Institutional Biosafety Committee (IBC)

Policies and Procedures

The University of Texas Rio Grande Valley™

2023-2026

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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 (HBAs) 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.

The IBC policies should be used in conjunction with other UTRGV policies, manuals, and committees overseeing work with other hazardous materials such as chemical and radiological agents, the Institutional Animal Care and Use Committee (IACUC), and the Institutional Review Board (IRB), as applicable.

Purpose of the IBC

The purpose of the IBC at UTRGV is to review 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 and register an Institutional Biosafety Committee (IBC) with the NIH Office of Science Policy (OBA) in compliance with the *NIH Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines).*

Function of the IBC

The IBC is an advisory committee responsible for the oversight, administration, and review of UTRGV research laboratory policies and projects involving research with recombinant or synthetic nucleic acid molecules and HBA that may pose safety, health, or environmental risks. To this end, the IBC assists and advises Principal Investigators (PIs) and other researchers in meeting NIH designated responsibilities to ensure that the biological aspects of research are conducted in a safe manner using established biosafety standards and principles. Specifically, this includes:

- Recommendations to the Institutional Official (IO) regarding the policies and procedures to ensure the health

and safety of faculty, staff, students, and visitors that may be potentially exposed to HBA's and rDNA in research programs at UTRGV.
- Recommendations to the IO regarding the policies and procedures to 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.
- Review and approval of protocols involving recombinant DNA research conducted at or sponsored by UTRGV ensuring compliance with *NIH Guidelines*.

The role of the IBC in this review and approval process is to:

- Conduct independent assessments of containment levels required for research involving rDNA as per *NIH Guidelines*.
- Assess the facilities, procedures, practices, training, and expertise of personnel involved in rDNA research.
- Ensure that all aspects of the *NIH Guidelines*' Appendix M have been appropriately addressed by the PI.
- Ensure that research is not initiated until IBC approval at the research site , and the NIH Recombinant DNA Advisory Committee (RAC) review process has been completed including all applicable regulatory authorizations and IBC approval has been obtained.
- Ensure that consideration of issues raised, and recommendations made for human gene transfer protocols selected for public RAC review and discussion are addressed in the PI's response.
- Ensure that final IBC approval of rDNA research is granted only after the RAC review process has been completed
- Ensure compliance with all surveillance, data reporting, and adverse event reporting requirements set forth in the *NIH Guidelines*.
- Notify the PI of the results of the IBC review process.
- Review and approve potential biohazardous agents (BSL-2 and BSL-3) research for compliance with CDC's *Biological Safety in Microbiological and Biomedical Laboratories (BMBL)* guidelines.
- Review and approve research involving select agents and exempt strains of select agents.
- Oversee the development and maintenance of plans to ensure personnel are utilizing proper engineering, administrative and procedural controls.
- Adopt emergency plans to cover accidental spills and/or personnel contamination resulting from rDNA research or the use of HBAs in research.

The IBC will investigate and report any significant violations of the *NIH Guidelines* and any significant research-related accidents or illnesses involving recombinant genomic materials to the PI, the Biological Safety Officer, the IO and the NIH Office of Science Policy (OBA) within 30 days, unless the IBC determines that the PI or lead researcher has already filed a report.

Scope of Authority of the UTRGV IBC

The UTRGV IBC has the following authority and responsibility over research at UTRGV:

- Review all research projects that will involve potential HBAs or genetically modified activity, prior to commencement of research.
- Approve, disapprove, or require changes in all such research.
- Notify federal government agencies and sponsors of approvals and disapprovals or forward such notifications to investigators for submission as applicable.
- Ensure prompt reporting by investigators to the RAC as well as any sponsoring agency of unanticipated problems involving risk to humans or environmental releases.
- Observe inspection of laboratories conducting recombinant DNA research, and HBA research.
- Assess compliance with NIH and CDC guidelines.
- Request that research involving recombinant DNA, microbiological or biomedical research, and chemical usage without an approved Biosafety Application or which are in deviation of submitted protocols and/or current regulations be stopped.
- Recommend disciplinary action to the appropriate university administrator concerning noncompliance or any type of hazard.
- Require corrective action concerning any noncompliance or type of hazard. Ensure prompt reporting to the IBC by investigators of noncompliance with the IBC or federal policies or regulations and report serious or continuing noncompliance to appropriate federal agencies.
- Suspend or terminate a previously approved project and notify applicable agencies and conduct continuing reviews of ongoing research as well as any other monitoring such research may require.

Structure of the IBC

The NIH requires that the IBC have at least five 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.

Composition of Committee

Based on the types of research activities at UTRGV, the IBC will typically have the following minimum representation:

- Five tenured or tenure-track faculty representing UTRGV research programs that employ rDNA and/or HBAs materials who have at least a 5% time and effort commitment at UTRGV.
- Two community members who work and/or reside in the Rio Grande Valley and are not affiliated with UTRGV.
- The Environmental Health, Safety and Risk Management (EHSRM) Director and/or a Biological Safety Officer or designated EHSRM official will be an *ex officio* member.

- A Research Compliance Officer or designated official from the Office of Research Compliance (ORC) will be an *ex officio* member.
- In cases where IBC review is requested for the use of rDNA in clinical trials, the IBC will be required to recruit *ad hoc* unaffiliated community members residing within the city/town where the trial is to be performed. Under these circumstances, standing community members not residing in the city/town where such study takes place will be excused from review.

Federal Registrations

The IBC must be registered with the Office of Science Policy (OBA). 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 that are 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.

Procedures for Appointing Members

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

- The IBC Chair is a member of the IBC recommended by the EHSRM Director and serves at the pleasure of the IO for three-year terms.
- Candidate IBC members are identified by the IBC Chair who in consultation with the Director of EHSRM presents their credentials to the committee for review. The IBC Chair forwards the committee's recommendation to the UTRGV IO by means of the Research Compliance Officer or designated official.

IBC Members

Serving on the IBC is considered an important honor. Members serve in addition to their regular teaching, research, and service responsibilities and are required to complete any necessary IBC and biosafety training. Therefore, it is understood that on occasion, a member may need to miss a scheduled IBC meeting. However, it is very important for continuity, scheduling, and well-rounded reviews that members attend IBC meetings. Membership is chosen based on the unique expertise that each member brings to the IBC. If a member cannot attend a meeting, he/she should notify the IBC Chair in advance (two weeks before meeting) so that an alternate can be secured. Because of frequency of the meetings, members who miss more than two meetings in one calendar year, or two meetings in a row, may be subject to removal from the committee by the IO at the recommendation of the IBC Chair.

IBC Chair

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

- Conducting reviews, delegating reviewers for protocols and initial reviews of adverse event reports.
- Ensuring that the IBC members are adequately informed concerning the requirements of the regulations for protocol review to maintain consistency in the review process.
- Acting as liaison between the IBC, IBC administrative personnel and research personnel.
- Approving the agenda for the convened meeting of the IBC.
- Review by the entire committee of the meeting minutes generated by the IBC administrative personnel for clarity.
- Calling meetings, directing meeting deliberations, requesting motions and seconds, and

adjourning meetings once business is concluded.

- Provide personalized guidance and support to PI's submitting protocol registrations.
- Serve as point of contact for science-related IBC inquiries.

Terms of Membership

IBC committee membership is renewed biennially, and re-appointment issued by the IO. As long as they meet their responsibilities towards the committee, members may serve without obligation. The IBC Chair may request replacement of a committee member who does not regularly attend meetings or actively contribute 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 EHSRM Director and request consideration of a replacement nominee to the appropriate Institutional Officer (IO).

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 conflictual interest (financial or otherwise, such as considerations for personnel actions and other conflicts) that will 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 chairperson is the PI on a project, an alternative IBC committee member present at the meeting will provide a signature for the approval/rejection form.

The Office of Research Compliance (ORC)

The ORC will provide administrative support and will coordinate the IBC meetings. The ORC responsibilities include, but are not limited to:

- Providing the necessary liaison between the research personnel, the IBC, federal and regulatory agencies.
- Serving as the office of record for IBC documentation.
- Providing all necessary documentation, forms, regulatory guidelines, and regulations, to PIs.
- Maintaining IBC registration forms and records.
- Assisting the IO in filing annual updates and other reports to the NIH/OBA.
- Communication with the IRB or IACUC when protocols involve human subjects or animals.
- Assisting with initial reviews of non-compliance with NIH Guidelines and preparing reports for the IBC.
- Monitoring federal and state regulation, drafting revised policies and procedures to remain in compliance with those regulations.
- Providing administrative support to the IBC by scheduling meetings, arranging meeting space, and taking meeting minutes.

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 commitments 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 five times a year during the months of October, December, February, April, and June on Friday afternoons between 1:30 and 3:30 pm and posted on https://www.utrgv.edu/ehsrm/committees/ibc/index.htm.

Standing meetings must be conducted in person at previously designated UTRGV locations and posted on the IBC web site at the onset of the academic year. The proposed agenda is generated and distributed before the meeting by the ORC. Meeting minutes will be taken by the ORC to accurately 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 are open to the public unless otherwise posted, and minutes will be provided to the public upon request by the public and in accordance with the scope and requirements of the *NIH Guidelines*.

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.

The IBC may also be attended through alternative means of communications that allow a live meeting to be conducted (e.g., video conference or teleconference) as allowed by NIH OBA under the following circumstances:

I. Unforeseen or emergency situations such as the occurrence of natural disasters, riots, closures, pandemics, and other occurrences outside the control of UTRGV that affect the operations of the IBC including, but not limited to, the in-person meeting requirement.
II. As called for by UTRGV policy.
III. Inability of individual committee members to attend in person due to the distance between campus locations.

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. Meetings held remotely must

remain accessible to the public through an announcement on the IBC UTRGV web page.

These procedures are intended to facilitate maintenance of quorum necessary to conduct IBC official business.

Procedures for Defining a Quorum

In the event of IBC Chair absence or recusal for any reason, the Vice Chair will act as Chair. Meetings will proceed with no less than four voting members present and must consist of at least three members from the UTRGV faculty and at least one non-affiliated member.

All IBC members, except those who are *ex-officio* appointments, are voting members. Decisions such as approval of research projects or policies are approved when a majority of IBC members present vote for approval. The IBC may use consulting experts or establish working groups to execute its responsibilities or acquire needed expertise for select tasks. Consultants or working group members are not IBC voting members unless nominated and appointed as described previously.

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

The ORC or designee will prepare the IBC minutes of each meeting. The minutes will include the following information:

- Attendance;
- Actions taken by the IBC;
- Number of Members voting for;
- Number of Members voting against;
- Abstentions;
- Basis for requiring changes in a study or disapproving;
- Basis for suspending or terminating a study;
- Summary of the discussion of issues or concerns and their resolution.

External requests of IBC meeting minutes will be forwarded to the Office of Legal Affairs for review and minutes redacted by legal counsel before release.

Comments 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 the Office of Science Policy of the National Institutes of Health.

Members of the general public are encouraged to attend exclusively portions of IBC meetings when protocols involving use of rDNA are reviewed but not those declaring other biological hazards. Individuals of the general public wishing to attend may do so in-person or via zoom upon

request; however evidence must be provided that they are members of the local community.

Member Roles and Responsibilities

The IBC is responsible for reviewing, approving, and monitoring all UTRGV research projects involving biological materials that may pose differing levels of safety, health, or environmental risk

to plants, animals, or humans. The objective of the committee is to ensure that the research is conducted in a safe manner and that all personnel involved in handling the agents are appropriately trained. To accomplish this task, the IBC performs initial and periodic risk assessment, reviews as well as approval of required project biosafety documentation that details safety measures taken in the process of investigation, and demonstrates personnel training records. Once the PI has submitted a Registration for use of rDNA or hazardous biological agents to the IBC, the committee is responsible for:

- Assessing 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 IO, the Director of EHSRM, and/or responsible officials on strategic biosafety matters.

The IBC is responsible for maintaining reviews, minutes, and reports in an orderly and retrievable fashion. The IBC Chair is responsible for ensuring that the IBC members are appropriately trained in research guidelines, regulations, and any mandated safety training.

IBC Members are responsible for:

- Reviewing applications on a regular basis and participating in convened meetings.
- Holding in confidence the deliberations of the IBC and any information that may lead to the development of intellectual property, give rise to conflicts of interest or jeopardize the integrity of the committee.

IBC Actions

IBC members discuss each project and vote to approve or disapprove the project or proposed modification to an already approved project, or to defer a decision until revisions are implemented, additional information is provided, or further expert review is obtained (including the invitation of consultants). Under certain circumstances, if minor revisions in the submitted documents are required or a missing document is to be obtained, the IBC may delegate the chair to subsequently issue an approval of the project on behalf of the IBC, upon completion of these tasks.

Review/Approval via Electronic Routing System

IBC uses the electronic routing system to document the processing of protocols. This review process can lead to assigning a protocol to Full Committee Review (FCR), or approval of protocol by the committee via the *ad hoc* process (defined as Designated Member Review [DMR] on the electronic routing system).

If during the FCR or *ad hoc* review processes further revisions are requested from the PI, the protocol is forwarded back to the PI to review and complete. Once approved, the protocol is marked as approved on the electronic routing system and an approval letter is issued to the PI

when required personnel trainings have been completed.

IBC Notification of Meeting Decisions

After each IBC meeting, the Chair will notify the PI in writing of the outcome of the review whether:

- the project was approved or deemed exempt and a rationale for the decision,
- the registration requires revisions before approval may be granted,
- additional information is needed from the investigator, or
- the registration was rejected (insufficient detail for the investigator to understand).

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 assigned reviewers enough time to conduct a thorough review prior to the scheduled meeting of the full committee.

On certain occasions, however, some protocols require a rapid response due to an extenuating circumstance that falls beyond the control of the PI. 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 giving rise to 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

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

- Research endorsed by UTRGV, both funded and unfunded.
- Research conducted by or under the direction of any employee or agent of UTRGV in connection with his or her responsibilities, even if conducted elsewhere.
- Research conducted by or under the direction of any employee or agent of UTRGV using any property or facility of UTRGV.

These categories cover all research involving rDNA or HBAs in which UTRGV and its faculty, staff, and students may be involved. The IBC must review this type of research under the direction of any employee or agent of UTRGV even when conducted at another institution. In such situations, the investigator and home institution remain legally responsible for the conduct of research at the other institution. Where another IBC also has jurisdiction over the research, the investigator should inform UTRGV's IBC. The general policy of the IBC is to require submission of the project to the home IBC for review first, with submission to the other institution's IBC to follow. Final IBC approval at the home institution of the project as amended by the other IBC is required.

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 entity does not have an IBC and is the recipient of a grant under which UTRGV faculty will be conducting research (under a subcontract/award), the UTRGV IBC may agree to serve as review committee for the grantee. If the UTRGV IBC agrees to this type of arrangement, a memorandum of understanding (MOU) will be drafted and signed by an official representative of UTRGV and by the IBC chair to permit the UTRGV IBC to act as the review committee.

Research Conducted on UTRGV campus by third parties unaffiliated with UTRGV without a UTRGV Faculty Co-Investigator

All research conducted by other entities without a UTRGV faculty member as co-investigator will require a memorandum of understanding (MOU) with appropriate signatures on file with the IBC. No research may begin until all approvals have been obtained. The protocol package must be submitted with approval from the requesting organization's IBC. Third parties conducting research on the UTRGV campus are expected to comply with the same training requirements as UTRGV researchers.

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

The IBC has the responsibility of dual research oversight which falls under the United States Government Policy for Oversight of Life Sciences DURC.
These duties include but are not limited to the following:

- Notification of the designated personnel (consisting of the IBC members plus any additional experts/consultants recruited to evaluate a specific DURC protocol) that a dual use protocol is in review by the IBC and that their input is needed.
- Notification to the PI of IBC's final review.
- Development of a collaborative plan with EHSRM to implement any necessary and appropriate mitigation measures based on risk assessment. These measures may include the following:

    1. Request that the PI modify the design or execution of the research.
    2. Application of specific or enhanced biosecurity or biosafety measures
    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.

Oversight of Non-Exempt Research Proposals

The IBC has the responsibility of oversight of all research proposals which fall under the *NIH Guidelines* at UTRGV. These duties include but are not limited to the following actions:

- Notify the PI of the results of the IBC's review or approval.
- 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.
- Review recombinant and synthetic nucleic acid research conducted at or sponsored by UTRGV for compliance with the *NIH Guidelines*.
- Submission of an annual report to NIH OBA 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 (Registration of recombinant DNA experiments, use of transgenic animals or plants are valid for four years but require annual renewal).
- Support of information flow between UTRGV's IBC, Institutional Review Board (IRB), and the Institutional Animal Care and Use Committee (IACUC).
- Assessment and inspection of all facilities submitting protocols for approval will be conducted on an ongoing basis by the EHSRM Department and reports shared with IBC. All laboratories and laboratory safety plans will be inspected on a yearly basis as will standard operating procedures declared in IBC registration forms. PIs are responsible for informing the IBC of any changes to facilities, personnel or practices as they occur.
- Adoption of emergency plans covering accidental spills and personnel contamination resulting from recombinant or synthetic nucleic acid research.
- Development of training requirements as stipulated by *NIH Guidelines* and adopted by the IBC.
- Assessment of approved protocols will be conducted by Post Approval Monitoring (PAM)

Notification to RAC, NIH/OBA or Other Agencies of Approvals, Suspensions or Terminations, and Serious or Continuing Non-compliance

The IBC is required under the *NIH Guidelines* to ensure that PIs submit selected protocols to the RAC for approval. The IBC must also certify certain approvals and notify NIH/OBA regarding specific actions and activities. The IBC acts on behalf of UTRGV to certify compliance of the project with the IBC Policies and Procedures to the relevant federal regulatory agencies and sponsors of the research, as applicable, and will provide such certifications to the PIs for forwarding to the applicable agency.

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In the case of a suspension or termination, the IBC will consult with the IO. The IBC will notify the funding agencies of the decision of the IBC. In the event the IBC receives a report of noncompliance with IBC policies or procedures or federal guidelines or regulations, the IBC will inform 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 recommend the investigator suspend all activity at once to the IO. The IBC then implements procedures for investigating, remedying, and reporting noncompliance.

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. No person or other committee - whether internal or external - can overturn an IBC decision to disapprove, terminate, or suspend a research protocol.

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

Significant problems with, or violations of, the NIH Guidelines and any significant research related accidents or illnesses will be reported to NIH OBA within 30 days (or immediately depending on the nature of the incident).

Principal Investigator (PI)

Definition

The PI designation is given to UTRGV faculty employees who have primary responsibility and accountability to direct the proper conduct of 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. With regard to the IBC, the PI has overall responsibility of all laboratory personnel working under the requirements of *the NIH Guidelines*.

The PI must be the individual who submits the IBC/HBA registration form and multiple PIs can work under the same registration as long as they are listed as personnel. PIs conducting research with rDNA and/or HBAs are responsible for notifying the IBC (e.g., IBC member, EHSRM Director or designated official, the Office of Research Compliance) about permitting requirements.

Inclusion of new PIs into UTRGV IBC

- PIs that join UTRGV with an existing IBC/HBA protocol from an external institution are grandfathered in during the first year until the registration comes up for annual renewal.
- Upon expiration of the one-year grandfathered registration, instead of an annual renewal, new UTRGV PI must submit a full registration.
- If the grandfathered registration requires an amendment (change) before the annual

renewal, a full registration application must be submitted to the IBC.

IBC and Biosafety Standards

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

- *Guidelines for Research Involving Recombinant and Synthetic Nucleic Acid Molecules (NIH Guidelines)*, Federal Register (April 2019).
- Biosafety in Microbiological and Biomedical Laboratories, 5th Edition, (December 2009) CDC and NIH.

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

- Bloodborne Pathogens Standard, Occupational Safety and Health Administration (OSHA) 29 CFR 1910.1030.
- Federal Select Agent Program (CDC & USDA) 7 C.F.R. Part 331, 9 C.F.R. Part 121 42 C.F.R. Part 73.
- Plant Pathogens and Pests, United States Department of Agriculture (USDA) 9 CFR Parts 92,94,95,96, 122 and 130.
- CDC – Import Permit Program 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 during a regularly scheduled meeting of the committee and vote on acceptance of each amendment.

Records Access, Location, and Retention

The UTRGV IBC records are considered confidential and only made accessible to others as required by law, regulation, or the university. The IBC 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;
3. Registration protocols currently under review;
4. Copies of any type of communication between the IBC and PIs;
5. A detailed list of all IBC members and meeting times is posted at https://www.utrgv.edu/ehsrm/committees/ibc/
6. Written procedures for the IBC as recommended by OBA are also posted at https://www.utrgv.edu/ehsrm/committees/ibc/

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