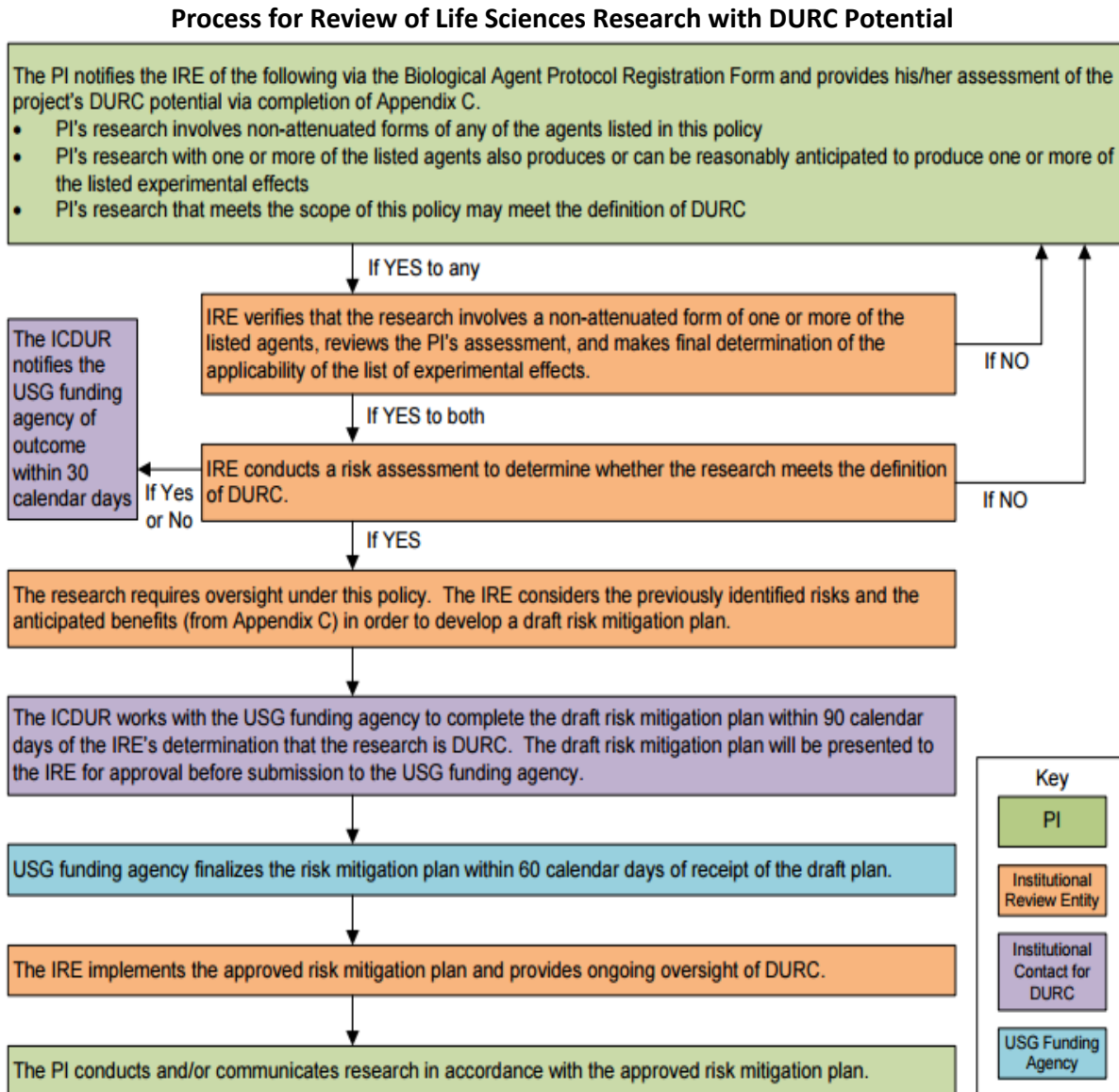


## Review Process for Life Science Research with DURC Potential:

The UT IRE will use the following process to review research which involves non-attenuated forms of one or more of the above listed agents and toxins for DURC potential.



This review process will allow the IRE to assess the potential that the information, technology, or products generated by the proposed research could be misused to harm public health, agriculture, or national security. In making this determination, the IRE will consider the following.

- The types of knowledge, information, technology, or products anticipated to be generated through the research.
- How the results or product of the research will be shared or distributed.
- The novelty of the information provided by the research or of the research methods.
- Whether the products of the research are applicable to other pathogenic organisms or agents.
- Whether the research highlights vulnerabilities in existing public health or agricultural infrastructure.
- The expertise and/or resources that would be required to apply the knowledge, information, technology, or product for malevolent purposes.
- Whether the products of the research could be directly misused to pose a threat to public health and safety, agriculture, plants, animals, the environment, materiel, or national security.
- How readily the knowledge, information, technology, or products from the research could be used to threaten public health and safety, agricultural crops and other plants, animals, the environment, materiel, or national security.
- The nature of the potential consequences (e.g., harm to the economy, the environment, agriculture, or public health) that could result from misuse of the research results.

If the IRE determines that the research does not meet the definition of DURC, the research is not subject to additional institutional DURC oversight. However, if the IRE determines that the research does meet the definition of DURC, the PI will be notified and a draft risk mitigation plan will be prepared.

The ICDUR will inform the appropriate USG funding agency of the IRE's assessment of the DURC potential of the project within 30 days of the determination. For research that is not funded by the USG, notification will be made to the National Institutes of Health (NIH) Program on Biosecurity and Biosafety Policy.

#### (4) Risk Mitigation Plan

If the IRE finds that the proposed research meets the definition of DURC, the committee will work with the PI to develop a draft risk mitigation plan based on an assessment of the risks and benefits associated with the research. The plan will be specifically tailored to the research in question and will outline the strategies that will be used to mitigate all identified risks. Possible risk mitigation measures may include the application of additional biosafety or biosecurity measures, modification of the experimental design or methodology, and/or the application of medical countermeasures. Additionally, the plan may include information regarding the responsible communication of DURC findings.

This draft plan will be submitted to the USG funding agency or NIH within 90 days of the IRE's determination that the research in question is DURC. The USG agency will provide an initial response regarding the draft risk mitigation plan within 30 days and will finalize the plan within 60 days. The project may not be initiated until an approved risk mitigation plan is received from the USG funding agency or NIH.

(5) Ongoing Review of DURC

The IRE will review all DURC protocols and associated risk mitigation plans on an annual basis. The USG funding agency or NIH will be notified of any modifications or updates to DURC research protocols or risk mitigation plans within 30 days.

(6) Training

All PIs and laboratory personnel (i.e., those under the supervision of laboratory leadership, including graduate students, postdoctoral fellows, research technicians, laboratory staff, and visiting scientists) who will conduct research with one or more of the listed agents or toxins must complete training on DURC before beginning work and every three years thereafter.