, animals, the environment, material, or national security.

1.4.2 Category 2 Research

Category 2 research meets three criteria: (1) it involves, or is reasonably anticipated to result in, a PPP; (2) it is reasonably anticipated to result in, or does result in, one or more specific experimental outcomes or actions; and (3) based on current understanding, the research institution and/or federal funding agency assesses that the research is reasonably anticipated to result in the development, use, or transfer of a PEPP or an eradicated or extinct PPP that may pose a significant threat to public health, the capacity of health systems to function, or national security.

1.4.2.1 Biological Agents within Scope of Category 2 Research

Research within the scope of Category 2 are those experimental outcomes or actions with a pathogen that are reasonably anticipated to:

i Enhance transmissibility of the pathogen in humans;

ii Enhance the virulence of the pathogen in humans;
iii Enhance the immune evasion of the pathogen in humans such as by modifying the pathogen to disrupt the effectiveness of pre-existing immunity via immunization or natural infection; or
iv Generate, use, reconstitute, or transfer an eradicated or extinct PPP, or a previously identified PEPP.

A PPP, or any pathogen that will be modified in such a way that is reasonably anticipated to result in a PPP.

1.4.2.2 Category 2 Risk Assessment

The research can be reasonably anticipated to result in the development, use, or transfer of a PEPP or an eradicated or extinct PPP23 that may pose a significant threat to public health, the capacity of health systems to function, or national security.

1.5 Responsibilities of the Principal Investigator

- Be knowledgeable about and comply with or follow all applicable institutional and U.S. government policies, requirements, and regulations for oversight of biological agent
- Assess their research at the proposal stage, and continuously throughout the research lifecycle, to identify whether there is research reasonably anticipated to be within scope of Category 1 (i.e., that (1) includes one or more of the agents of interest, and (2) is reasonably anticipated to result in one or more of the experimental outcomes of interest; or within scope of Category 2 (i.e., that (1) involves, or is reasonably anticipated to result in, a PPP, and (2) is reasonably anticipated to result in one or more of the experimental outcomes or actions of interest).
- Following identification of potential Category 1 or Category 2 research, notify the federal funding agency and research institution, refer the research to an appropriate IRE, and be prepared to develop a risk-benefit assessment and a risk mitigation plan.
- Work with the IRE to assess the risks and benefits of the proposed research and submit the risk-benefit assessments and draft risk mitigation plan for Category 1 or Category 2 research to the federal funding agency for review and approval when appropriate.
  NOTE: If research is being proposed as part of a new funding proposal, submit the risk-benefit assessments and draft risk mitigation plan to the federal funding agency for review and approval following scientific merit review.
- If the research is being funded under an existing funding mechanism but has not yet been reviewed by the federal funding agency, then submit the risk-benefit assessments and draft risk mitigation plan to the federal funding agency for approval before conducting such work.
- If research is first identified as potentially within scope of Category 1 or Category 2 during the course of experimentation, halt further work and work with the IRE to develop the risk-benefit assessment and risk mitigation plan for submission to the federal funding agency for further review and approval to continue.

- Conduct Category 1 and Category 2 research in accordance with the provisions identified in the risk mitigation plan approved by the federal funding agency.
- Provide annual progress reports for Category 1 research and semiannual progress reports for Category 2 research, and as requested by the federal funding agency (e.g., as part of terms and conditions of award or risk mitigation plans), for review, evaluation, assessment, and, where necessary, clarification or confirmation.
- Ensure that laboratory personnel conducting life sciences research 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) are properly trained and supervised.

1.5 IRE Membership

- Be composed of at least five members (Includes one member who is familiar with the organization's policies and procedures);
- Be sufficiently empowered by the research institution to ensure the research institution's research oversight policies are followed;
- Have sufficient breadth of expertise, to include biosafety and biocontainment expertise, to assess the applicability of the range of relevant life sciences research conducted at a given research institution and understand biosafety and biosecurity implications of such research.

Meetings are held on the fourth Tuesday of the month. Members are expected to attend in person or via video conference call. Attendance of the following members is required for a meeting to occur:

- Member representing genetics/microbiology
- Member representing animal resources
- Member representing the community (unaffiliated member)
- Member representing biosafety

Meeting minutes will be reviewed and confirmed by the Chair of the Institutional Review Committee. Minutes will contain the date and place of the meeting, whether minutes of the prior meeting were approved, individuals in attendance, whether and why the meeting was open or closed, all major motions, major points of discussion and the committee's rationale for particular decisions, documenting that the IRE has fulfilled its review and oversight responsibilities.

1.6 IRE Training

New IRE members will review the following documents:

- IRE Standard Operating Procedures

Institutional Review Committee members are required to take the Collaborative Institutional Training Initiative (CITI) Dual Use Research of Concern (DURC) member training. The course must be retaken every 3 years.

1.7 IRE Responsibilities

- Have knowledge of PPPs, PEPPs, dual use concerns, and related institutional and U.S. government policies;
- Understand risk assessment and risk management considerations, including awareness of a variety of risk mitigation measures and that designating research as Category 1 or Category 2 research does not necessarily mean the research should not be conducted or communicated;
- Make its procedures for reviewing life sciences research for Category 1 or Category 2 research accessible to the public. The publicly available policies of the institution should include an overview of the institution's procedures or review process, but need not include details of particular cases or the minutes of the IRE's proceedings, or specifics of the mitigation plan(s);
- On a case-by-case basis, recuse any member of an IRE who is involved in the research project in question or has a direct financial interest, except to provide specific information requested by the review entity;
- Engage in an ongoing dialogue with the PI of the research in question when developing appropriate risk mitigation plans; and
- Maintain records of institutional Category 1 and Category 2 research reviews and completed risk mitigation plans for at least three years after the completion of the funded project unless a longer period is required by law or regulation.
- Conduct an institutional oversight process by an IRE when a PI makes an initial assessment that research may constitute Category 1 or Category 2. The IRE will then:
    - Assesses whether the research is within scope of Category 1 or Category 2 by determining:
        - For Category 1, whether the research (1) includes one or more of the agents specified; (2) is reasonably anticipated to result in one or more of the experimental outcomes; and (3) constitutes DURC and
        - For Category 2, whether the research (1) involves, or is reasonably anticipated to result in, a PPP; (2) is reasonably anticipated to result in one or more of the experimental outcomes or actions; and, (3) is reasonably anticipated to result in the development, use, or transfer of a PEPP or an eradicated or extinct PPP that may pose a significant threat to public health or the capacity of health systems to function.
    - If the IRE determines that the research in question does not meet the definition of Category 1 or Category 2 research, the IRE should communicate this determination to the federal funding agency. This research is not subject to additional review or oversight under this Policy, unless the federal funding agency, while reviewing the IRE's determination, determines otherwise. In these cases, the research should continue to be managed throughout the research life cycle;
- Work with the PI to conduct a risk-benefit assessment and develop a risk mitigation plan for Category 1 or Category 2 research, as necessary;

- Ensure that the federal funding agency is notified and a risk mitigation plan is reviewed, approved, and implemented prior to the initiation of the proposed Category 1 or Category 2 research;
- Assist with and oversee the implementation of the risk mitigation plan. The research should be conducted in accordance with the approved risk mitigation plan and should be periodically reviewed by the research institution to determine if additional modifications to the risk mitigation plan are appropriate;
- Evaluate the risk mitigation plan at least annually (a shorter mitigation plan review cycle may be elected, especially for Category 2 research) and modify it as necessary for the duration of the research. Institutions are responsible for ensuring that the research is conducted in accordance with the risk mitigation plan. Research evaluated prior to this Policy and determined to be within scope of Category 1 and Category 2, and for which a risk mitigation plan has already been developed, does not need a new risk mitigation plan, but the extant risk mitigation plan will be subject to ongoing review and modification based on the recommended periodicity, as necessary, by the research institution;
- Within 30 calendar days of the institutional review, notify the federal funding agency of any research within the scope of Section 4, including whether it meets or does not meet the definition of Category 1 or Category 2 research;
- Ensure that internal policies establish a mechanism for the PI to refer an existing project to the IRE if, at any time, the research uses a biological agent or toxin and can be reasonably anticipated to produce one or more of the outcomes or, or if the PI otherwise believes the project should undergo IRE review.
- Designate an ICDUR to serve as an internal resource regarding oversight of Category 1 or Category 2 research. If questions arise regarding implementation of this Policy, or when guidance is needed about identifying Category 1 or Category 2 research or developing risk mitigation plans, the ICDUR serves as the liaison (as necessary) between the research institution and the federal funding agency.
- Within 90 calendar days from the time that the research institution determines the research to be Category 1 or Category 2 research, provides a copy of the risk mitigation plan to the federal funding agency for review. Category 1 or Category 2 research, the IRE should communicate this determination to the federal funding agency. This research is not subject to additional review or oversight under this policy, unless the federal funding agency, while reviewing the IRE's determination, determines otherwise. In these cases, the research should continue to be managed throughout the research life cycle;
- Designate an ICDUR to serve as an internal resource regarding oversight of Category 1 or Category 2 research. If questions arise regarding implementation of this policy, or when guidance is needed about identifying Category 1 or Category 2 research or developing risk mitigation plans, the ICDUR serves as the liaison (as necessary) between the research institution and the federal funding agency.
- Provide education and training on research oversight for Category 1 or Category 2 research for individuals conducting life sciences research that may be within the scope of this policy. Institutions should also address Category 1 or Category 2 research in existing courses on research ethics and/or the responsible conduct of research

- Maintain records of personnel training on research oversight for at least three years after the completion of the funded project, unless a longer period is required by law or regulation.
- Maintain appropriate records of IRE reviews and completed risk mitigation plans for the term of the research grant, contract, cooperative agreement, or other agreement or transaction, plus three years after its completion, unless a longer period is required by law or regulation.
- Establish a mechanism to ensure that the resulting biological agent or toxin from Category 1 and Category 2 research are properly accounted for and destroyed when no longer needed if not already required to do so by existing law and regulation.
- Report instances of failure to follow this policy, as well as mitigation measures undertaken by the research institution to prevent recurrences of similar failures, within 30 calendar days of research institution awareness or research institution receipt of notification of a failure to the federal funding agency.
- As necessary, assist the PIs of life sciences research when questions arise about whether their research may entail further review or oversight.
- Establish an internal mechanism for PIs to appeal institutional decisions regarding research that is determined by the IRE to meet the definition of Category 1 or Category 2 research.
- On an annual basis, provide a formal assurance to relevant federal funding agencies that the research institution is operating consistent with this policy.
- Make relevant information available to local authorities on Category 1 and Category 2 research, as appropriate.

On behalf of the institution, the IRE:

- Assesses whether the research is within scope of Category 1 or Category 2 by determining: For Category 1, whether the research (1) includes one or more of the agents specified in that are reasonably anticipated to result in one or more of the experimental outcomes; and (3) constitutes DURC; and
- For Category 2, assesses whether the research (1) involves, or is reasonably anticipated to result in, a PPP; (2) is reasonably anticipated to result in one or more of the experimental outcomes or actions; and, (3) is reasonably anticipated to result in the development, use, or transfer of a PEPP or an eradicated or extinct PPP that may pose a significant threat to public health or the capacity of health systems to function.

NOTE: If the IRE determines that the research in question does not meet the definition of Category 1 or Category 2 research, the IRE should communicate this determination to the federal funding agency. This research is not subject to additional review or oversight under this policy, unless the federal funding agency, while reviewing the IRE's determination, decides otherwise. In these cases, the research should continue to be managed throughout the research life cycle.

1.8 Risk Mitigation Plan

The risk mitigation plan must have the following:

- Name and contact information for the PI

- Name and contact information for the authorized institutional official
- Name of the ICDUR (if different from the authorized institutional official)
- Dates and details of the reviews and assessments of the research by the IRE
- Dates and details of the PI's initial review or ongoing assessment of the research
- Identification of whether the research has been identified as DURC
- Details of the risks identified by the IRE in its review of the research and an explanation of the risk mitigation strategy or strategies that the organization is implementing to address those risks
- Other materials, such as proposals and progress reports related to the research that may be requested by the USG funding agency.

A risk mitigation plan may include, but not be limited to, the following risk mitigation measures:

- Modifying the design or conduct of the research.
- Applying specific or enhanced biosecurity or biosafety measures.
- 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.
- Referring the institution to available DURC educational tools such as: http://oba.od.nih.gov/biosecurity/biosecurity.html
- Regularly reviewing, at the institutional level, emerging research findings for additional DURC
- Requesting that institutions notify funding departments or agencies if additional DURC is identified, and propose modifications to the risk mitigation plan, as needed.
- Determining the venue and mode of communication (addressing content, timing, and possibly the extent of distribution of the information) to communicate the research responsibly.
- 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.

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:

- Request voluntary redaction of the research publications or communications;
- Classify the research:
  - In accordance with National Security Decision Directive/NSDD-189, departments and agencies will make classification determinations within the scope of their classification authorities and appropriate classification guidelines or may consult with other departments and agencies to make these determinations.
  - Departments and agencies may consider whether to refer classified research to another department or agency for funding.
- Not provide or terminate research funding.

1.9 Consultation

Consultation with the federal funding agencies. Institutions may seek advice from federal funding agencies on matters related to research oversight. Such consultations should involve the ICDUR and are not mandatory or intended as a substitute for institutional review or reporting. Such consultations may be particularly helpful when:

- The IRE seeks guidance on developing a risk mitigation plan commensurate to the assessed risks;
- The IRE considers the only viable risk mitigation measure to be not conducting or not communicating the research in question;
- The PI does not agree with the finding of the IRE and so would like to request outside technical advice;
- The research in question represents a particularly complex case or appears to be outside the scope of the current definition of Category 1 or Category 2 research, but presents significant concerns; or
- Guidance is beneficial to ensure a clear understanding of how the U.S. government interprets the definition of Category 1 or Category 2 research and related terms.