RESPONSIBLE RESEARCH
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Research & Innovation

Institutional Biosafety Committee

Policy: IBC-01.02

Title: When is an IBC Protocol Required?

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I. Purpose

Institutional oversight is required for the scholarly use of certain biological materials and activities to ensure proper containment as well as personnel and environmental safety. The purpose of this policy is to provide a framework for the Institutional Biosafety Committee (IBC) to determine when an IBC Protocol is required for work conducted at or funded by Texas Tech University (TTU). Links to all documents referred to are available in the references section and to request a deviation from the IBC policy, please see IBC-06.

Background

As a condition for NIH funding of recombinant or synthetic nucleic acid molecule research, institutions shall ensure that such research conducted at or sponsored by the institution, irrespective of the source of funding, shall comply with the NIH Guidelines (Section I-D, NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines)). Each institution conducting or sponsoring recombinant or synthetic nucleic acid molecule research which is covered by the NIH Guidelines is responsible for ensuring that the research is conducted in full conformity with the provisions of the NIH Guidelines (Section IV-B-1, NIH Guidelines) and as the mechanism for doing so, has established an Institutional Biosafety Committee (IBC) that meets the requirements set forth in Section IV-B-2-a of the NIH Guidelines and carries out the functions detailed in Section IV-B-2-b of the NIH Guidelines. As is the case at many institutions, the TTU IBC has been charged with oversight of more than research subject to the NIH Guidelines (see TTU OP 74.05). Noncompliance with these federally required institutional responsibilities can result in suspension, limitation, or termination of funding to individual researchers and the institution.

II. Review

This document will be reviewed every 2 years or more frequently to accommodate institutional needs and or regulatory changes.

III. Definitions

Application: The document submitted to the IBC. All applications are submitted to the TTU IBC electronically through the Hazard Safety module in Cayuse.

Approval: The IBC's official authorization of a reviewed application which marks completion of the review process.

Gene Drive: A technology whereby a particular heritable element biases inheritance in its favor, resulting in the heritable element becoming more prevalent than predicted by Mendelian laws of inheritance in a population over successive generations.

Protocol: An application that has been sanctioned by the IBC. Such applications have completed the review and approval process outlined in IBC-02 IBC Application Review & Approval.

Registration: The process of submitting the initial application to the IBC Office for pre-review prior to IBC review. Registration is completed when the application is sent to the IBC members for committee review. If you have a question about where you application is in the process, contact the IBC Office at ibc.ehs@ttu.edu.

Review: The IBC's act of examining and discussing submitted applications to determine changes or clarifications necessary for the application to be approved.

IV. Policy

A. All recombinant and/or synthetic research is required to be reviewed and approved by the IBC regardless of exemption per NIH Guidelines in Sections III-E, III-F, or Appendix C except for Animal Biosafety Level 1 (ABSL1) transgenic animal work described in Section III-E-3 and Appendix C-VIII, or involve purchase or transfer of transgenic rodents for experiments at ABSL1 according to Appendix G-III-M of the NIH Guidelines.

B. Certain activities involving recombinant and synthetic nucleic acids may be started after registration but before IBC approval is granted. These activities include those that:

1. Involve the formation of recombinant or synthetic nucleic acid molecules containing no more than 2/3 of the genome of any eukaryotic virus.

2. Involve nucleic acid molecule-modified whole plants, and/or experiments involving recombinant or synthetic nucleic acid molecule-modified organisms associated with whole plants, except those that fall under Section III-A, III-B, III-D, or III-F of the NIH Guidelines.

3. Involve synthetic nucleic acids that: (1) can neither replicate nor generate nucleic acids that can replicate in any living cell, and (2) are not designed to integrate into DNA, and (3) do not produce a toxin that is lethal for vertebrates at an LD50 of less than 100 nanograms per kilogram of body weight.

4. Involve recombinant or synthetic nucleic acid molecules that are not in organisms, cells or viruses and that have not been modified/manipulated to render them capable of penetrating cellular membranes.

5. Involve recombinant or synthetic nucleic acid molecules that consist solely of the exact recombinant or synthetic nucleic acid sequence from a single source that exists contemporaneously in nature.

6. Consist entirely of nucleic acids from a prokaryotic host including its indigenous plasmids or viruses when propagated only in that host (or a closely related strain of the same species), or when transferred to another host by well-established physiological means.

7. Consist entirely of nucleic acids from a eukaryotic host including its chloroplasts, mitochondria, or plasmids (but excluding viruses) when propagated only in that host (or a closely related strain of the same species).

8. Consist entirely of DNA segments from different species that exchange DNA by known physiological processes, though one or more of the segments may be a synthetic equivalent. See NIH Guidelines, Appendices A-I through A-VI, for a list of natural exchangers that are exempt from the NIH Guidelines.

9. Involve genomic DNA molecules that have acquired a transposable element, provided the transposable element does not contain any recombinant and/or synthetic DNA.

10. Do not present a significant risk to health or the environment as determined by the NIH Director following appropriate notice and opportunity for public comment:

a) Recombinant or synthetic nucleic acid molecules containing less than one-half of any eukaryotic viral genome (all viruses from a single family being considered identical), that are propagated and maintained in cell in tissue culture unless they are subject to the guidelines in Section III-B, -C, or -D.

b) Use the following host-vector systems:

- *Escherichia coli* K12 (with the exception of those experiments listed in Appendix C-II-A of the NIH Guidelines);
- *Saccharomyces cerevisiae* and *Saccharomyces uvarum* (with the exception of experiments listed in Appendix C-III-A of the NIH Guidelines);
- any asporogenic *Bacillus subtilis* and *Bacillus licheniformis* (which does not revert to a spore-former with a frequency greater than 10-7 may be used for cloning DNA (except for those experiments listed in Appendix C-V-A of the NIH Guidelines); and
- *Kluyveromyces lactis*, except for experiments listed in Appendix C-IV-A of the NIH Guidelines, provided laboratory-adapted strains are used (i.e. strains that have been adapted to growth under optimal or defined laboratory conditions).

11. Involve recombinant or synthetic nucleic acid molecules derived entirely from extrachromosomal elements of the organisms listed in Appendix C-VI of the NIH Guidelines (including shuttle vectors constructed from vectors described in Appendix C), propagated and maintained in organisms listed Appendix C-VI of the NIH Guidelines (except for experiments listed in Appendix C-VI-A of the NIH Guidelines).

C. Recombinant or synthetic nucleic acid activities that require IBC review and approval prior to initiation per Section III-C and III-D of the NIH Guidelines include:

1. Use risk group 2, 3, 4, or restricted agents as host-vector systems.

2. Involve DNA from risk group 2, 3, 4, or restricted agents is cloned into nonpathogenic, prokaryotic, or lower eukaryotic host-vector systems.

3. Involve the use of infectious DNA/RNA virus, or defective DNA/RNA virus in the presence of helper virus in tissue culture systems.

4. Involve whole plants or animals unless the work meets criteria defined in part A or B of this document.

5. Involve more than 10 liters of culture.

6. Involve influenza viruses.

7. Involve Gene Drive Modified Organisms (GDMOs).

8. Involve the deliberate transfer of recombinant or synthetic nucleic acid molecules, or DNA or RNA derived from recombinant or synthetic nucleic acid molecules, into one or more human research participants.

D. Recombinant or synthetic nucleic acid activities that require NIH-OSP and IBC approval before initiation include those that involve the cloning of toxin molecules with LD50 of less than 100 nanograms per kilogram body weight (e.g., microbial toxins such as the botulinum toxins, tetanus toxin, diphtheria toxin, and *Shigella dysenteriae* neurotoxin), and those that have been approved under section III-A-1-a as Major Actions as stated in Section III-B on the NIH Guidelines.

E. Recombinant or synthetic nucleic acid activities that require NIH Director and IBC approval before initiation include those that involve the deliberate transfer of a drug resistance trait to microorganisms that are not known to acquire the trait naturally, if such acquisition could compromise the ability to control disease agents in humans, veterinary medicine, or agriculture as stated in Section III-A of the NIH Guidelines.

F. Other research that requires IBC review and approval prior to initiation includes research and teaching activities when work involves:

1. Materials or agents potentially infectious to humans, plants, and/or animals – including the storage or concentration of any potentially biohazardous materials.
2. Arthropods that may serve as vectors of disease to humans, plants, or other animals, as well as arthropods that are considered an environmental hazard, except for general arthropod surveillance.
3. Soil, seed, plants, plant pathogens (e.g., bacteria, viruses, fungi, parasites, or insects), or other material received under a USDA-APHIS compliance agreement or permit.
4. Potentially infectious human and/or non-human primate materials.
5. Cell lines that pose a danger to humans, animals, and/or plants, and/or those immortalized by means that render them dangerous to humans, animals, and/or plants.
6. Biologically derived toxins.
7. Prions or prion-like proteins.
8. Select Agents or Toxins per 7 CFR 331, 9 CFR 121, and 42 CFR 73;
9. Category 1 and 2 Dual Use Research of Concern and Pathogens with Enhanced pandemic Potential as per the United States Government Policy for Oversight.
10. The necropsy of animals not under the care of the TTU Veterinarian, necropsy that includes hands-on student involvement, necropsy of animals with unknown health status, and/or necropsy of animals reasonably suspected or known to be infectious.
11. Other work as deemed necessary for review by the Biological Safety Officer; and/or
12. Work requiring an IBC protocol per this policy that is conducted at or sponsored by TTU, for which an IBC protocol has not been approved, or an administrative review of another institution's approved IBC protocol was determined to be noncompliant with this policy or the references in section IV.

G. Texas Tech University-funded scholarly activity, subject to this policy, conducted in collaboration with another institution or organization, including government and commercial entities, must be approved by an IBC.

1. When IBC approval or exemption is through the collaborating institution, the exemption or protocol documentation must be provided to the TTU IBC for administrative review to determine if a TTU IBC protocol is required.

H. Amendments to active protocols that increase or introduce additional risk(s) or objectives associated with the work previously approved by the TTU IBC require a new review to be conducted. This is at the discretion of the Biosafety Officer or their proxy within the IBC Office, and depending on the nature of the amendment, may or may not include consultation with the IBC Chair or Associate IBC Chair.

V. References & Resources

Contact the IBC by email to ibc.ehs@ttu.edu or call 806.742.3876.

A. Institutional References

TTU IBC Protocol Registration Webpage

TTU IBC Policies Webpage

TTU OP 74.05 Institutional Biosafety Committee

TTU IBC Researcher Toolbox

B. Government References

CDC-NIH Biosafety in Microbiological and Biomedical Laboratories, 6th Edition.

NIH Guidelines; NIH Guidelines Animal Experiments Reference Table

Federal Select Agent and Toxin Program

NIH Dual Use Research of Concern

United States Government Policy for Oversight of Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential

Occupational Safety and Health Administration Bloodborne Pathogen Standard