UTHealth Institutional Biosafety Committee (IBC)

Title: Institutional Biosafety Committee (IBC) Policy and Procedures

Section: Biological Safety

IBC Approval Date: February 2016

Revision Date: April 9, 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

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 effecter 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.

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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

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 UTHealth 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

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 meeti

The IBC Chair may take any of the following actions for protocols undergoing annual review: 1)