The University of Texas at El Paso

Institutional Biosafety Committee
Operational Handbook

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Chair of the IBC
and IBC Office
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ACRONYMS

BMBL	Biosafety and Microbiological and Biomedical Laboratories
BSL	Biosafety Level
BSO	Biological Safety Officer
DMR	Designated Member Review
EH&S	Department of Environmental Health and Safety
FCR	Full Committee Review
IACUC	Institutional Animal Care and Use Committee
IBC	Institutional Biosafety Committee
IO	Institutional Officer
IRB	Internal Review Board
NIH	National Institutes of Health
OBA	Office of Biotechnology Activities
OHS	Occupational Health Services
OSP	Office of Science Policy
PI	Principal Investigator
PPE	Personal Protective Equipment
RCRA	Research Compliance and Regulatory Assurances
rDNA	Recombinant Deoxyribonucleic Acid
RG	Risk Group
R&I	Research & Innovation
SNAM	Synthetic nucleic acid molecules
VPR	Vice-President for Research

INTRODUCTION

As of now, research activities reviewed by the UTEP IBC, regardless of the PI's funding source(s), include the following:

- Creation and use of rDNA or SNAMs.
- Work with all RG2/BSL2 Agents or higher agents, all human, animal, and plant pathogens, and non-indigenous plant pathogens or pests
- Work with biological samples (e.g., animal tissues, fluids, etc.) known or highly suspected to be contaminated with RG2/BSL2 or higher agents.
- Work with non-human primate and human derived materials, including work with human embryonic, fetal, pluripotent, and neural stem cells.
- Work with arthropods.
- Any work with transgenic plants or non-rodent transgenic animals, including purchase of non-rodent transgenic animals.
- Work with acute biological toxins (LD_{50} ≤ 100 µg/kg body weight), select agents/toxins, or export-controlled toxins

At UTEP, biological research is conducted following federal and state regulations and standards. These include:

- *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines version April 2024)*
- NIH Office of Scientific Policy
- Institutional Environmental Health and Safety Guidelines
- Guidelines for Working Safely with Human Cell Lines
- OSHA Bloodborne Pathogens Standards
- CDC Biosafety and Microbiological and Biomedical Laboratories (BMBL 6th edition)
- *American Committee of Medical Entomology; American Society of Tropical Medicine and Hygiene (Arthropod Containment Guidelines, Version 3.2)*
- Select Agents and Select Agent Toxins
- *Guidance on the Inventory of Select Agents and Toxins (7 CFR Part 331, 9 CFR Part 121, 42 CFR Part 73)*

According to the *NIH Guidelines*, research institutions receiving NIH funding must establish an Institutional Biosafety Committee (IBC). The IBC and Environmental Health & Safety (EH&S) will collaborate closely to review protocols and procedures submitted by the Principal Investigators (PI), NIH-funded or not. The IBC review and approval results are conveyed to the PI. Additionally, the IBC can sanction new or substantially revised Biosafety policies or plans submitted by Facility Directors, the Biological Safety Officer (BSO), or the IBC Office. This document outlines the responsibilities and procedures IBC uses to implement, promote, and manage safe, ethical biological research activities at UTEP. On the IBC website (https://www.utep.edu/orsp/institutional-biosafety/), the PIs will find helpful resources to assist them in understanding and complying with biosafety and compliance requirements.

STATEMENT OF PURPOSE

The IBC is an internal review and oversight body for research by UTEP faculty, students, and employees. UTEP must ensure its research is conducted in full compliance with the *NIH Guidelines*. The IBC is responsible for evaluating the safety of research protocols to identify potential risks to the well-being of research personnel, other individuals, or the environment. To ensure safety, the UTEP IBC strives to mitigate risk to researchers and the surrounding community by:

- Create and execute institutional biosafety policies that UTEP researchers must follow.
- Ensure the implementation of appropriate measures and protocols when conducting research involving biological agents.
- Review proposed research and teaching activities involving biological materials that could affect the biosafety of UTEP personnel and the surrounding community.
- Provide assistance and guidance to UTEP's research personnel to ensure compliance with biosafety regulations and guidelines at the international, federal, state, and local levels.

Ensuring the safety of health and the environment is a collective obligation. The IBC strives to establish clear guidelines and standardize the necessary protocols that shall be adhered to before commencing research activities. However, the PI and research team are responsible for efficiently containing pathogens, rDNA, and SNAMs.

The IBC's mission is to safeguard human health and the environment by balancing adherence to the *NIH Guidelines* regarding research involving rDNA or SNAMs, the BMBL, and the United States Government Policy for Oversight of Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential. The IBC assures that the research activities conducted at the institution meet ethical and legal standards by minimizing risk to the research personnel, the community, and the local environment.

UTEP IBC COMPOSITION

As an Institutional Officer (IO), the Vice-President for Research (VPR) is responsible for appointing members to the IBC annually for three years. To ensure effective evaluation of research proposals, consecutive terms may be allowed to maintain collective experience and expertise in assessing safety and risks. The Biological Safety Officer (BSO) is the only permanent voting member of the IBC, but the BSO, IBC Chair, or any existing member can nominate new committee members. The appointment of new members is confirmed after a vote during a full committee meeting. If an IBC member fails to attend at least half of the scheduled meetings a year, the BSO or IBC Chair may propose a replacement nomination.

Members are selected to ensure compliance with membership requirements articulated in the *NIH Guidelines*. The UTEP IBC has **at least five** voting members.

<u>The UTEP IBC membership will consist of the following:</u>

1) IBC Chair
2) BSO
3) At least two members not affiliated with UTEP (apart from their membership on the IBC). These individuals will represent the interest of the surrounding community concerning health and protection of the environment (*e.g.,* officials of state or local public health or environmental protection agencies, members of other local governmental bodies, or persons active in medical, occupational health, or environmental concerns in the community).

4) At least two members with expertise in creating and using rDNA or SNAMs.
5) At least one member with knowledge and experience handling RG2 or RG3 infectious agents and biocontainment.
6) At least one member with expertise in the use and containment of arthropods.
7) When applicable, at least one individual with expertise in animals and animal containment principles.
8) When applicable, at least one individual with expertise in plants, plant pathogens, or plant pest containment principles when experiments utilizing *Appendix L* of the *NIH Guidelines* require prior approval by the IBC.

ROLES AND RESPONSIBILITIES

Institutional Official (IO)

The IO, appointed by the UTEP President, represents the IBC to federal and regulatory agencies. Their role includes assigning members to the IBC and ensuring the committee adheres to the *NIH Guidelines*. Additionally, they manage all incoming and outgoing biosafety communications and distribute messages accordingly.

IBC

The IBC's primary role is to provide local review and oversight of research involving rDNA or SNAMs as specified in Section III of the *NIH Guidelines*. In addition, the UTEP IBC will review protocols involving RG2 and RG3 infectious agents, select agents, toxins, human, animal derived, plant derived, primate and non-primate-derived materials, and arthropods. The IBC must ensure that these research projects conducted at or sponsored by the institution comply with the *NIH Guidelines*. The review of the protocols shall include (*i*) an independent assessment of the containment levels required by the *NIH Guidelines* for the proposed research; (*ii*) an assessment of the facilities, procedures, practices, and training and expertise of personnel involved in research with rDNA or SNAMs, RG2/RG3 agents, toxins, select agents, human-derived, animal derived, plant derived, primate and non-primate materials, and arthropods.

More specifically, as per the *NIH Guidelines* (*see* ***Section IV-B-2***), the IBC's responsibilities include, but are not limited to:

- Notifying the Principal Investigator of the IBC's review and approval results.
- Assessing the proposed reduction of containment levels for specific experiments mentioned in Section III-D-2-a. These experiments focus on cloning DNA from Risk Groups 2, 3, or 4 and Restricted Agents into nonpathogenic prokaryotic or lower eukaryotic host-vector systems.
- Setting containment levels as specified in Sections III-D-4-b, *Experiments Involving Whole Animals*.
- Periodically reviewing the institution's rDNA or SNAM research to ensure compliance with the *NIH Guidelines*.
- Adopting emergency plans covering accidental spills and personnel contamination from rDNA or SNAM research. This includes reviewing and approving facility biosafety manuals (*e.g.,* BSL-2 and BSL-3 manuals), general biosafety policies, and SOPs.

The IO has granted the IBC the authority to enforce these guidelines and ensure that investigators and laboratory personnel follow approved protocols. The IBC evaluates each

project's risk level, and only those that meet safety and compliance standards are approved. Any significant incidents, violations, or research-related accidents and illnesses involving rDNA or SNAMs must be reported to the NIH Office of Science Policy (NIH OSP) by email (NIHGuidelines@od.nih.gov) through the IO, per the *NIH Guidelines*.

IBC Chair

The IBC Chair is a member appointed by the VPR. The Chair works closely with the IBC members, IBC Coordinator, and PIs to ensure the safe conduct of activities involving biohazardous materials.

The IBC Chair's duties include:

- Conducting monthly meetings and calling for additional meetings as necessary.
- Assigning reviewers for Full-Committee Review (FCR) and Designated Member Review (DMR).
- Reviewing policies and biosafety manuals.
- Signing official IBC documentation as needed.
- Ensuring that all IBC members are appropriately trained as described in the *NIH Guidelines* Section IV-B-1
- Submitting an annual report on the IBC's activities to the IO.

BSO

A BSO must be appointed and be a permanent member of the IBC if UTEP conducts research involving the use of rDNA SNAMs for either large-scale research or production (>10 L), in the BSL-3 containment or gene drive-modified organisms (*ref. Section IV-B-3-a, b, and c*).

As per the *NIH Guidelines (ref. Section IV-B-3-d*), the BSO's duties include:

- Provide training, conduct facility inspections, and communicate related regulatory requirements to assist laboratories in conforming to regulatory and IBC Handbook guidelines.
- Conduct regular inspections to ensure that laboratory standards are strictly adhered to.
- Report any significant problems, violations of the *NIH Guidelines*, and any significant research-related accidents or illnesses to the IBC and IO unless the BSO determines that the PI has already filed a report.
- Develop emergency plans for handling accidental spills and personnel contamination and investigate any laboratory accidents associated with the research of rDNA or SNAMs.
- Provide advice on laboratory security.
- Provide technical advice to PIs and the IBC on research safety procedures.

Principal Investigator

The PI is the faculty member who conducts research, whether funded or not. The PI must comply with UTEP's biosafety policies, practices, and procedures. This responsibility extends to all individuals who enter or work in the PI's laboratory or collaborate in carrying out the PI's research. Although the PI may assign some aspects of the Biosafety Program in their laboratory to other personnel like laboratory directors, supervisors, or faculty, the PI is still accountable for all activities happening in their laboratory. Documenting training and compliance with appropriate biosafety practices and procedures is crucial. The PI is responsible for ensuring proper employee

safety training and correcting errors and unsafe working conditions. As part of their general responsibilities, the PI shall:

- Never initiate or modify research involving biological materials that require IBC review and approval until the IBC has approved that research or proposed modification.
- Inform laboratory personnel, maintenance personnel, and visitors about the potential risks of exposure to biohazardous agents and the necessary safety measures to minimize them. Educating everyone about the hazards and appropriate safety practices before entering or working under such threats is essential.
- Be adequately trained in microbiological techniques and ensure that laboratory staff is adequately trained to ensure safety and the procedures for dealing with accidents.
- Notify the BSO of significant issues, accidents, or policy violations.
- Ensure that all individuals covered under their research protocol are up-to-date with mandatory training (*e.g.,* Laboratory Safety triennially and Biosafety/Bloodborne Pathogens annually) and be enrolled in the UTEP Occupational Health Program (OHP), if applicable.
- Work with the BSO to create emergency protocols that address accidental spills and personnel contamination.
- Establish a laboratory environment that promotes open communication regarding biosafety concerns, incidents, and violations. The PI shall not penalize or reprimand individuals who report such issues to the appropriate authorities, such as the IBC, BSO, Risk Management, or State or Federal agencies.
- Ensure lab personnel comply with shipping regulations for biohazardous and/or select agents. The BSO provides shipping training to ensure compliance. Before shipping microbiological cultures, tissues (human or animal), body fluids, or dangerous goods, the PI must contact the BSO to verify that all applicable transportation safety regulations have been met.

IBC POLICIES AND PROCEDURES

General Guidelines

The UTEP IBC typically conducts monthly meetings on the **third Friday of each month**, which are open to the public. Advanced notice of these meetings is posted on the UTEP IBC website. Protocols are approved for three years, and the IBC reviews initial and triennial submissions and procedural modifications. The PI will receive a formal letter via the institution submission platform, notifying them of the IBC's decision regarding all protocols. Except for the PI, personnel modifications are reviewed and approved administratively by the IBC Coordinator after training verification.

Per the *NIH Guidelines*, the IBC Chair is responsible for submitting an annual report on IBC's activities to the NIH OSP. The report will include biographical sketches and details of each member and will be forwarded to NIH. For any queries or information regarding IBC, individuals may contact the IBC Chair or IBC Coordinator. In case of a request for information under the Texas Public Information Act, the IBC Coordinator will provide the necessary information to the Vice President for Business Affairs Office (VPBA) for processing according to the regulations of the Texas State Attorney General's Office. The IBC Coordinator will inform the IBC Chair, IO, and BSO about the request.

All approved protocols will be valid for **3 years** and will adhere to the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (refer to

https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.pdf). The PI will receive a formal letter via the submission platform, notifying them of the IBC's decision regarding all protocols.

SUBMISSION TYPES

New Protocol

The IBC protocol application is the primary tool used in the review process. The PI uses it to communicate to the IBC what they are doing, the risks involved, the controls in place, and who will perform the activities.

Amendment

The PI must seek approval for any changes or additions to previously approved activities during the three-year approval period. This includes changes in personnel, funding sources, locations, biohazardous materials, or activities with those materials.

Renewal

The IBC typically approves new protocols for three years. A protocol may be renewed on a triennial basis unless the IBC stipulates more stringent requirements. Renewal submissions must be received at least 30 days before expiration.

Incident Report

In the event of a significant research-related incident, the IBC may suspend, limit, or terminate a Principal Investigator's authorization to use biological materials pending a formal investigation. The IBC may take further actions deemed appropriate if a Principal Investigator has repeated compliance violations that are not corrected, any severe safety violations, or multiple less serious safety concerns are identified that create a significant risk to laboratory workers, other persons, or the environment. The PI is responsible for reporting research-related incidents immediately to the UTEP IBC Chair (915-747-6607) and BSO (915-747-8124). The IBC is accountable for reporting significant incidents, violations, and research-related accidents and illnesses involving rDNA or SNAMs to the IO and the NIH Office of Science Policy (OSP) within 30 days or immediately, depending on the gravity of the incident unless the Institutional Biosafety Committee determines that the PI has already filed a report.

REVIEW TYPES, PROCESSES, AND TIMELINE

All research projects involving rDNA, SNAMs, and/or other biological materials must be registered and may require approval from the IBC before initiation. The submitted protocols will undergo an administrative check and screening to determine the applicable Category(ies) (A1, A2, or B) and Section(s) of the *NIH Guidelines*, as well as the necessary containment level. This determination will be based on the table below:

Category/Approval/Review Type	New Protocol	Renewal/Amendment/Reports
Category A1 IBC approval is required before initiation Full Committee Review (FCR)	Work with rDNA and SNAMs falling under Sections III-A through D of the NIH Guidelines Work with recombinant RG2 and RG3 agents Work with non-recombinant RG3 agents Work with biological toxins classified as Select Agents Work with recombinant human-derived materials and rDNA Work with arthropods with rDNA or RG2 agents (ACL-2) Work with Select Agents Dual Use Research of Concern Any protocol an IBC Member requests for FCR	NIH Guidelines require IBC approval before initiation (Sections III-A through D) Increase in risk group Increase in biosafety level Significant change in procedures Significant change in species, organisms, etc. Change in PI Any IBC Member requests FCR

Category A2 IBC approval is required, but work can be initiated with simultaneous registration FCR	Work with rDNA and SNAMs falling under Section III-E	NIH Guidelines require IBC notice simultaneous with initiation or exempt experiments (Sections III-E and F) Minor change in procedures Minor change in species, organisms, etc. Change in location
Category B Notifying the IBC by submitting a protocol is mandatory and requires the IBC committee to provide a determination and risk assessment of the proposed project. Designated Member Review (DMR)	Exempt experiments (Section III-F) Work with non-recombinant ≤BSL-2 biological agents, human-derived materials, biological toxins (other than those classified as Select Agents), or arthropods (ACL-1)	Amendment with minor changes in exempt procedures Amendment with minor changes in species, organisms, etc. Change in location
Administrative	N/A	Change in key personnel Change in funding source(s) Contact information Protocol termination and closing report Incident report

Category A1: Research protocols involving either handling recombinant organisms (RG2 and RG3 infectious agents, human-derived materials, and arthropods), work falling under Sections III-A through III-D of the NIH Guidelines will require approval of the IBC, using the Full Committee Review (FCR) process, and/or other relevant regulatory bodies (*e.g.,* IACUC and IRB) before the research can begin.

Category A2: Research protocols involving procedures under Section III-E of the NIH Guidelines must be approved by the IBC but may begin upon submission of an IBC Protocol Application Form and acknowledgment by the IBC coordinator. At UTEP, these lower-risk protocols must be reviewed for approval using the FCR process.

Category B: Protocols that fall under Section III-F of the NIH Guidelines, any teaching activities involving BSL-1 rDNA or SNAMs, and any research or teaching activities involving non-recombinant ≤BSL-2 biological agents, materials, or toxins must be registered with, reviewed, and approved by the IBC before initiation. The IBC Chair may assign the protocol to a committee member or an ad hoc reviewer with the relevant expertise, utilizing the Designated Member Review (DMR) process.

All IBC protocol submissions, appendices, and supporting documents must be submitted electronically through the submission platform. Applications and procedural amendments requiring FCR must be submitted by the **first business** day of each month to be considered for the next meeting. Renewals must be submitted at least **sixty days** before the expiration date. These periods are necessary for pre-review and allow the committee members sufficient time to review the submission before the meeting. Due dates are available on the UTEP IBC website.

Application forms and appendices can be found on the submission platform library or the UTEP IBC website. If you have questions about submission, please contact the IBC office by e-mail at ibc@utep.edu or by phone at 915-747-7913.

For a new project, procedural amendment, or renewal (triennial), the PI must ensure that all the personnel listed have completed or are at least completing training requirements (*e.g.,* GLS, BBP, BSL-3) and OHP, whenever applicable. Additionally, revised submissions going to FCR must be received no later than the published receipt deadline to be placed on the agenda for that

month's meeting. Once a PI submits a protocol through the submission platform to the IBC, the IBC coordinator conducts a pre-review within **two business days** to ensure the submission is complete. At the same time, the protocol is sent to the IBC Chair and the BSO to determine the protocol category(ies) and review process. After the administrative pre-review, protocols are either sent for FCR or polled for potential assignment to DMR by the IBC Chair. The IBC coordinator will notify the PI that if their protocol only falls under category A2, work can begin while FCR reviews it.

Assigned reviewers have **seven days** from the IBC Coordinator's notification to submit their comments/questions. Both the FCR and DMR process include the consideration of the following:

- Assessing the containment levels A/BSL1, A/BSL2, or A/BSL3, as required by the *NIH Guidelines*), and ACL1 or ACL2 for work with arthropods.
- Assessing the facilities, procedures, practices, training, and expertise of personnel included in the PI protocol, including using rDNA or SNAMs and biohazardous materials, agents, and toxins.
- Determining the physical and biological containment for rDNA or SNAMs, biohazard material, agents, toxins, and containment levels as necessary.
- Assessing the possession and procedural usage of rDNA or SNAMs, biohazard material, agents, and toxins.

FCR

All new and renewing protocols and procedural amendments falling under Category A1 and A2 must be reviewed by the full committee. The IBC Chair will designate primary and secondary IBC reviewers who are regular members of the IBC and have the necessary expertise to review the protocol. If necessary, the IBC chair will appoint an expert as an ad hoc reviewer. This protocol will be reviewed at an upcoming convened meeting of a quorum of the full committee. This protocol will be reviewed at an upcoming meeting with a quorum of the full committee.

At the meeting, the committee will review the protocol, hear reviewers' comments, and decide if any revisions are necessary.

Motions

A member must call for a motion after discussing and reviewing a submission. A motion should be one of the following regarding the outcome of the vote on the proposal:

- Approved
- Approved with contingencies: To complete approval, the PI must complete the modifications requested by the IBC for the proposed work at the indicated containment level.
- Approved with minor modifications: To finalize approval, the PI must implement the modifications requested by the IBC for the proposed work at the specified containment level.
- Modification requested: Send the submission back to the PI with significant modifications to be reviewed and approved by FCR.
- Not approved

After the IBC meeting, the investigator will receive a notification informing them of the committee's decision. If the motion is approved with minor modifications, the motion must include how those modifications will be reviewed: 1) DMR assigned or 2) IBC Coordinator. When the motion is to review the modifications by DMR, the IBC Chair then assigns up to two reviewers.

The assigned designated reviewers are authorized to approve or require further modification(s) to secure approval, and their decision must be unanimous. If the motion is for modifications requested, the investigator must submit all revisions back to the submission platform, to be reviewed by a quorum of the full committee.

DMR

New protocols and procedural amendments that fall under Category B submitted to the IBC are reviewed by the IBC committee using the DMR process. Each eligible DMR protocol is distributed to the entire IBC with specific instructions regarding the designated member review process and a three-day (72-hour) deadline from the IBC Coordinator's notification to call for potential FCR. Affirmation from all IBC members is not required. Written rationale to the IBC coordinator must accompany a call for FCR. If no one calls for FCR, the protocol is sent through the DMR process. At that point, the chair will assign one or more qualified members to review the category of new protocol or procedural amendment submissions. The designated member(s) can approve, request modifications (to secure approval), or send the submission to an FCR.

The Designated Reviewer(s) will have **five business days** from the IBC Coordinator's notification to evaluate the documents and submit comments on the PI's submission via the submission platform. The IBC coordinator will share the reviewer's comments with the PI via the submission platform IRBNet. If the designated reviewer has not completed the review in the required period, the Chair can reassign another reviewer. Upon sharing the reviewer's comments, the PI will be granted access to the protocol submission platform and will have **five business days** from the IBC Coordinator's notification to address any additional comments and submit revisions. The reviewer will re-evaluate these revisions within **three business days** of the PI submission. If the PI does not submit revisions on time, the submission will be withdrawn from the agenda. Following assessment of the PI revisions, the DMR can either:

a. Approve: The submission for the proposed research is approved.
b. Request Information/Modification: The reviewer may request additional information or modifications from the PI before making a final decision.
c. Bring the Submission for FCR: If the reviewer believes further discussion or evaluation by the entire committee is necessary, the submission is escalated to the FCR.

Once the DMR process is complete, the IBC coordinator will notify the PI of the designated reviewer's decision and recommendations for approval.

Administrative Review

Personnel amendments without changes to the protocol may be reviewed and approved administratively. Administrative approval can be performed outside a convened IBC meeting.

IBC MEETING

Meeting Time and Quorum

The IBC meets at scheduled times and votes on the protocols, provided there is a quorum. A quorum is established with **at least five** voting members. Members may attend the IBC meeting by video conference or by telephone. IBC Members with a potential conflict of interest with the activities under review must be recused from the vote and will not be counted as part of the quorum. See Conflict of Interest for additional information below.

Conflict of Interest

The NIH Guidelines state that no member of an IBC may be involved (except to provide information requested by the IBC) in reviewing or approving a project in which he/she has been or expects to be engaged or has a direct financial interest. If an IBC member is a Principal Investigator of a protocol undergoing review or has a personal or financial interest, they must abstain from voting. The minutes of the meeting will contain a record of this action.

Voting

Each member is allowed one vote, and proxy votes are not permitted. Members must vote in favor of, against, or abstain from voting on a motion. If a member decides to vote against the motion or abstain, they may request that their reason be recorded in the minutes.

PI Attendance

PIs are strongly encouraged to attend meetings where they will briefly (5-10 min) describe their planned activities and address any questions or concerns from the committee. The IBC Coordinator will send a meeting invitation to the PI approximately one week before the meeting.

Meeting Minutes

Meeting minutes summarize the committee's business and discussions. The IBC Coordinator prepares them, and the minutes from the previous meeting are reviewed at the next meeting.

Approval of Suspension and Termination

The IBC can suspend or terminate activity approval based upon non-compliance with regulatory obligations or University policies and programs. Typically, the IBC Chair and/or IBC Coordinator will work with the PI to resolve any issues. The IBC must vote on a suspension or termination of approval at a convened meeting and suspension can carry with a simple majority of votes.

PROTOCOL TERMINATION

The PI will notify the IBC when a research protocol involving rDNA and biohazardous materials, agents, and toxins is completed or no longer active. The IBC shall contact the PI with any questions or concerns regarding the Termination of Approval.

If the PI fails to provide a renewal or resubmission form to the IBC before the protocol expires, a letter will be sent to the PI and copied to the Department Chair. All research covered in the expired protocol must cease. If the PI does not provide renewal or resubmission by the next IBC meeting, this issue will be added to the agenda, and the IBC will determine whether to terminate the IBC protocol. Terminating the IBC protocol may necessitate the termination of any related IACUC or IRB protocols and notification of the IO, who may in turn inform other relevant agencies (e.g., National Institutes of Health Office of Laboratory Animal Welfare, granting agencies) for further action.

PROTOCOL DEVIATIONS AND ALLEGATIONS OF NON-COMPLIANCE

Definitions

Protocol Deviation:

- A protocol deviation occurs when there is an inconsistency in a research study between the protocol that has been reviewed and approved by the IBC and the actual activities being done. As defined below, protocol deviations may be minor, moderate, or major. Protocol deviations involving a human gene transfer study will be subject to IRB and IBC policies.

Minor Protocol Deviation:

- The deviation has no substantive effect on the biosafety risks and does not meet any criteria listed for Moderate or Major Protocol Deviations.

Major Protocol Deviation**:**

- The deviation has harmed or posed a risk of substantive harm to the safety of personnel or human subjects.
- The deviation has posed a risk of minimal harm to the safety of personnel or human subjects.
- The deviation resulted in a regulatory violation that can be acceptably resolved or; There is a history of repeated minor protocol deviations from the same laboratory, site, or research team.
- There has been a failure to follow up on actions and recommendations ordered by the IBC to correct minor or moderate protocol deviations.
- The deviation resulted from willful or knowing misconduct on the part of the investigator(s).
- The deviation involves severe or continuing noncompliance with federal, state, or local research regulations.
- The deviation resulted in a violation of the select agent regulations.
- There have been repeated minor or moderate protocol deviations from the same investigator.
- There has been a failure to follow action ordered by the IBC to correct minor or major protocol deviations

Reporting Requirements

Minor Protocol Deviations. Minor protocol deviations do not need to be reported to the IBC. However, the IBC Coordinator will review any minor protocol deviations that come to the IBC's attention and may require corrective action.

Major Protocol Deviations. All major protocol deviations must be reported to the IBC as described below.

- Direct substantive harm or risk of substantive harm is a significant protocol deviation. It must be reported to the UTEP IBC (and IRB if human subjects are involved) within **72 hours** of discovery of the deviation

Procedure for Reporting Allegations of Non-compliance

The concerned individual may report allegations to any of the following:

- Associate Vice President, RCRA
- IBC Chair
- Any IBC member
- Biological Safety Officer
- Vice President for Research & Innovation

The IBC chair is responsible for the receipt and disposition of all complaints. All allegations will remain confidential to the extent possible. When the complainant wishes to be openly identified, the IBC Chair will acknowledge receipt of the allegations to the complainant in writing. The UTEP: Whistleblower Policy should be consulted for specific information on individual protection.

The IBC Chair will appoint a subcommittee to determine if the complaint has sufficient grounds to warrant a full investigation. All individuals involved in the investigation will be informed about the purpose of the investigation and how it will be conducted. In its investigation, the subcommittee will examine all pertinent documents and procedures, interview involved personnel and report its findings to the entire IBC. The IBC will then vote either in a convened meeting or electronically for the following options:

- Accept the recommendations of the investigating subcommittee
- Offer further suggestions or comments
- Request a convened meeting to discuss the concern and/or the report. A single member's request for a convened meeting to consider a concern will result in a convened meeting

Based on the investigation report, the IBC will determine the required actions. IBC determinations may include, but are not limited to:

- Investigation did not reveal an issue of non-compliance
- Investigation revealed non-compliance
- Related aspects of the program require further review
- Other related institutional programs may require review

For any noncompliance with IBC policy, the IBC must prescribe corrective actions, appropriate deadlines, and reporting requirements. The IBC must determine whether the noncompliance meets the criteria for actionable as determined by the IBC.

Examples of corrective actions include:

- Terminate approval of the respective research protocol
- Suspend approval of the respective research protocol pending completion and acceptance by the IBC of an independent audit of the study and/or the submission, by the PI, of a written plan for the correction and/or prevention of the problem
- Institute an IBC-mandated corrective action plan and independent audit of the study
- Other actions as the IBC deems appropriate, including recommendations to the Vice President for Research for confiscating and destroying rDNA and/or biohazardous materials

In writing, the IBC Chair will communicate the results of the IBC evaluation of a reported concern to the person responsible for reporting the concern, the PI, the Vice President for Research, the PI's Department Chair, and the Associate Vice President of RCRA. The communication will include a summary of the concern, the findings of the investigation, determinations of the IBC, and the recommended corrective actions/sanctions. The letter will also inform the person(s) who initiated the report of their option to appeal the decision within ten days of receipt of this letter by writing the IBC Chair detailing the basis of the appeal and requesting a meeting with the IBC. The IBC is obligated to report within **thirty days**, through the Vice President for Research & Innovation, any significant problems, violations of the NIH Guidelines, or any significant research-related accidents and illnesses to NIH's Office of Biotechnology Activities unless the institution determines that the PI or Biological Safety Officer has already filed a report.

Failure to comply

PIs must comply with the IBC standards outlined in this Handbook. Noncompliance includes, but is not necessarily limited to:

- Failure to register biohazardous agents, including non-exempt rDNA or SNAMs
- Poor biological safety/containment practices documented through routine lab inspections
- Failure to correct a documented (confirmed) biological safety complaint or concern

Any infractions will be reported to the IBC, potentially leading to suspending or canceling all authorized registrations. The PI's Department Chair, Dean, and other relevant administrators will be informed of the violation(s).

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