PRINCIPAL INVESTIGATOR'S GUIDE TO IBC

Institutional Biosafety
Environmental Health and Safety
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Fort Worth, Texas 76107
ibc@unthsc.edu

Institutional Biosafety Committee	
Title: Protocol Submission, review and approval Process	**UNTHSC**

A. BACKGROUND INFORMATION

a. The IBC at the University of North Texas Health Science Center has the responsibility to assure that all biosafety activity meets federal law mandates, Public Health Service policy, the Guide recommendations and all accreditation expectations. The goal is to maintain a safe workplace, prevent environmental contamination and comply with federal, state and local requirements.

B. RESPONSIBILITIES

a. It is the responsibility of the Principal Investigator (PI) to submit protocol submissions in a timely manner to allow for proper review.

C. PROCEDURES

a. INITIAL PROTOCOL REVIEW

i. For protocols to be considered for review at an IBC meeting, they must be submitted by the submission deadline listed on the IBC website (this is three weeks before the meeting date). Submission deadlines and meeting dates are posted on the IBC website.

ii. The protocol form can be downloaded from IBC webpage, https://www.unthsc.edu/safety/biological-safety/institutional-biosafety-committee-ibc/ibc-meeting-schedule-and-protocol-submission/. Please select the appropriate form and email the completed from to ibc@unthsc.edu and copy Maya Nair, BSO (maya.nair@unthsc.edu).

iii. The BSO does pre-reviews to assure that all regulations are followed and that all necessary information is included. The review comments are sent to the (PI) for revisions, if necessary.

iv. All corrections to a protocol must be submitted to the Administrator by the date designated by the Administrator in the correspondence to the PI to be considered to be reviewed at the next meeting. If changes are not completed by this time, this may result in the protocol being delayed until the following month's convened meeting.

v. After revisions are received, the protocol is sent to two IBC members for designated review. If any comments are noted by the IBC members, the designated reviewers will present it to the committee during the IBC meeting.

vi. The protocol will be reviewed by the full committee. The outcomes of the meeting will be one of the following:

Approval in current form: Meets all standards approved in current form by full committee. The PI will be notified of the approval.

Approval with modification

1. Modifications required to secure approval by administrative review: This is final approval by the biosafety officer after modifications received by the PI.
2. Modifications required to secure approval by designated review: This is

final approval by designated IBC reviewers after modifications received by the PI.

3. Modifications required to secure approval by full committee review: This is review after modifications at the next month's convened meeting.

Withhold Approval: The reasons for approval to be withheld are given to the PI who may submit a revised protocol for review at a subsequent meeting.

vii Based on the IBC review, PI will be notified the IBC review comments and requested to address the reviewer's comment and email the updated protocol to BSO for review and process based on the IBC decision.

viii Once the PI address all the concerns and the review were completed, IBC approval letter and approved version of the protocol will be emailed to the PI to notify the IBC protocol approval.

ix. If modifications are required to secure approval, the administrator will email the committee comments to the PI.

i. If modifications are required to secure approval by designated review, the PIs response to the committee's comments, along with the revised protocol are submitted to the designated reviewers for review. Any correspondence leading up to the review, will be handled through the Administrator. The PI will be notified of the approval.

ii. If Modifications are required to secure approval by full committee review, the PIs response to the committee's comments, along with the revised protocol, will be presented at the next committee meeting.

x. If modifications are required to secure approval, and the PI is non- responsive to the administrator for at least three months, the administrator will contact the PI, indicating that if no response is received within two weeks, the study will be withdrawn from further IBC consideration. At that time, if there is still no response, then the protocol will be withdrawn. If the PI wishes to pursue this study after it has been withdrawn, a new protocol application will need to be submitted for review.

b. THREE YEAR RENEWALS

i. The PI will receive a 30 day written renewal notice from the administrator.

ii. PIs are responsible for submitting their renewals in a timely manner if they wish to continue the project. The Administrator may send out additional reminders as a courtesy.

iii. The review process for three-year renewals is the same as for initial protocol submissions, listed above.

iv. In the case of a renewal not being approved before the protocol's expiration date, the PI will be notified in writing, and no procedures may be done until protocol approval.

v. If a renewal protocol is not received or needed, the PI may close the protocol, or it will be allowed to expire.

c. EXPEDITED REVIEW by DESIGNATED MEMBER REVIEW – not allowed for rDNA, and synthetic DNA protocols.

vi. Expedited Review can be requested by PI under certain circumstances. IBC chair in consultation with BSO will approve the expedited review process where the application can be reviewed at a time other than at a full committee meeting. Minimum 5 members need to review and approve protocol. Approval can be done via email.

d. CLOSING OF PROTOCOLS

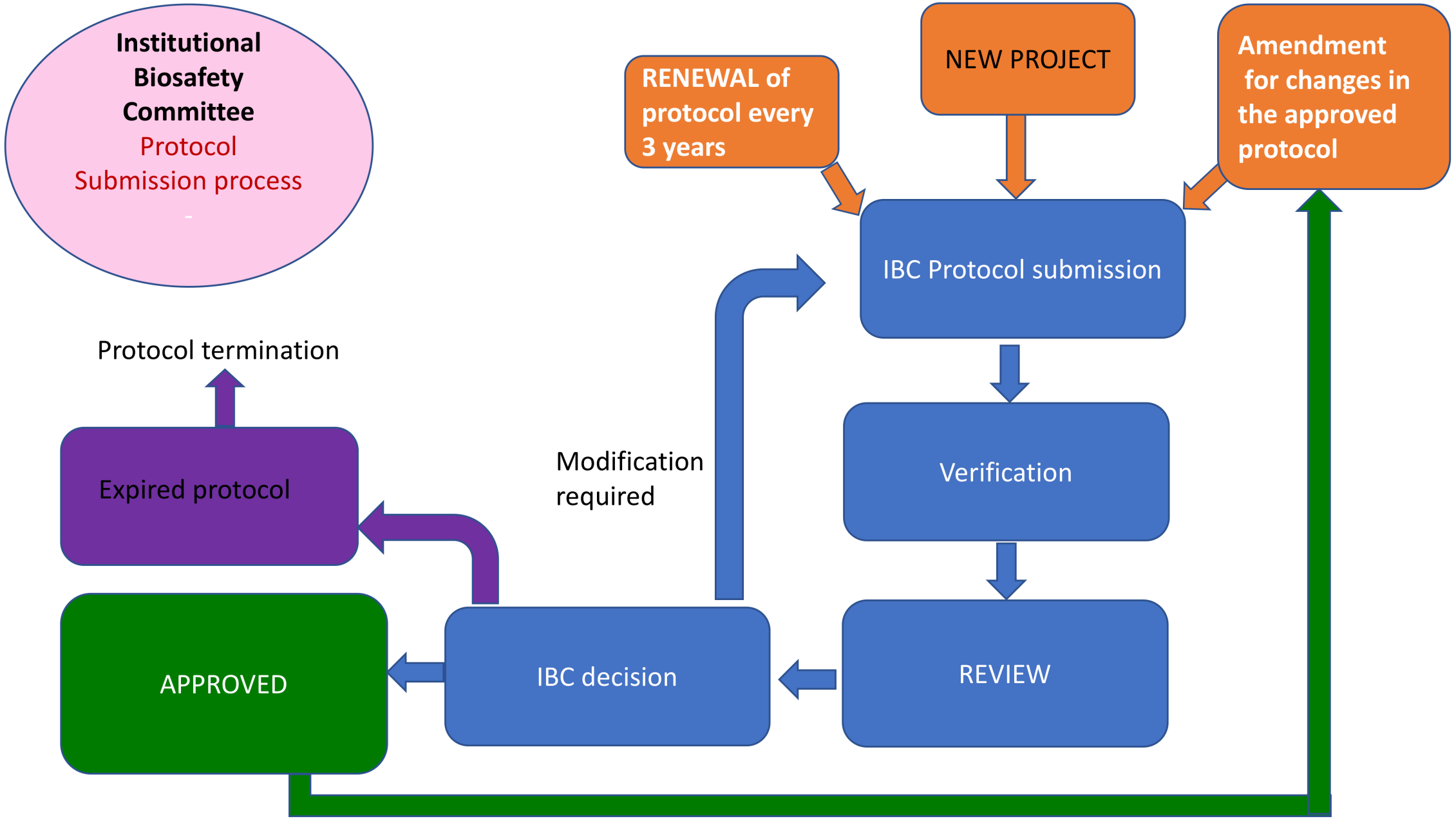
i. A PI at any time may close the protocol by submitting an amendment form to close the protocol. Once a protocol is closed, it cannot be re-opened. If a PI wishes to re-initiate a closed study, a new protocol will need to be submitted to the IBC for review.

ii. All protocols expire at the three ear expiration date. If the study continues, the PI may submit a renewal protocol for the IBC to review. This renewal is handled as a new submission.

iii. The IBC may reserve the right to administratively close out protocols in which the PI is no longer able to fulfill the role as PI, and there is no one available to take the PI's place.

e. CHANGES TO APPROVED PROTCOLS:

Any changes to the protocol within the 3-year term should be submitted to IBC using UNTHSC IBC amendment form for review and approval.


Institutional Biosafety Committee
Protocol Submission process
RENEWAL of protocol every 3 years
NEW PROJECT
Amendment for changes in the approved protocol
IBC Protocol submission
Verification
REVIEW
IBC decision
Modification required
APPROVED
Expired protocol
Protocol termination

While conducting research subject to the *NIH Guidelines*, the PI must:

- Determine the need for IBC review before modifying recombinant or synthetic nucleic acid research already approved by the IBC.
- Submit any subsequent changes (e.g., changes in the source of DNA or host-vector system) to the IBC for review and approval or disapproval.
- Remain in communication with the IBC throughout the duration of the project.
- Report any significant problems pertaining to the operation and implementation of containment practices and procedures, violations of the *NIH Guidelines*, or any significant research-related accidents and illnesses to the IBC, NIH OSP, and, as applicable, the Biological Safety Officer, Greenhouse or Animal Facility Director, and other appropriate authorities.

PIs conducting human gene transfer research subject to Section III-C of the *NIH Guidelines* must:

- Not enroll research participants in a human gene transfer clinical trial until IBC approval (from the clinical trial site) and all applicable regulatory authorization(s) have been obtained.

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For more information

To receive updates on current initiatives, policies, and news from OSP, subscribe to our listserv, "OSP News," by sending a message to: listserv@list.nih.gov with the message: subscribe OSP_NEWS

Visit the following websites for additional information:

NIH Office of Science Policy

https://osp.od.nih.gov/

NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules

https://osp.od.nih.gov/biotechnology/nih-guidelines/

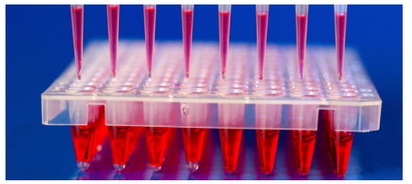
National Institutes of Health

Office of Science Policy

INVESTIGATOR RESPONSIBILITIES

under the

NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules



Safety and science go hand in hand.

What are the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules*?

The *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines)* detail procedures and practices for the containment and safe conduct of various forms of research involving recombinant and synthetic nucleic acid molecules, including research involving genetically modified plants and animals, and human gene transfer research.

Who must comply with the *NIH Guidelines*?

All institutions that receive NIH funding for research involving recombinant or synthetic nucleic acid molecules must comply with the *NIH Guidelines*. Researchers at institutions that are subject to the *NIH Guidelines* must comply with the requirements even if their own projects are not funded by NIH.

What is an Institutional Biosafety Committee?

Institutional Biosafety Committees (IBCs) provide local review and oversight of nearly all forms of research utilizing recombinant or synthetic nucleic acid molecules. They ensure that recombinant and synthetic nucleic acid research conducted at or sponsored by the institution is in compliance with the *NIH Guidelines*.

What is the NIH Office of Science Policy?

The NIH Office of Science Policy (OSP) promotes science, safety, and ethics in biotechnology through the advancement of knowledge, enhancement of public understanding, and development of sound public policies. A core responsibility of OSP is to foster awareness of, and adherence to, the standards and practices set forth in the *NIH Guidelines*.

Principal Investigator Responsibilities

Principal Investigators (PIs) are responsible for full compliance with the *NIH Guidelines* during the conduct of research involving recombinant or synthetic nucleic acid molecules. As part of this general responsibility, the PI should:

- Be adequately trained in good microbiological techniques.
- Provide laboratory research staff with protocols describing potential biohazards and necessary precautions.
- Instruct and train laboratory staff in: (i) the practices and techniques required to ensure safety, and (ii) the procedures for dealing with accidents.
- Inform the laboratory staff of the reasons and provisions for any precautionary medical practices advised or requested (e.g., vaccinations or serum collection).
- Supervise laboratory staff to ensure that the required safety practices and techniques are employed.
- Correct work errors and conditions that may result in the release of recombinant or synthetic nucleic acid materials.
- Ensure the integrity of physical containment (e.g., biological safety cabinets) and biological containment (e.g., host-vector systems that preclude survival of the agent outside the laboratory).
- Comply with permit and shipping requirements for recombinant or synthetic nucleic acid molecules.
- Adhere to IBC-approved emergency plans for handling accidental spills and personnel contamination.

Before initiating research subject to the *NIH Guidelines*, the PI must:

- Determine whether the research is subject to Section III-A, III-B, III-C, III-D, or III-E of the *NIH Guidelines*.
- Propose physical and biological containment levels in accordance with the *NIH Guidelines* when registering research with the IBC.
- Propose appropriate microbiological practices and laboratory techniques to be used for the research.
- Submit a research protocol to the IBC for review and approval.
- Seek NIH OSP's determination regarding containment for experiments that require case-by-case review.
- Petition NIH OSP, with notice to the IBC, for proposed exemptions from the *NIH Guidelines*.
- Obtain IBC approval before initiating, or at the time of initiating research as applicable, based on the section of the *NIH Guidelines* the research is subject to.
- Seek NIH approval, in addition to IBC approval, to conduct experiments specified in Sections III-A and III-B of the *NIH Guidelines*.