
UTHealth Institutional Biosafety Committee (IBC)

Title: Institutional Biosafety Committee (IBC)
Policy and Procedures**Section:** Biological Safety**IBC Approval Date:** February 2016**Revision Date:** September 12, 2024

PURPOSE

The University of Texas Health Science Center at Houston (UTHealth) Institutional Biosafety Committee (IBC) reports to the UTHealth Executive Vice President and Chief Academic Officer on matters related to the use of use of infectious agents and/or recombinant and synthetic nucleic acid (rDNA) technology in research, clinical and educational activities at UTHealth. The committee is charged with ensuring full compliance with *CDC/NIH Biosafety in Microbiological and Biomedical Laboratories (BMBL)*, *NIH Guidelines for Research Involving Recombinant and Synthetic Nucleic Acid Molecules* (referred to herein as the *NIH Guidelines*) and the UTHealth Institutional Biosafety Manual. The most recent version of the *BMBL* (6th Ed., June 2020) is available on the CDC's website ([BMBL 6th Ed.](#)) and shall apply to all infectious agent research performed at UTHealth. The most recent version of the *NIH Guidelines* (April 2024) is available at the NIH Biosafety, Biosecurity, and Emerging Biotechnology Policy Division website ([NIH Biosafety and Biosecurity policies](#)) and shall apply to all rDNA research performed at UTHealth, regardless of the rDNA research project funding source.

Specific tasks of the Institutional Biosafety Committee include:

- To recommend to the Executive Vice President and Chief Academic Officer policies and procedures that ensure the health and safety of all individuals within UTHealth, and to ensure compliance with all applicable federal, state and local statutes, regulations, procedures and principles relating to the purchase, storage, use, and disposal of biological hazards and/or rDNA used in UTHealth research, clinical and educational programs.
- To assess the safety of rDNA research experiments, including review of Human Gene Transfer protocols, and recommend policies and procedures to ensure the health and safety of all faculty, staff, students, patients, and visitors within UTHealth.
- To review the protocols provided by principal investigators, clinical directors or laboratory instructors relating to the use of biological hazards and to review the activities of UTHealth Environmental Health and Safety (EHS) in verifying the appropriate biosafety containment level of those laboratories, clinics and/or practices. Activities requiring work at Biosafety Level 2 and greater may not initiate without written consent of the IBC.
- To recommend to the Executive Vice President and Chief Academic Officer the need for general and specific training programs for research, clinical, and teaching activities dealing with biological hazards, including infectious agents and/or rDNA, and to review the appropriateness and effectiveness of such UTHealth training programs.

- To submit reports at least annually, to the Executive Vice President and Chief Academic Officer summarizing activities and reviewing the status of significant biological safety issues identified during the year.
- Approving Principal Investigators (PI), their laboratories and/or practices for work at graded biosafety levels, as appropriate, in accordance with the *NIH Guidelines*.
- Overseeing the development and maintenance of written biological safety plans that specify practices for minimizing occupational exposures to infectious biological agents and/or rDNA (including exposures to organisms and viruses containing rDNA, and products of rDNA) for all affected populations through the use of proper engineering controls and work practices; making the plan available to the institutional community; recommending updates to the plan, as necessary; and overseeing the development and implementation of educational programs related to infectious biological agents, rDNA and biological safety.
- Identifying tasks that carry a risk for exposure to infectious agents, rDNA, and the occupational groups involved.
- Overseeing the follow-up and monitoring of those persons with potential exposure to infectious agents and/or rDNA.
- Responding to all public comments/recommendations on IBC actions. IBC will also notify NIH Office of Biotechnology Activities in writing of posed questions and response given.

UTHealth Environmental Health and Safety (EHS) is designated as the monitoring and effector arm of the IBC to ensure the details specified in protocols are feasible and appropriate.

All activities of the committee are coordinated, as necessary, with other institutional components including the Office of Sponsored Projects (OSP), UT Employee Health Services, Center for Laboratory Animal Medicine and Care (CLAMC) and other UTHealth oversight committees, such as the IRB [Committee for the Protection of Human Subjects (CPHS)] and the IACUC [Animal Welfare Committee (AWC)].

Infectious Diseases Review Panel

The IBC has identified a subset of its membership, called the “Infectious Diseases Review Panel” to assume the responsibility to review and advise on the following:

- To review instances of HIV, HBV, HCV or other bloodborne pathogens and TB and other serious infectious diseases in students, researchers, and health care workers, to identify exposure-prone procedures and to determine those circumstances, if any, under which a student, researcher, or health care worker who is infected may perform such procedures.
- To recommend to the Executive Vice President and Chief Academic Officer, infectious disease control policies and procedures to ensure the health and safety of all patients, staff and faculty of UTHealth.

- To recommend to the Executive Vice President and Chief Academic Officer, policies and procedures to ensure UTHealth compliance with all federal, state, and local statutes, regulations, procedures and principles relating to TB, HIV, HBV, HCV, and other significant pathogens.
- To identify tasks that carry the risk for transmission and the employees or occupational groups that are involved.
- To review and contribute to the update of the Institutional Biosafety Manual, Bloodborne Pathogen Exposure Control Plan, and TB Exposure Control Plan annually, or as necessary.
- To define and monitor compliance with the written plan and to monitor follow-up for those employees who test positive for any of the identified pathogens.
- All activities of the subcommittee are coordinated, as necessary, with other institutional components including the Office of Sponsored Projects (OSP), UT Health Services, Center for Laboratory Animal Medicine and Care (CLAMC) and other UTHealth oversight committees, such as the IRB [Committee for the Protection of Human Subjects (CPHS)] and the IACUC [Animal Welfare Committee (AWC)].

Dual Use Research of Concern (DURC) Review Committee

On November 24, 2014, the federal government issued the policy “United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern,” which addresses institutional oversight of DURC. Oversight includes policies, practices, and procedures to ensure DURC is identified and risk mitigation measures are implemented, where applicable. The policy can be found here: <http://www.phe.gov/s3/dualuse/Pages/default.aspx>.

On May 6, 2024, the White House Office of Science and Technology Policy (OSTP) released an expanded and unified [Policy for Oversight of Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential](#).

Members of IBC will also function as the DURC Review Committee. The IBC has developed a screening question that has been incorporated into the IBC protocol application form to determine if the research being conducted qualifies as DURC. The question is based on the recommendations of the policy and requires the research investigator to disclose whether they are conducting a listed experiment with a pathogen of concern. If the investigator answers affirmatively, then a full DURC review will be conducted by the committee membership. Additional expertise from outside of the committee membership may be enlisted if the proposed work is outside the existing membership’s realm of expertise.

Specific information can be found in the UTHealth Dual Use Research of Concern policies and procedures, located online at: <https://www.uth.edu/safety/biological-safety/index.htm>

COMMITTEE MEMBERSHIP

Composition:

The IBC consists of a minimum of five voting members so selected that they collectively have experience and expertise in various infectious agents, rDNA technology, infection control and the

capability to assess the safety of rDNA research and to identify any potential risk to public health or the environment. At least two members shall be unaffiliated with UTHealth (except as members of the IBC) and shall represent the interest of the surrounding community with respect to health, safety, and the protection of the environment. At least one member shall be a scientist or veterinarian with expertise in animal containment principles for studies requiring approval by the IBC. At this time there is no recombinant plant research being conducted at UTHealth; however, if this research is proposed to the committee in the future then at least one member will be sought out with expertise in plant, plant pathogen, or plant pest containment principles for review of those studies.

The current UTHealth committee is comprised of the following voting members serving on three-year, staggered terms of appointment:

- Three or more faculty members with experience in infectious agent research, infection prevention, rDNA technology and/or biological safety and containment *
- One faculty member with experience in Human Gene Transfer or clinical studies
- Two or more community members *
- One or more student member
- One laboratory technician *
- A CLAMC veterinarian with expertise in animal containment
- Biological Safety Officer (currently fulfilled by the Assistant Vice President of EHS) *

Ex Officio Members - the following are designated as members without vote:

- Representative from Legal Affairs
- Vice President for Safety, Health, Environment, and Risk Management
- Safety Manager, Biological Safety Program
- Safety Manager, Environmental Protection Program
- Executive Vice President and Chief Academic Officer
- Center for Laboratory Animal Medicine and Care representative
- Employee Health Clinical Services representative

* Required members by the *NIH Guidelines for Research Involving Recombinant and Synthetic Nucleic Acid Molecules*

The current list of IBC members can be found online at: <https://www.uth.edu/safety/biological-safety/institutional-biosafety-committee.htm>

Appointment of Members:

The IBC Chair, Vice Chair, and other members are appointed by and serve at the discretion of the UTHealth President on recommendation from the UTHealth Executive Vice President and Chief Academic Officer. The Chair and Vice Chair serve as regular voting members of the IBC and must fully understand all functions, policies and procedures relevant to the IBC.

IBC Chair: Dr. Catherine Denicourt (713-500-5696)
Vice Chair: TBD

A *curriculum vitae* (CV) and a list of the membership is maintained and submitted annually to the NIH/OSP for renewal of the IBC registration. Updated CVs are sent to the Biological Safety Manager (713-500-8162) upon appointment and as requested there forward.

Conflict of Interest:

IBC members must not be involved in the review or approval of a project in which he/she has been or expects to be engaged in or has a direct financial interest, *except* to provide information requested by the committee.

Attendance Requirements:

Each member of the IBC is expected to attend meetings of the IBC on a regular basis. Failure to attend regularly may result in removal of the member from the IBC.

Media Inquiries:

IBC members must immediately direct any media inquiries regarding committee participation or content to the UTHealth Office Public Affairs, University Communications. They may be reached 24 hours per day at 713-500-3030.

Institutional Biosafety Committee Meetings:

The IBC meets on the second Thursday of every month. For further scheduling information or to obtain committee meeting minutes contact EHS at 713-500-8100 or online:

<https://www.uth.edu/safety/biological-safety/index.htm>

All voting at a convened meeting of the IBC with regard to protocol approval requires a quorum of members (defined as half of the members plus one) to be present and a majority vote of the quorum for approval.

IBC Authority and Operations

The IBC has the authority to assess the risks associated with the undertaking of infectious agent research and/or rDNA research and based on their findings, to exempt, approve, require modifications to, or disapprove all research activities under its jurisdiction. The IBC also has the authority to suspend or terminate a study approval for failure to meet the requirements as set forth herein or as a result of a serious adverse event. Any notification of suspension or termination of a study shall be given in writing to the principal investigator of a study and shall include a statement giving the reason(s) for the suspension or termination. The IBC may also notify the appropriate university official(s) and funding source (if the project is funded by an external source) and as appropriate the NIH/OSP. The IBC may also place restrictions on studies as it may deem appropriate and necessary, and may supersede the BMBL, *NIH Guidelines* or the Institutional Biosafety Manual when deemed necessary.

Applicability:

The IBC shall approve all research deemed BSL-2 or higher at UTHealth, and review all rDNA research to ascertain if it requires approval or if it is exempt.

The *NIH Guidelines* shall apply to all rDNA research performed at UTHealth, unless such research falls within categories that are exempt from the *NIH Guidelines*. The following types of rDNA molecules are exempt from the *NIH Guidelines*, as provided in Section III-F of the *NIH Guidelines*:

- **Section III-F-1.** Those synthetic nucleic acids that: (1) can neither replicate nor generate nucleic acids that can replicate in any living cell (e.g., oligonucleotides or other synthetic nucleic acids that do not contain an origin of replication or contain elements known to interact with either DNA or RNA polymerase), and (2) are not designed to introduce a stable genetic modification, and (3) do not produce a toxin that is lethal for vertebrates at an LD50 of less than 100 nanograms per kilogram body weight. If a synthetic nucleic acid is

deliberately transferred into one or more human research participants and meets the criteria of Section III-C, it is not exempt under this Section.

- **Section III-F-2.** Those that are not in organisms, cells, or viruses and that have not been modified or manipulated (e.g., encapsulated into synthetic or natural vehicles) to render them capable of penetrating cellular membranes.
- **Section III-F-3.** Those that consist solely of the exact recombinant or synthetic nucleic acid sequence from a single source that exists contemporaneously in nature.
- **Section III-F-4.** Those that 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.
- **Section III-F-5.** Those that 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).
- **Section III-F-6.** Those that 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. A list of such exchangers will be prepared and periodically revised by the NIH Director after appropriate notice and opportunity for public comment (see Section IV-C-1-b-(1)-(c), Major Actions). See Appendices A-I through A-VI, Exemptions under Section III-F-6--Sublists of Natural Exchangers, for a list of natural exchangers that are exempt from the NIH Guidelines.
- **Section III-F-7.** Those genomic DNA molecules that have acquired a transposable element, provided the transposable element does not contain any recombinant and/or synthetic DNA.
- **Section III-F-8.** Those that do not present a significant risk to health or the environment (see Section IVC-1-b-(1)-(c), Major Actions), as determined by the NIH Director following appropriate notice and opportunity for public comment. See Appendix C, Exemptions under Section III-F-8 for other classes of experiments which are exempt from the NIH Guidelines..

All work with rDNA molecules that are not recognized as exempt must be approved through a full committee review process. An “Institutional Biosafety Committee Application Form” must be submitted to the EHS Biological Safety Program to initiate the approval process. This form can be found online at:

<https://safety-assistant.uth.edu/EHSAQuestionnaire/EHSAWebisapi.dll/11y6ff41tfjx5q14va3u71xh5wks/?protocol=BIO>

Research Review:

On behalf of the institution, the IBC is responsible for the initial and continuing review of infectious agent and/or rDNA research conducted at or sponsored by UTHealth for compliance with the BMBL and/or *NIH Guidelines* as specified in *Section III, Experiments Covered by the NIH Guidelines*, and approval of those research projects that are found to fall under the *NIH Guidelines*.

The review shall include: 1) an independent assessment of the containment levels required by the *NIH Guidelines* for the proposed research; 2) an assessment of the facilities, equipment (including personal protective equipment), procedures, training, and expertise of the personnel involved in the research; and 3) an assessment of provisions for ensuring compliance with all adverse events and incident reporting as required by the *NIH Guidelines*. The IBC must seek expertise outside its membership in cases where members of the committee have insufficient knowledge to assess risks associated with the proposed research. Continuing review of infectious agent and/or rDNA research studies shall be conducted at least annually via the annual protocol renewal form.

Determining Containment Levels:

On behalf of the institution, the IBC is responsible for setting containment levels as necessary that are specified in the BMBL and *NIH Guidelines*.

Adopting Emergency Plans:

On behalf of the institution, the IBC is responsible for adopting emergency plans covering releases, spills and personnel exposure involving infectious agents and/or rDNA. These plans and specific information, including definitions of releases, accidental spills, and personnel exposure, can be found in the Emergency Response Plan for Biohazardous Materials or in the UTHHealth Institutional Biosafety Manual, located online at: <https://www.uth.edu/safety/biological-safety/index.htm>

Records:

IBC Meeting Packets – Prior to each IBC meeting, copies of the following shall be provided to each member:

- IBC meeting agenda
- Minutes of the previous IBC meeting
- Protocol application documents for each new submission or renewal including:
 1. Memorandum of Understanding and Agreement for the Use of Biological Agents and DNA Technology (MUA),
 2. Risk Assessment (Protocol) Summary, and
 3. Any other supporting documents

Protocol Application Form / Risk Assessment Summary – In accordance with requirements in the *NIH Guidelines*, all protocols will contain a description of the following information:

- Agent characteristics
- Types of manipulations planned
- Source of inserted DNA sequence(s)
- Nature of inserted DNA sequence(s)
- Host(s) and vector(s) to be used
- Whether a foreign gene will be expressed, and if so, the protein to be produced
- Containment conditions or biosafety level (BSL) to be implemented
- Applicable section of the *NIH Guidelines*

IBC Meeting Minutes – At each meeting, minutes will be recorded in accordance with guidance provided by the NIH/OSP. These minutes will be reviewed and approved by all members during the next convened IBC meeting.

For each meeting, the following information must be included in the minutes:

- Date and place of meeting
- Whether minutes of the previous meeting were approved

- Individuals in attendance
- Time of meeting adjournment

For each protocol, the following minimum information must be included in the minutes:

- IBC protocol number, PI name and title of protocol
- Applicable section of *NIH Guidelines*
- Whether this protocol was reviewed or not
- What significant questions were asked (if any), and their corresponding answers
- The decision made about this protocol
- The total number and type of votes

Review Process:

Submission of New Protocol Applications – All new protocol applications shall be directed to the EHS Biological Safety Program in electronic format. The following are required of all new submissions: 1) a completed protocol application form; 2) relevant grant proposal, if applicable; 3) supporting documents, such as laboratory standard operating procedures, as applicable.

Upon receipt of a protocol application, EHS Biological Safety Program personnel will assign a protocol number that will be used for tracking purposes.

EHS Biological Safety Program personnel will work with the submitting PI to provide technical advice on any necessary research safety procedures. Once these procedures are determined, properly documented, and agreed upon by the PI, the protocol will be submitted (usually via email) to a group of subcommittee members for preliminary review of the protocol prior to full committee review. This process, known as a “subcommittee review,” is intended to capture committee member expertise to address any significant protocol issues or questions before the protocol reaches the full committee. Generally, subcommittee review members are notified at least one week in advance of the IBC meeting to allow time for thorough review and discussion. Questions or concerns from subcommittee reviewers shall be submitted back to EHS Biological Safety Program personnel to mediate clarification or addressing of issues from the PI prior to the IBC meeting.

The protocols are then submitted to the IBC for full committee review.

Voting – After presentation of new or renewal protocol submissions to the committee, adequate time will be allowed for discussion. A vote will be conducted to approve or oppose the research project. A majority of the membership must be present to transact this business. This majority must include at least one unaffiliated member. An IBC member may not vote on his/her own study. Any member having a conflict of interest must abstain from both the discussion of the research study (except to provide information to the committee) and the voting process.

Decisions of the IBC may be:

- **Approved.** A majority of the votes cast is needed for study approval. This majority must be maintained even if some members have abstained themselves from voting. If the study is approved, the EHS Biological Safety Program will forward to the PI an approval letter, a copy of the signed MUA, a copy of the protocol’s final “Risk Assessment Summary,” and a copy of the PI’s responsibilities for work involving rDNA.

Each protocol approval is granted for a maximum period of five years. After this period, the protocol will either be terminated or a new protocol application must be submitted to the IBC

for full review and approval. The old protocol number will be inactivated at the time of termination or the time of approval of the new protocol application, and the EHS Biological Safety Program will assign a new protocol number to the recently approved protocol.

- **Disapproved.** If a majority of the votes cast are for disapproval (or opposition), then the protocol is disapproved. If a research study is disapproved by the IBC, a written statement including the reason(s) for the disapproval shall be sent to the investigator. The investigator will be given an opportunity to respond to this statement, which may be given either in person or in writing.
- **Approved pending modifications.** The IBC may approve a study contingent upon minor or specific changes or modifications being made to the protocol submission. Once the appropriate changes have been made, the protocol submission is approved. The EHS Biological Safety Program will then provide written approval to the PI as noted above.
- **Tabled.** If the IBC requires additional information to make an appropriate decision regarding the study, the EHS Biological Safety Program will so inform the investigator, identifying the specific documentation required. This documentation, along with the initial submittal, will be reviewed at the next meeting of the IBC following receipt of such documents or distributed electronically to the full committee for review and approval. The investigator may be invited to present the additional information to the IBC in person.

Communication of IBC Decisions – The EHS Biological Safety Program will notify each PI of the IBC’s decision regarding his/her protocol submission.

Once a protocol is approved the IBC Chair signs and dates the original MUA form, a copy is sent back to the PI with a copy of the protocol summary and the approval memo and another copy is retained in the local EHS Biological Safety Program office protocol file. The original form is retained in the master IBC files located at the EHS biosafety office, 6431 Fannin St., CYF G.102, Houston, TX 77030.

Appeal of an IBC Decision:

If an investigator wishes to appeal a decision of the IBC, the appeal must be made and submitted to the IBC in writing. The appeal will be considered at the next meeting of the IBC. If a dispute arises, the NIH/OSP may be contacted for consultation or clarification of the *NIH Guidelines*, if necessary.

Expedited Review:

Minor changes may be granted by the IBC Chair or his/her designee and reported to the IBC on a case by case basis for protocols previously approved by the IBC. Committee approval may not be granted for new protocols without full committee review.

Annual IBC Protocol Reviews:

All research protocols require an annual review. The EHS Biological Safety Program will send an “Annual Protocol Review Form” to the PI for each active research protocol. The investigator must complete the “Annual Protocol Review Form,” sign and date it, and return it to the EHS Biological Safety Program. An EHS biosafety representative shall sign and date the form and submit it to the IBC Chair for review and approval. Once the IBC Chair signs and dates the original form, a copy is sent back to the PI and another copy is retained in the local EHS Biological Safety Program office

- Institutional Biosafety Committee Chair
- Animal Facility Director (if applicable)

A copy of all reports submitted by the IBC on behalf of the institution shall be sent to the Executive Vice President and Chief Academic Officer for review.

Record Requirements

Records of the IBC meetings and protocol approvals shall be retained for at least 3 years. These records shall include:

- Protocol records, copies of all research proposals, reports of serious adverse events or incidents associated with the research studies, and any scientific evaluations and/or progress reports submitted by researchers
- Records of continuing review activities
- Minutes of IBC meetings showing attendance and actions taken

Training

IBC Members – Training will be conducted at least annually for all IBC members to provide initial and refresher training on the *NIH Guidelines*, member responsibilities, and reporting adverse events or incidents involving rDNA. Additionally, IBC members are provided with a copy of the *BMBL*, *NIH Guidelines*, a copy of this policy and procedures document, and a copy of the IBC Member Responsibilities (found in the NIH guidelines): <https://www.uth.edu/safety/biological-safety/index.htm>

Principal Investigators – Upon hire, all PIs receive awareness training on the responsibilities of the PI with respect to infectious agents and/or rDNA work and the *NIH Guidelines* at the Basic Laboratory and Clinical Safety training course mandated for all new employees working in the lab or clinical setting at UTHealth. PIs that submit protocols to the IBC for review, will receive a copy of the rDNA PI User Responsibilities: <https://www.uth.edu/safety/biological-safety/index.htm>

Associated Policies

Accidental Spills – Loss of Containment

Accidental Spills – Personal Contamination

Dual Use Research of Concern (DURC)

UTHealth PI Responsibility

Fully and Conditionally Exempt Institutional Biosafety Committee Protocols

Any issues not specifically addressed in this document shall be governed by the BMBL and *NIH Guidelines*.

This policy has been reviewed and approved by the Institutional Biosafety Committee.

UTHealth Houston Institutional Biosafety Committee Chair