Institutional Biosafety Committee (IBC)

Policies and Procedures

The University of Texas Rio Grande Valley™

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Brownsville ∗ Edinburg ∗ Harlingen ∗ McAllen

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Institutional Biosafety Committee (IBC) Policies & Procedures University of Texas Rio Grande Valley (UTRGV)

Introduction

The University of Texas Rio Grande Valley (UTRGV) is committed to the safety of faculty, staff, students, community at large and the environment through deliberate and legislated oversight of research activities involving the use of potentially Hazardous Biological Agents (HBA) and recombinant nucleic acids (rDNA) at UTRGV or authorized by UTRGV. The University recognizes and accepts this responsibility shared with UTRGV investigators and other researchers in determining that research involving HBAs meets or exceeds any applicable federal, state, and local regulations, and accepted best management practices. Policies and procedures of UTRGV's Institutional Biosafety Committee (IBC) described herein serve as bylaws of the committee for evaluation of protocol registrations, committee membership, responsibilities, recommendations, and any other aspects of IBC activity.

At UTRGV rDNA and HBAs are defined as follows:

- rDNA include (1) molecules that a) are constructed by joining nucleic acid molecules and b) can replicate in a living cell, i.e. recombinant nucleic acids, or (2) nucleic acid molecules that are chemically or by other means synthesized or amplified, including those that are chemically or otherwise modified but can base pair with naturally occurring nucleic acid molecules, i.e. synthetic nucleic acids, or (3) molecules that result from the replication of those described in (1) or (2).
- HBAs consist of any microorganism/cell, virus, or toxin (such as Select Agents) of plant, products of animal or human origin, cell culture, parasite, including those that have been genetically modified, which may cause infection, allergy, inflammation, toxic reaction, malignancy, or otherwise produce a hazard to human, animal, plant and/or environmental health. HBA's also include select agents such as toxins and belong to BSL-2 or above risk groups according to their hazard level.

The IBC together with the office of Environmental Health, Safety and Risk Management (ESHRM), Post Approval Monitoring (PAM), the Office of Research Compliance (ORC), the Institutional Animal Care and Use Committee (IACUC), and the Institutional Review Board (IRB) constitute the framework of research compliance at UTRGV.

Purpose of the IBC

The IBC at UTRGV reviews research conducted at or sponsored by UTRGV involving recombinant or synthetic nucleic acid molecules and HBAs. Institutions that receive support from the National Institutes of Health (NIH) for recombinant or synthetic nucleic acid research are required to establish, register, and operate an IBC with the NIH Office of Science Policy (OSP) in compliance with the *NIH Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines).*

The IBC reviews, evaluates, and, through PAM and EHSRM monitors all UTRGV research projects

involving synthetic/recombinant nucleic acids, and biological agents or practices classified as BSL-2 or above that may pose differing levels of safety, health, or environmental risk to plants, animals, humans, and/or the environment. The objective of the IBC committee is to ensure that the research is conducted safely, that research infrastructures provide adequate containment, and that all personnel involved in handling the agents are appropriately trained. The IBC performs initial and periodic risk assessments, continuing reviews, and requests inspection of research infrastructures. With the support of EHSRM, ORC, and PAM the IBC provides a comprehensive collaborative oversight framework to ensure administrative, procedural, and infrastructural research compliance with applicable federal agencies regulations and UTRGV best practices. Once the Principal Investigator (PI) has submitted a protocol registration for the use of rDNA or HBAs to the IBC, the committee is responsible for:

- Assessing proposed containment levels, facilities, procedures, practices, training, and expertise of personnel involved in the proposed research relative to established biosafety standards and best management practices.
- Reviewing and approval of UTRGV biosafety policies and making recommendations to the Director of EHSRM and/or Director of ORC on strategic biosafety matters.

IBC Function, Role, and Responsibilities

At UTRGV the IBC is an advisory body that exercises the following legislative research oversight functions:

- Review protocol registrations to ensure that research conducted at or sponsored by UTRGV employing rDNA and/or HBAs meets compliance standards and containment levels set by the *NIH Guidelines* and CDC's Biosafety in Microbiological and Biomedical Laboratories (BMBL) respectively.
- Assess new and current facilities, procedures, practices, training, and expertise of personnel involved in rDNA research by soliciting PAM and/or EHSRM review.
- Ensure compliance with all surveillance, data reporting, and adverse event reporting requirements set forth in the *NIH Guidelines* and/or sponsoring agencies.
- Notify the PI of the results of the IBC review process.
- Assist PIs with risk group determination.
- Oversee the development and maintenance of plans to ensure personnel are utilizing p roper engineering (through EHSRM), administrative and procedural controls (through PAM).
- Develop/adopt emergency plans to cover accidental spills and/or personnel contamination resulting from rDNA research or the use of HBA's in research with EHSRM.
- Recommend PAM and EHSRM inspection of laboratories conducting recombinant DNA and/or BSL-2 or above research.
- Develop forms, policies and procedures consistent with institutional mandates, the *NIH Guidelines*, CDC's BMBL and any other applicable federal agencies recommendations.
- Hold deliberations and any information that may lead to the development of intellectual property in confidence, declare any conflict of interest, and recuse from deliberations and voting when applicable.
- Advise the Director of ORC that research involving recombinant or synthetic nucleic acids and/or

HBAs lacking an approved IBC registration or deviating significantly from declared practices or agents employed be stopped.

- Forward recommendations to the Institutional Official (IO) regarding policies and procedures to ensure the health and safety of faculty, staff, students, and the community at large that may be potentially exposed to HBA's and rDNA in research programs at UTRGV.
- Recommend policies and procedures to the IO that ensure compliance with applicable local, state, and federal rules and regulations and best management practices relating to the use of potentially HBA's and rDNA in research programs at UTRGV.

Oversight of Non-Exempt Research Protocols

The IBC is responsible for oversight of all research activities which fall under the *NIH Guidelines* and at UTRGV also for research involving the use of HBAs. These duties include but are not limited to the following actions:

- Serve as a forum to review, make recommendations to appropriate stakeholders, and raise awareness related to biosafety concerns, institutional needs, emerging biosafety issues, and new biosafety requirements.
- Submission of an annual report to NIH/OSP that includes a roster of IBC members, member roles, and curriculum vitae of each member.
- Stipulation of terms for updating and renewal of registrations.
- Notification to investigators when updates are required for annual IBC registrations (protocols for rDNA experiments, use of transgenic animals or plants, and HBAs are valid for four years but require annual renewal).
- Support of information flow between UTRGV's IBC, IRB, and the IACUC.
- Assessment and inspection of all facilities submitting protocols for approval will be conducted on an ongoing basis by EHSRM and reports shared with IBC. Laboratories and laboratory safety plans, standard operating procedures declared in IBC registration forms will also be reviewed by PAM.
- Remind PIs of their responsibility to inform the IBC of any changes to facilities, personnel or practices as they occur.
- Develop emergency plans addressing management of accidental spills and personnel contamination resulting from rDNA or HBA research.
- Recommend training requirements as stipulated by *NIH Guidelines* and institutional, State of Texas and/or applicable federal agencies.

Structure of the IBC

The NIH requires that the IBC consist of at least five institutional voting members that collectively have the experience, expertise, and capability needed to assess the breadth and safety of recombinant and synthetic nucleic acid molecules as well as other biological materials, agents, and organisms as needed to identify any potential risks to workers, public health, or the environment. Members also need to be knowledgeable of biosafety and physical containment, institutional commitments and policies, applicable laws, standards of professional conduct and practice, community attitudes and environmental considerations. The NIH also requires membership of two representatives non-affiliated with the institution who represent the interests of the surrounding community with respect

to the environment and public health.

Federal Registration

The IBC must be registered with the NIH/OSP. UTRGV must file an annual report consisting of an updated committee roster indicating the role of each committee member, contact information for committee members and a bio-sketch for each committee member. The annual report will be submitted by ORC.

EHSRM maintains an updated list of all potentially hazardous biological agents reported to the IBC committee employed in research at UTRGV. In the event of select agent identification, possession, use, transfer, incident notification or request for exemption EHSRM will contact the Federal Select Agent Program (https://www.selectagents.gov/) to assist UTRGV investigators in the registration process.

Committee Composition

Based on the types of research activities taking place at UTRGV, the IBC will typically consist of the following membership:

- A minimum of five tenured/tenure-track faculty voting members representing the breath of academic units at UTRGV research programs that employ rDNA and/or HBAs and hold a primary appointment at UTRGV.
- The committee shall include individuals with expertise in 1) plants, GMOs, plant pathogen or plant pest containment principles; 2) animal containment principles when utilizing transgenics, recombinant/synthetic nucleic acids and infectious agents; 3) eukaryotic transfection, cancer, gene transfer, editing, and manipulation technology, and 4) molecular biology of infectious agents including bacteria, virus, and parasites.
- An IBC Vice Chair is recommended to the IO by the committee Chair and serves to lead discussions, voting, and issue approval letters in the event of the Chair's absence or recusal for conflict of interest.
- Two members not affiliated with UTRGV who represent the interest of the surrounding community with respect to health and protection of the environment that reside within 50 miles of the official IBC address at UTRGV Clinical Education Site, 2102 Treasure Hills Blvd, Harlingen, TX 78550.
- The EHSRM Director and/or a Biological Safety Officer or designated EHSRM official is a voting member.
- The individual responsible for managing the BSL-3/ABSL-3 will be an *ex officio* member.
- Research Compliance Officer and/or designated official from ORC will be a non-voting *ex officio* member.
- In cases where review is requested for the use of rDNA in clinical trials or gene-drive modified organisms, the IBC will recruit *ad hoc* consultants and non-affiliated members residing within the city/town where these trials/experiments are to be performed. Under these circumstances, standing non-affiliated members not residing in the city/town where such study takes place will be excused from review.

Procedures for Appointing Members

The UTRGV IO formally appoints all IBC members. IBC member nominations are managed as follows:

- The IBC Chair is a current member of the committee nominated by quorum of established IBC members and appointed by the IO.
- Potential IBC members are identified by the IBC Chair who upon review vets the candidates, evaluates credentials, and verifies contributions towards the establishment of quorum.
- The ORC Director forwards the recommendation(s) to the IO Office to initiate the administrative process of membership appointment.

IBC Members

Serving on the IBC is considered an important honor. Information members are privy to may be sensitive, include intellectual property, and/or be confidential. Members must ensure they maintain confidentiality and not share or discuss this information outside of the committee. UTRGV faculty members serve in addition to their regular responsibilities and are required to complete any necessary IBC and biosafety training. Therefore, it is understood that on occasion, a member may miss a scheduled IBC meeting. However, it is very important for continuity, scheduling, and well-rounded reviews that members attend most IBC meetings. Membership is chosen based on the unique expertise that each member brings to the IBC. IBC member responsibilities include:

- Review and vote on protocol registrations reviewed by the committee.
- Attend the majority of scheduled committee meetings.
- Contribute to annual standard operating procedures/policy evaluations.
- Participate in professional development activities relevant to IBC, research oversight, state & federal policies, and biotechnology advances.
- Participate in reviews of time sensitive protocols when called upon.
- Assist with review/evaluations of reportable events, unanticipated problems, and noncompliance.
- Provide advice and support to PIs regarding policies and best practices involved in handling biohazardous materials and rDNA research.
- Maintain current knowledge of relevant federal and state guidelines, policies, and laws applicable to research pertinent to IBC oversight.

IBC Chair

The IBC Chair is a senior faculty member with tenure and expertise in rDNA technology and in microbiology of infectious agents and is responsible for conducting all meetings. The IBC Chair responsibilities (shared by the Vice Chair when the Chair is indisposed or recused) include:

- Conduct reviews, delegating reviewers for protocols and initial reviews of adverse event reports.
- Ensure that IBC members are adequately informed concerning the requirements of the regulations for protocol review to maintain consistency in the review process.
- Act as liaison between the IBC, the ORC and research personnel.
- Review and approve the agenda for the convened meeting of the IBC.
- Lead the review by the entire committee of the meeting minutes generated by the IBC

administrative personnel for clarity.

- Call meetings, direct meeting deliberations, request motions and seconds, and adjourn meetings once business is concluded.
- Provide personalized guidance and support to PI's submitting protocol registrations.
- Serve as a point of contact for research-related IBC inquiries.
- Provide guidance and support to the Office of Contracts & Industry Agreements in executing Material Transfer Agreements based on agents permitted on IBC registration forms.
- Ensure that IBC members are appropriately trained in research guidelines, regulations, and any mandated safety training through the support of the ORC.
- Report IBC activities to ORC and IO annually.

Terms of Membership

IBC members are appointed to an initial two-year term, committee membership is renewed and renewed every two years with re-appointments issued by the IO. As long as members meet their responsibilities towards the committee, they may continuously be reappointed provided willingness and ability to continue serving. The IBC Chair may request replacement of a committee member who does not regularly attend meetings or actively contributes to the discussion and review of protocols or respond to communications in a timely manner. Furthermore, members that do not maintain the required training, have not disclosed possible conflicts of interest, or who do not follow best practices will be considered for replacement. The IBC Chair will consult with the ORC and request consideration of a replacement nominee to the IO.

The sitting IBC Chair is appointed for an initial three-year term. The sitting Chair is reviewed and renewed at the end of each triennial term by the IO with a quorum of support from IBC members and reappointment issued by the IO. As long as the Chair meets his or her responsibilities towards the IBC and receives the majority of support from committee members, he or she may continuously be reappointed provided willingness and ability to continue serving. In the event of resignation or request of removal by IBC members, a new IBC Chair may be nominated from the pool of current, UTRGV members who have served the IBC for, at least, two consecutive terms.

Conflict of Interest Policy

No member of the IBC may be involved (except to provide information requested by the IBC) in the review or approval of a project in which he/she has been or expects to be engaged or has a direct conflict of interest (financial or otherwise, such as considerations for personnel actions and other conflicts) that may bias his or her evaluation. Each member is expected to notify the IBC chair in these circumstances and recuse themselves when such proposals or actions are being discussed and/or during a vote. In addition, in the event that the IBC Chair is the PI on a project, or recuses him or herself from review of a registration, the IBC Vice Chair will lead the discussion, vote on the protocol, and provide a signature for the approval letter(s).

Consultants

The IBC may invite consultants to participate in discussions and deliberations on particular projects

where additional expertise is required. Consultants or working group members may include, for example, persons knowledgeable in institutional procedures and policies, applicable law, standards of professional conduct and practice, community attitudes, the environment, or any scientific area where the IBC members do not have sufficient expertise. The IBC Chair has the authority to invite such persons to participate. However, a consultant does not contribute to quorum and cannot vote.

Meetings

Standing IBC meetings are scheduled in advance of each academic year, for a minimum of nine times a year during the months of September, October, November, December, February, March, April, May, and July on Friday afternoons between 1:30 and 3:30 pm and are posted at: https://www.utrgv.edu/research/departments/research-integrity/research-compliance/institutional-biosafety-committee-ibc/meeting-schedules/index.htm

Standing meetings are scheduled at a designated UTRGV location and posted on the IBC web site at the onset of the academic year; however, IBC members may remotely join in real-time via video conference with camera and microphones turned on to participate in discussion and voting. All instances of remote meeting participation must be documented in the meeting minutes. If meetings are conducted through alternative means of communications, the minutes must describe the means used by each member who participated in the meeting. The meeting agenda is prepared and distributed before the meeting by the ORC support personnel. Meeting minutes will be taken by ORC personnel to reflect the topics of discussion. The minutes of the previous meeting are reviewed, approved by the members at the onset of each meeting and maintained on file by the ORC.

All meetings addressing the use of rDNA in research are open to the public.

Ad hoc meetings may be called by the IBC Chair as required by case load, to review time-sensitive requests, training or other administrative necessities but are limited to protocols requesting use of HBAs and/or administrative issues.

Procedures for Defining a Quorum

Convened meetings will proceed with a quorum of at least more than half voting IBC members with at least one non-affiliated member present. Scheduled meetings anticipated not to meet quorum will be rescheduled ahead of time.

Non-voting members are strongly encouraged to participate and contribute to the discussion. Decisions such as reviews of protocol registrations or policies are taken when a majority of IBC members present vote.

IBC Meeting Minutes, Correspondence, and Attendance by the General Public

The ORC or designee will prepare the IBC minutes of each meeting. Posted minutes will be in compliance with NIH/OSP's recommendations and guidelines for IBC minutes. The minutes will include the following information in accordance with NIH/OSP's recommendations:

- Institution name, meeting location, and time
- Attendance; committee roster present and roles, any other attendees/participants
- PI name, project title, registration number, and a brief summary of the project

- Determination of appropriate biocontainment and biosafety level approved
- Applicable *NIH Guidelines* sections
- Risks identified and mitigation measures employed
- Facilities, procedures, practices, personnel training and expertise assessment
- Actions taken by the IBC; including number of members voting for, against, abstentions, and recusals
- Basis for requiring changes in a study or requesting changes
- Basis for suspending or terminating a study
- Incidents, if applicable
- Time meeting is call to order and adjournment

Approved minutes are posted at: https://www.utrgv.edu/research/departments/research-integrity/research-compliance/institutional-biosafety-committee-ibc/approved-meeting-minutes/index.htm for 5 years in accordance with NIH/OSP's recommendations.

Comments or queries received from the general public about IBC activities will be sent to the Office of Legal Affairs which will assist the IBC with the formulation of a response. Comments received and IBC responses will subsequently be forwarded to NIH/OSP.

Members of the general public who are residents of regional community are encouraged to attend exclusively portions of IBC meetings when protocols involving use of rDNA are reviewed but not those declaring other biological hazards.

IBC Actions

The IBC has authority to:

- approve,
- table or return the registration to the PI for proposed modification may that be for a new or already approved project, or
- defer a decision until revisions are implemented, additional information is provided, or further expert review is obtained (including the invitation of consultants).

If minor revisions in the submitted documents are required or an inconsequential document is missing, not impacting risk assessment, the IBC may delegate the chair to subsequently issue an approval of the project on behalf of the IBC, upon completion of these tasks. The IBC will also inform ORC to make a recommendation of suspension.

Review/Approval via Electronic Routing System

The electronic routing system used to record and process federally-mandated research oversight committee documentation (protocol registrations) at UTRGV is tick@lab, a product of the A-Tune third-party vendor. All PIs at UTRGV have access to tick@lab through the UTRGV credentials portal and any additional UTRGV personnel is added manually on a need-be basis. PIs can fill and submit registration forms independently and request pre-evaluation of the submission prior to committee review. Committee members have access to tick@lab and can view submission ahead of time in preparation of scheduled or *ad hoc* meetings. The tick@lab platform is managed and maintained by

UTRGV and IBC registration and workflow of protocols are updated by ORC personnel under advisement of and with the participation of the IBC.

IBC Notification of Protocol Decisions

After each IBC meeting, notification will be sent to the PI via tick@lab, of the outcome of the review whether:

- the protocol was approved and approval letter issued, or deemed exempt and the rationale for the decision,
- the registration requires revisions before approval,
- approval is conditional on additional information provided by investigator,
- the review of the submission was tabled for insufficient details provided to assess risk, or,
- whenever applicable, a detailed list of proposed changes will be provided.

Time Sensitive Protocols

Typically, protocols must be received at least two weeks prior to the committee meeting at which time they will be reviewed. This allows IBC members sufficient time to conduct a thorough review prior to the scheduled meeting.

On certain occasions, however, some IBC protocols require a rapid response due to an extenuating circumstance that falls beyond the PI's control. Protocols in this category may warrant a waiver of the required two-week submission period to allow a review by the IBC at the earliest regularly scheduled meeting or may require convening an *ad hoc* meeting.

In such cases, the protocol must be submitted with a memorandum explaining the circumstances justifying the request in enough detail that the request may be considered. The IBC Chair will make a determination whether the protocol qualifies for special handling and if it does, will advance the protocol to the next IBC meeting for early review or convene an *ad hoc* IBC meeting. The investigator will be notified by the IBC Chair of the decision to grant or deny the request.

Jurisdiction of UTRGV's IBC

UTRGV's IBC is responsible for reviewing all research involving rDNA or HBAs falling within the following categories:

- Research conducted by or under the direction of any employee or agent of UTRGV in connection with his or her responsibilities, regardless of location.
- Research conducted by an individual regardless of UTRGV affiliation taking place on any of the UTRGV campus locations.

When UTRGV investigators conduct research elsewhere, the investigator and UTRGV remain legally responsible for the conduct of research. In the event another IBC also has jurisdiction over the research, the investigator should inform UTRGV's IBC and explore the possibility of an agreement between institutions to avoid effort duplication and redundancy. Likewise, research conducted at UTRGV by PIs with a primary appointment elsewhere will require a collaborative agreement between institutions such that either institution has full IBC oversight over the work performed. In either of these cases, approval letters from third party institutions will be kept on file by the ORC.

Unaffiliated Entities

Generally, the IBC reviews only research conducted at, or involving UTRGV employees or sponsored by UTRGV. However, on occasions, such as in the event that another sponsoring agency does not have an IBC or is out of the home institution's IBC jurisdiction and requests IBC oversight services UTRGV may agree to offer project review. Unaffiliated entities may enter into an agreement with UTRGV through a collaborative agreement.

Oversight of Dual Use Research

Dual Use Research of Concern (DURC) consists of life science research that, based on current understanding, can be reasonably anticipated to provide knowledge, information, products, or technologies that could be directly misapplied to pose a significant threat with broad potential consequences to public health and safety, agricultural crops and other plants, animals, the environment, or national security.

At UTRGV the IBC is responsible for DURC oversight acting as the Institutional Review Entity (IRE) under the United States Government Policy for Oversight of Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential as follows:

- PIs are responsible for declaring any recognizable DURC in their own risk assessment upon submitting proposal for funding to federal agencies. If the research proposed involves any DURC potential, the PI will have notified the sponsoring federal agency. In this scenario the IBC acting as IRE will assess and confirm whether the scope of research falls into the DURC Category 1 or 2 and will carry out a risk-benefit assessment and draft a risk mitigation plan to the federal funding agency which will be shared with Export Control and the ORC. Together with EHSRM the IBC, Export Control, and the ORC will devise an enhanced framework for mitigation and/or containment commensurate with the DURC risk assessment.
- In the event that undisclosed DURC is recognized during a protocol registration the IBC will notify the PI and request notification to the sponsoring agency (if applicable) and carry out a risk-benefit assessment together with EHSRM, Export Control, and ORC to devise an enhanced framework for mitigation and/or containment commensurate with DURC risk assessment.
- Development of containment and/or mitigation strategies based on risk assessment may include:
    1. Request that the PI seek out alternate experimental design, procedures, model organisms, and/or genetic vectors.
    2. Application of specific or enhanced biosecurity or biosafety measures including containment level enhancement.
    3. The IBC and EHSRM will continue to consult with the PI in the event research plans change or deviate from the protocol as necessary.
- The PIs and ORC will be notified of IBC's final review.

Notification to NIH/OSP

The IBC at UTRGV will attempt to rectify any instance of non-compliance conforming to the requirements of the *NIH Guidelines* internally. Any significant problems with or violations of the *NIH Guidelines* and any significant research-related accidents or illnesses will be reported to NIH/OSP

within 30 days via the ORC unless a report was filed by the PI. OSP staff will respond with comments on the incident and on the institutional response. In general, OSP will evaluate the adequacy of that response and make recommendations on any additional measures that should be taken.

Reports of non-compliance received by the IBC will be reviewed, investigated, and forwarded to the ORC accompanied by a recommendation. The IBC may advise in favor of suspension or termination of a research project to the ORC which will make a recommendation to the IO. If a project appears to have been initiated without required IBC approval, or that other serious violations may have occurred, the IBC will advise ORC and the IO that the investigator suspend all activity.

Reporting Relationships

The IO is ultimately responsible for oversight of all research activities at the UTRGV. The IBC is responsible for overseeing the effective operation, policies, and compliance of the conduct of research involving rDNA and HBAs at UTRGV in collaboration with the ORC and EHSRM.

Enforcement of IBC advice is the prerogative of the IO who is expected to act on recommendations of the IBC by tasking appropriate campus departments with action items.

Principal Investigator (PI) definition

The PI designation is given to UTRGV faculty employees who have primary responsibility and accountability to direct a scientific research project or program. The PI is responsible and accountable for compliance with all rules, regulations and best management practices pertaining to biological safety for their respective protocols. If the research is conducted by a team of researchers at a research site, the PI is the leader responsible for that team whose name appears as such on the grant application or award.

The PI is the individual who submits and signs the IBC registration form PIs conducting research with rDNA and/or HBAs are responsible for notifying the IBC about permitting requirements. The PI of a project must demonstrate an established track record of competence and expertise in the research proposed in the protocol registration documentation by submitting an updated Curriculum Vitae.

Students are not permitted to serve as PI but are allowed to participate on research projects in the capacity of research personnel.

IBC and Biosafety Standards

The following standards have specific requirements for IBC's and HBA work:

- NIH Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines).
- Biological Safety in Microbiological and Biomedical Laboratories (BMBL)

Additional biosafety standards related to UTRGV HBA work are listed below:

- Bloodborne Pathogens Standard, Occupational Safety and Health Administration (OSHA) 29 CFR 1910.1030.
- https://www.selectagents.gov/sat/exclusions/index.htm
- Plant Pathogens and Pests, United States Department of Agriculture (USDA) 9 CFR Parts 92,94,95,96, 122 and 130
- Texas Regulations On Medical Waste , TCEQ 30 TAC 326.3(23)

- Texas Department of State Health Services- Bloodborne Pathogens
- UTRGV Biological Safety Manual (2019)
- UTRGV Exposure Control Plan (2019)

IBC Policies and Procedures Approval

IBC members will review proposed amendments to this Policy and Procedures document and vote on acceptance of each amendment.

Records Access, Location, and Retention

The UTRGV IBC records are retained and managed by the ORC, considered confidential and only made accessible to others as required by law, regulation, or UTRGV. The ORC prepares and maintains adequate documentation of all IBC activities for at least 3 years after the study closes. These activities include:

1. Copies of protocol registration forms submitted to IBC for review;
2. IBC meeting minutes (made available on the UTRGV web site as required by NIH/OSP);
3. Registration protocols currently under review;
4. Copies of any type of communication between the IBC and PIs;
   A detailed list of all IBC members, meeting times, minutes, and policies & procedures is posted at:https://www.utrgv.edu/research/departments/research-integrity/research-compliance/institutional-biosafety-committee-ibc/index.htm

IBC records are available, accessible for inspection, and protected from unauthorized access.

The IBC manages its records in accordance with the UTRGV Records Management policies. Pending approval of its proposed retention schedule, the IBC will follow institutional norms for record retention and destruction.

This document is reviewed annually and amended according to IBC, NIH, and/or UTRGV policy changes.