IBC CHARTER/ PRINCIPAL INVESTIGATOR'S GUIDE TO IBC

EHS-400-02_V3

Institutional Biosafety
Environmental Health and Safety
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Abbreviations

BSO	Biosafety Officer
DLAM	Department of Laboratory Animal Management
DNA	Deoxyribonucleic acid
DURC	Dual Use Research of Concern
DR	Designated Review
EH&S	Environmental Health and Safety
GOF	Gain of Function
IBC	Institutional Biosafety Committee
ICDUR	Institutional Contact for Dual Use Research
IRE	Institutional Research Entity
NIH	National Institute of Health
OSP	Office of Science Policy
PEPP	Pathogen of Enhanced Pandemic Potential
PI	Principal Investigator
PPP	Pathogen of Pandemic Potential
rDNA	Recombinant DNA
RMSTA	Requires Modification To Secure Approval
SOP	Standard Operating Procedure
UNT	University North Texas
VPR	Vice President for Research

Approval and Implementation

The Principal Investigator's Guide to the IBC is hereby approved by the Institutional Biosafety Committee for the University of North Texas Health. This document shall apply to all UNT Health personnel at UNT Health facilities working with biological material. The details of this guide are developed to ensure regulatory compliance. This document is effective immediately and supersedes all previous editions.

This guide will be reviewed annually and updated as needed to ensure compliance with regulatory changes or changes in procedures.

Approved Signed by: Rance Berg 4E3708F2FE464A4...

Rance Berg, PhD
IBC Chair

Record of Changes

Change #	Date of Change	Change entered by	Description
1.	7/17/2023	Maya Nair	Existing document
2.	8/20/2025	AS Brocard	Update document to reflect new DURC, PEPP< GOF regulations and provide more guidance to the PIs Updated to knew branding
3.	1/29/2026	AS Brocard	Renumbered document and fixed hyperlink

A. Background information

The Institutional Biosafety Committee at the University of North Texas Health 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. Principal Investigator
   - i It Is the responsibility of the PI to ensure that no work is started without final IBC approval of a registration form.
   - ii It is the responsibility of the PI to submit registration form submissions in a timely manner to allow for proper review.
   - iii It is the PI's responsibility to ensure that all their staff have read and understood the information in the IBC registration form prior to starting a project.
   - iv It is the responsibility of the PI to identify research projects that may be classified as DURC, PEPP or GOF and report it to the IBC and ICDUR by informing the BSO.
   - v It is the responsibility of the PI to ensure that their registration is maintained up to date by submitting the needed amendments on time.
   - vi All PIs must submit accurate, current, and complete hazard registrations including providing all pertinent supplemental documents (e.g. plasmid maps, SOPs, etc.).
   - vii It is the PI and laboratory staff responsibility to report all incidents, exposures, and spills to the BSO.
   - viii Follow all approved protocols and registration forms, maintain strict compliance with biosafety and biosecurity standards.

b. Biosafety Officer
   - i the BSO will conduct a pre-review of all registration forms and amendments prior to their submission to the IBC and notify the IBC of administratively approved items.
   - ii The BSO serves as the IBC Coordinator and ICDUR for the institution.

c. IBC members
   - i It is the responsibility of the IBC members to review new registration forms, amendments and renewals to ensure they meet regulatory requirements, the PI and staff have the needed knowledge and that UNT Health has the appropriate facilities and containment devices to safely conduct the proposed research.

d. IBC Committee
   - i The IBC advises the VPR on policy matters concerning the protection of personnel from biological materials that may be present in laboratory or clinical areas.
   - ii The IBC shall also recommend guidelines relating to procedures and facilities used at UNT Health, including such matters as safety training and health surveillance.
   - iii The IBC will offer its counsel to all UNT Health personnel regarding matters of biological safety. The VPR may ask the IBC to inform the community about developments in the general area of biological safety.

C. IBC membership

The IBC membership shall be qualified and appointed in accordance with guidelines established by the NIH. Membership of the IBC consists of a minimum of five (5) persons, two (2) of which cannot be affiliated with the University and will represent the interests of the surrounding community with respect to health and protection of the environment.
The VPR appoints the members of the IBC on a three-year basis. Members are eligible for reappointment to multiple consecutive terms. The BSO is a mandatory member of the IBC and is eligible to be appointed as its chairperson. The IBC should have a representative from the Safety Office, a representative from the Office of Research Compliance and a representative from DLAM.

D. Meeting schedule

The IBC operates in accordance with its approved charter and holds monthly meetings on the third Wednesday of each calendar month with exceptions for holidays. The meeting schedule is available on the IBC webpage.
The IBC will keep meeting minutes; these minutes will be approved at the following month's meeting and will be posted on the IBC webpage.

E. Material requiring IBC notification/approval

PIs are required to notify the IBC that they possess or plan to use the following material:

- Human and non-human primate cell lines
- Human and non-human primate primary tissue, organs, body fluid, organs, and bones
- Animal primary tissue, organs, body fluid, organs, and bones
- Bacteria, viruses, fungus, protozoa
- Toxins
- Arthropods and insects
- Recombinant/Synthetic DNA

For a list of biological materials that require the submission of a hazard registration, please contact EH&S.

F. IBC Submission forms

All submission forms need to be submitted to the IBC at IBC@unthsc.edu and copied to the BSO, Dr. Maya Nair, PhD, RBP (ABSA) at maya.nair@unthsc.edu

a. Initial/renewal registration forms

An Initial registration form is submitted when a project with new biological material listed above is ready to be initiated.
A renewal registration form is submitted three (3) years following approval of an initial registration form, indicating that the project is still on going.

b. Amendments to registration form

An amendment or a resubmission to an approved registration form must be submitted when the following changes are needed:

- changes to the project objectives
- changes to the process
- adding/removing listed material
- adding/removing listed personnel
- changes in the use/storage location
- the purchase or acquisition of new infectious agents
- providing biological materials to another investigator on or off campus

- arranging for visiting researchers to work in your laboratory
- if minors will be working in their respective laboratories - refer to UNT Health's policy on minors on campus

The BSO will review the submission and determine if the amendment requires IBC evaluation or if the original risk assessment covers the proposed changes.

G. Registration form time frame

a. Approval time frame

All registration forms are approved for a three (3) year period from the month of the IBC approval.
Approved amendments do not change the date of the original registration approval.

b. Expiration time frame

Prior to the expiration date, PIs are required to resubmit an updated registration form for full IBC review.
The PI will receive a written renewal notice, from the BSO, 90-days prior to the registration expiration date.
The BSO may send out additional reminders as a courtesy.
PIs may request from the IBC an extension to the renewal of a registration, this request must be made in writing to the IBC and approved prior to the expiration date of a registration.
In the case of a renewal not being approved before the registration form's expiration date, the PI will be notified in writing that **no procedures** may be performed until the registration form is approved.
The IBC will be notified that the registration form has expired without securing a renewal approval.

Note: All work listed on an expired protocol must immediately stop, unless the IBC has granted a written exemption.
It is recommended that the PI submit a renewal protocol at least two (2) months prior to the expiration date.

c. Submission time frame

Registrations and amendments requiring full IBC review, must be submitted to the IBC three (3) weeks prior to the meeting to allow time for a pre-review and response by the BSO.
Registrations and amendments that are not received in time, may be deferred to the following months IBC meeting, delaying the project.

d. Response to the IBC time frame

The PI must respond to the IBC request for modifications within three (3) months of the IBC meeting. If the PI is non-responsive for three (3) months the BSO will contact the PI, indicating that if no response is received within two weeks, the study will be withdrawn from further IBC consideration. If the PI wishes to pursue this study after it has been withdrawn, a new registration form application will need to be submitted for review.

H. IBC review process

a. Pre-review

When a registration form or amendment is submitted to the IBC, the BSO will conduct a pre-review of the document to ensure all the needed information is provided. The BSO will inform the PI of any changes that are needed prior to submitting the document for IBC review and approval. If a PI fails to respond to the pre-review comments, the protocol/amendment will be submitted to the IBC as is. This may lead to significant changes needed to secure approval and lead to delays in the approval of the document.

b. IBC review

Registration forms are sent to two (2) designated IBC members for review and comments. These IBC members will present the proposed project and their comments to the rest of the IBC members. All IBC

members are provided with all registration forms to be reviewed and discussed at the meeting, and they will also be given the opportunity to provide comments on the project.
The registration form will then be put to vote with the following options:

a **Approved**: Meets all standards and is approved in the current form by full committee. No corrections or modifications are needed. The PI will be notified of the approval.

b **Requires Modification to Secure Approval (RMSTSA)**

i Modifications required to secure approval by administrative review: This final approval is done by the BSO after the requested modifications have been received from the PI.

ii Modifications required to secure approval by designated review (DR): This final approval is done by designated IBC reviewers after the requested modifications have been received from the PI.

iii Modifications required to secure approval by full committee review: This approval requires the registration form, following the required modifications have been completed, to be reviewed and approved at the next month's convened IBC meeting.

Note: at any time, the BSO or a DR can request the registration form to be brought back to the Full IBC committee for review and approval.

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

c. **IRE Review**

Registration forms that are identified by the PI or IBC to meet or potentially meet the definition for DURC, PEPP, PPP or GOF as defined by the regulations, will be submitted to the IRE for further review and approval, prior to the IBC being able to complete the approval process.
Refer to the DURC-PEPP-GOF-Guidance Document for further information on these regulations and procedures.
Registration forms that need IRE review will require significantly more time to secure final approval. It is recommended that the PI reach out to the BSO for further assistance with these registrations and plan for at least six (6) months prior to securing approval.

d. **EXPEDITED REVIEW by DESIGNATED MEMBER REVIEW-** not allowed for rDNA, and synthetic DNA registration forms.

A PI can request an Expedited Review of a registration. A formal request with supporting justification must be sent to the IBC. The IBC chair in consultation with the BSO will approve the expedited review process.
Expedited Review is when an IBC registration form is reviewed at a time other than during a full committee meeting. A minimum of 5 IBC members is needed to review and approve the registration form.
Expedited reviews can be done via email.
The registration form approval will be recorded in the following IBC minutes.

e. **Administrative approval**

The BSO has been granted by the IBC the ability to administratively approve minor amendment to registration forms. This reduces the approval time of the amendment.
All administrative approvals are recorded in the following IBC minutes.
Administrative approval includes:

- minor changes to the process
- removing listed material

- adding new cell lines if similar ones are already included in the registration
- adding/removing listed personnel
- changes in the use/storage location
- providing biological materials to another investigator on or off campus
- arranging for visiting researchers to work in your laboratory
- if minors will be working in their respective laboratories - refer to UNT Health's policy on minors on campus

The BSO has the authority to call any amendment to a full IBC board review if they deem it necessary to ensure proper review process.

f. Conflicts of Interest

IBC members must recue themselves from the review and vote of a registration if they have a conflict of interest. These include but may not be limited to:

- Listed as a PI, Co-PI or staff on a protocol
- Institutional conflict of interest
- Conflicts of commitment
- Individual conflicts
    - Financial
    - Competing

g. PI notification

Following the IBC meeting the PI will be notified in writing of the outcome of the vote.

- For Registration forms that have been approved, the PI will be provided with an approval letter from the IBC and work can commence/continue.
- For Registration forms that require modification to secure approval or withhold approval, the PI will be provided with the required changes to be addressed. The PI will email the updated registration form to BSO for review and processed based on the IBC decision.

Note: No work can commence or continue (renewals, amendments) without an IBC approval letter.

I. Minutes

The IBC coordinator will keep minutes of the IBC meetings. These minutes will include the following information on each reviewed registration.

- PI name
- Title of the project
- Agent
- Biosafety Level the work will be conducted at
- Brief description of the project
- Recommendations from the IBC of changes needed to secure approval if applicable
- The vote results

The minutes will also include the following information

- Registrations that have been administratively approved
- Registrations that have responded to IBC recommendations and have been approved.
- Incidents that have occurred
- Non-compliance situations
- General information presented to the IBC for discussion, input or training.

The minutes will be reviewed and approved at the following convened full meeting and will then be posted on the IBC webpage.

J. Closing of registration forms

a. A PI at any time may close a registration form by submitting an amendment form to close the registration form. Once a registration form is closed, it cannot be re-opened. If a PI wishes to reinitiate a closed study, a new registration form will need to be submitted to the IBC for review.
b. All registration forms expire at the three-year expiration date. If the study continues, the PI must submit a renewal registration form for the IBC to review prior to the expiration date. This renewal is handled as a new submission.
c. The IBC may reserve the right to administratively close out registration forms 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.
d. The IBC will be notified of closed registration form at the following convened meeting.

K. Non-Compliances with the IBC

a. **Failure to register with the IBC**

Any PI who fails to register the use and/or storage of applicable biological materials with the IBC will be reported to the BSO.
PIs who fail to register these materials following a request from the BSO will be immediately reported to the Director of EH&S, the IBC Chair, the VPR and Department Chair.

Failure to register work that involves recombinant/synthetic DNA may result in a non-compliance report being sent to the NIH OSP.

b. **Suspension of registrations**

Following non-compliances with safety regulations and UNT Health policies, the IBC Chair and/or Vice Chair have the authority to temporarily suspend all approved IBC registrations at which time the IBC will submit a suspension letter to the PI.
A copy of this letter will be sent to the VPR, PI's department Chair, and the Director of the Office of Research Compliance.
To obtain or regain IBC authorization to use applicable biological materials, the PI will be required to submit all pertinent registration forms and all applicable supplemental documentation to the BSO. This information will be provided to the IBC, at the next scheduled meeting, for evaluation.
The IBC may, at their discretion, authorize/re- authorize the PI's project, authorize the PI's project under specific/defined conditions, place the PI's hazard registration(s) under continued suspension, or terminate the PI's registration(s).
Additionally, the Director of EH&S and the IBC Chair may recommend to both the VPR appropriate action if an investigation reveals significant violations.

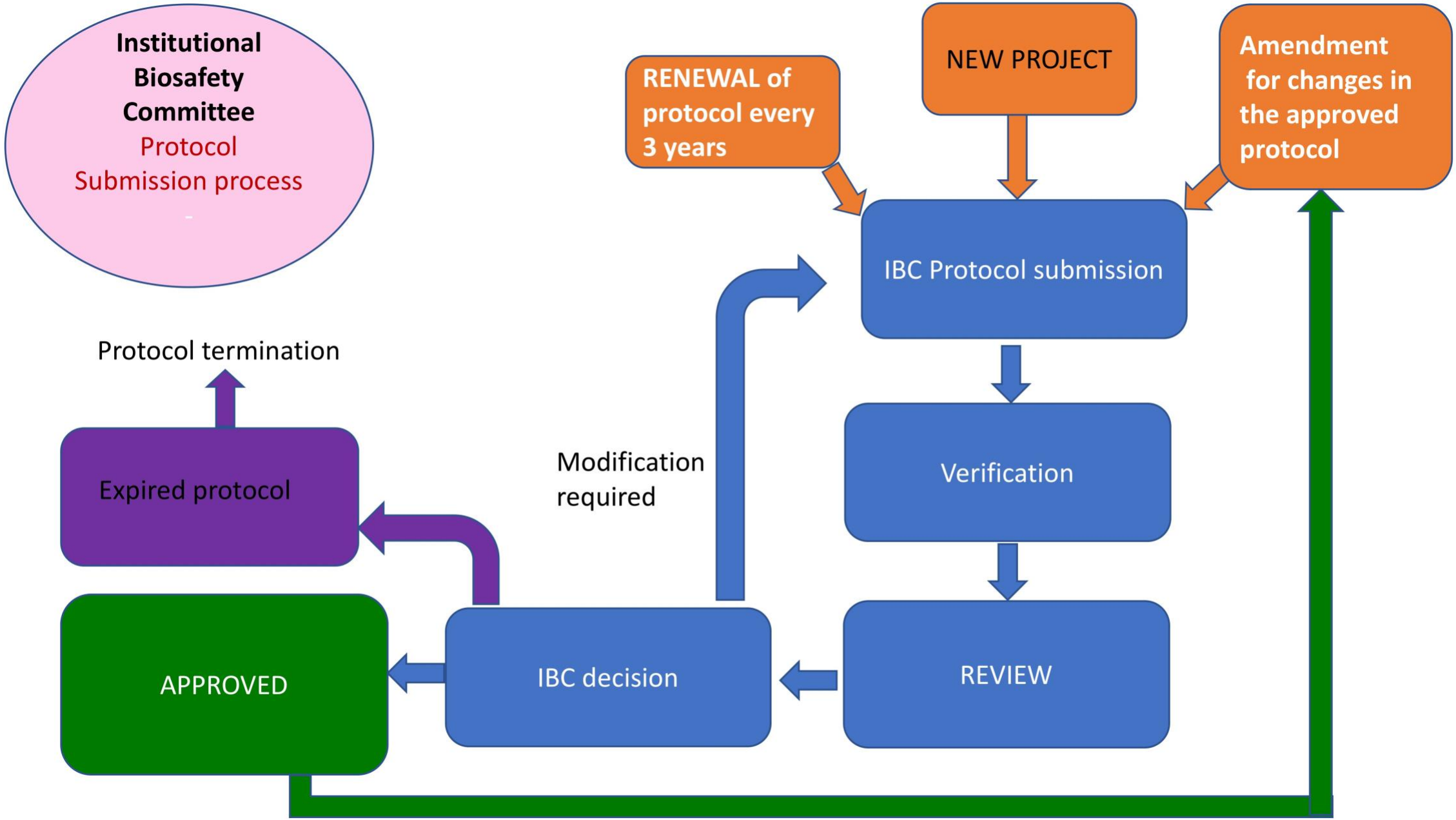
Suspension of registration forms that involve recombinant/synthetic DNA may result in a non-compliance report being sent to the NIH OSP.

L. References

- Biosafety manual
- Occupational Safety Manual
- DURC-PEPP-GOF-guidance document
- IRE Charter- EHS 300-02
- NIH Guideline https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.pdf
- United States Government Policy for Oversight of Dual Use Research of Concern (DURC) and Pathogens with Enhanced Pandemic Potential (PEPP), May, 2025

- United States Government Policy for Oversight of Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential (May 2024))
- Executive Order (EO) (May2025) (https://www.whitehouse.gov/presidential-actions/2025/05/improving-the-safety-and-security-of-biological-research/

Safety and science go hand in hand.



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 /

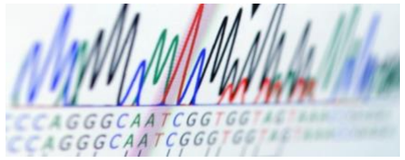
National Institutes of Health

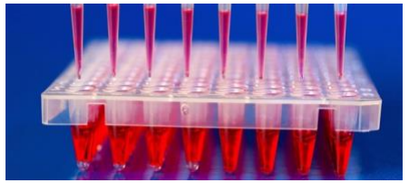
Office of Science Policy

INVESTIGATOR RESPONSIBILITIES

under the

NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules





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 registration forms 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 registration form 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*.