TEXAS TECH UNIVERSITY HEALTH SCIENCES CENTER EL PASO

INSTITUTIONAL BIOSAFETY COMMITTEE

POLICIES AND PROCEDURES MANUAL

Version 2.0

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CHAPTER 1 ORGANIZATION OF THE TEXAS TECH UNIVERSITY HEALTH SCIENCES CENTER EL PASO INSTITUTIONAL BIOSAFETY COMMITTEE

1.1 Introduction and Organizational Summary

Texas Tech University Health Sciences Center El Paso (TTUHSC El Paso) is committed to the safe, legal, and ethical use of hazardous chemical and biological materials in its facilities. Acting as an agent for the Institution in regulating work involving such materials, the Institutional Biosafety Committee (IBC) shall ensure that work in the following four categories (the "Covered Work") meets all applicable safety, legal, and ethical requirements:

- Work involving biological agents, including but not limited to, those agents in all risk groups as defined in Biosafety in Microbiological and Biomedical Laboratories (BMBL)
- Recombinant DNA (rDNA) as defined by the NIH Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines)
- Dual use research of concern as defined by the National Science Advisory Board for Biosecurity [NSABB, Department of Health and Human Services (DHHS)]
- Select agents and toxins (SAT), regulated either by DHHS or by the United States Department of Agriculture (USDA)

This TTUHSC El Paso IBC Policies and Procedures Manual (PPM) provides the TTUHSC El Paso research community with an overview of the federal regulations and institutional policies that govern the conduct of research utilizing covered work. The IBC will serve as the review committee for all relevant research.

The IBC PPM will be revised and updated as new guidelines, clarifications and/or other information becomes available. The IBC, in conjunction with the TTUHSC El Paso Department of Safety Services, will work with investigators and lab personnel to assist them in meeting federal and state requirements and TTUHSC El Paso policies and procedures related to the storage and use of hazardous chemical and biological materials, as well as recombinant DNA materials. Applications approved under any version of the IBC PPM may require modifications as federal, state and institutional rules change.

The IBC PPM is based on the following regulations, guidelines and TTUHSC El Paso policies:

- NIH Guidelines for Research Involving Recombinant or Synthetic DNA Molecules (NIH Guidelines), https://osp.od.nih.gov/biotechnology/nih-guidelines/(April, 2016 update)
- Biosafety in Microbiological and Biomedical Laboratories (BMBL) published by the Centers for Disease Control and Prevention (CDC) and NIH. The BMBL is generally considered the standard for Biosafety: Biosafety in Microbiological and Biomedical Laboratories—6th Edition (cdc.gov)

- Select Agents and Select Agent Toxins (SAT)—HHS and CDC regulations 42 CFR 73 (eCFR :: 42 CFR Part 73 -- Select Agents and Toxins) and USDA regulations 9 CFR 121eCFR :: 9 CFR Part 121 -- Possession, Use, and Transfer of Select Agents and Toxins
- Occupational Health and Safety Act (OSHA) Regulations,
- National Science Advisory Board for Biosecurity (NSABB) documents related to biosecurity and dual use research. Biosafety, Biosecurity, and Emerging Biotechnology – Office of Science Policy (nih.gov)
- TTUHSC El Paso Operating Policy 75.10--Biological and Chemical Hazards Policy for Research Facilities and Personnel http://elpaso.ttuhsc.edu/opp/_documents/75/op7510.pdf
- TTUHSC El Paso Operating Policy 73.05 Research Involving Hazardous Chemical and Biological Materials, and Recombinant DNA, http://elpaso.ttuhsc.edu/opp/_documents/73/op7305.pdf, and,
- TTUHSC El Paso Operating Policy 73.12 Possession and Use of Exempt Quantities of CDC Select Agent Toxins http://elpaso.ttuhsc.edu/opp/_documents/73/op7312.pdf
- TTUHSC El Paso Laboratory Compliance and Biosafety Manual (LCBM) http://elpaso.ttuhsc.edu/safety/_documents/Laboratory%20Compliance%20Manual%202016.pdf

1.2 Scope of Work

All persons, including, but not limited to faculty, staff, students and volunteers are included within the scope of these *Policies and Procedures*, as are collaborators and visitors from other organizations, physically on campus, working with TTUHSC El Paso faculty, staff, students and volunteers.

The IBC has oversight of all activities under "Covered Work," including those:

- Sponsored by the Institution;
- Conducted by Institutional research personnel;
- Conducted using the Institution's property and/or facilities; or
- Received, collected, handled, used, stored, transferred and/or disposed of at any of the Institution's facilities.

The IBC PPM and the LCBM provide a review of the relevant regulatory requirements and Institution policies. The PPM should be used in conjunction with the LCBM and Institutional policies and procedures.

1.3 Components of the IBC

In order to function effectively, the TTUHSC El Paso IBC requires commitments and assistance from many areas within the institution. The major components of the TTUHSC El Paso IBC include:

- **The Institutional Official.** The Vice President for Research (VPR) serves as the Institutional Official with overall responsibility for the TTUHSC El Paso IBC. Specific duties and responsibilities of the VPR with regard to the Institutional Biosafety Committee can be found under Institutional Authority. The VPR may appoint a designee to fulfill the duties and responsibilities.
- **Office of Research (OR)**. The Institutional Official recognizes the OR as the point of contact with the National Institute of Health (NIH). OR staff members exercise operational responsibility on a day-to-day basis for the IBC. This includes IBC administration, compliance, educational, and quality improvement components of the TTUHSC El Paso IBC.
- **Institutional Biosafety Committee (IBC)**. TTUHSC El Paso has one IBC. The IBC reviews research involving hazardous chemicals and biological materials, including recombinant DNA materials conducted under the oversight of Principal Investigators (PIs). The IBC has the authority to approve, require modifications to secure approval, or disapprove all research involving hazardous chemicals and biological materials, including recombinant DNA overseen and conducted by TTUHSC El Paso faculty, staff, students and volunteers. The IBC may also suspend or terminate approval of research not being conducted in accordance with the IBC's requirements, or that has been associated with unexpected serious harm to others.
- **Department Chairpersons/Signatory Authorities**. Each protocol submitted for IBC review must be electronically signed by a Department Signatory Authority (generally, the Department Chair) attesting to the PI's qualifications, to available facilities and resources, and to study feasibility, as described in more detail under Principal Investigator Sign-off. If the PI is the Department Chair, the President will be the designated signatory authority.
- **General Counsel**. The TTU System Office of General Counsel is available to provide advice upon request of the VPR, IBC, or other individuals involved with the IBC. The Office of General Counsel may provide legal guidance and interpretation of TTUHSC El Paso policies, and of State and Federal laws and regulations as they relate to the conduct of research involving hazardous chemicals and biological materials, including recombinant DNA.
- **Sponsored Programs (SP).** The TTUHSC El Paso SP handles grant and clinical trial contract administration. Personnel in this office review sponsor contracts and funding agreements for compliance with Federal and State regulations, and with TTUHSC El Paso and IBC policies and procedures.
- **Conflict of Interest in Research Committee (COIRC)**. Studies in which an investigator has a financial conflict of interest in the research must be reviewed by the COIRC and, if necessary, have an approved Conflict Management Plan in place prior to approval by a TTUHSC El Paso IBC. Further details are found in TTUHSC El Paso OP 73.09.
- **HIPAA Privacy Officers**. These individuals are responsible for HIPAA Privacy oversight at the TTUHSC El Paso campus. The HIPAA Privacy Officer reports to the Institutional Compliance Officer.

- **Investigators and Research staff**. Investigators and research staff have a responsibility to follow the IBC requirements described throughout this Manual and to comply with all determinations of the IBC and the VPR.
- **Deans/Department Chairs**. These individuals are responsible for "setting the tone" for responsible conduct and oversight of research involving hazardous chemicals and biological materials, including recombinant DNA, in their department or school, for providing opportunities for education regarding ethical actions and compliance as they relate to research, for fostering support for IBC members, and for providing adequate resources to conduct this research at TTUHSC El Paso.
- **All TTUHSC El Paso faculty, staff, students, and volunteers**. Everyone associated with TUHSC El Paso should have a general idea of research involving hazardous chemicals and biological materials, including recombinant DNA, and should consult the IBC when faced with uncertainty about whether an activity involves this type of research. Individuals should report allegations of possible research misconduct as outlined in TTUHSC El Paso OP 73.14, Research Compliance and TTUHSC El Paso OP 73.07, Honesty in Research and Allegations of Scientific Misconduct.

1.3.1 Communication between components

TTUHSC El Paso uses several mechanisms to communicate information relevant to the IBC. Issues specifically pertinent to research involving hazardous chemicals and biological materials, including recombinant DNA (for example: updates to the IBC PPM, relevant policy alterations) are communicated to investigators and staff via the iRIS Announcement feature on an as needed basis.

The Senior Director of the OR serves as a central liaison between the IBC and other research compliance committees, the IO, and various departments.

The IBC application form serves as a primary tool for assessment of the institutional requirements to be met to ensure appropriate conduct of research with hazardous chemicals and biological materials, including recombinant DNA. IBC members and IBC administrative staff review submissions to verify that these institutional components are adequately described. Examples include signatory authorization, training and financial disclosures of all study personnel, appropriate handling and safety measures indicated, and the presence of approved conflict management plans when necessary. If the IBC or IBC administrative staff determines that any of the institutional requirements necessary to protect participants are lacking, then the principal investigator (PI) will be notified in writing. The PI will be required to address the issue(s) and to provide additional necessary documents and/or information needed to comply with institutional policies and procedures.

1.4 About the IBC

1.4.1 Name, Authority, and Formation

The VPR, designated and charged by the TTUHSC El Paso President, has established the IBC, and has the authority to appoint members to the IBC. The VPR has charged the IBC with the responsibility and authority to regulate the Covered Work. The IBC shall base its decisions and

actions related to Covered Work on regulations and applicable guidance documents referenced in this manual, the TTUHSC El Paso LCBM, and other documents describing good laboratory practices.

The IBC shall report to the VPR regarding regulatory matters related to the Covered Work. The IBC membership shall be consistent with the NIH Guidelines. A Responsible Official (RO) and Alternate RO (ARO) would be designated before the institution registers with either the DHHS/CDC. The institution would register if and when it intends to use, possess, or transfer a select agent/toxin (or receive SA/toxin from outside US).

The Chair or authorized designee of the TTUHSC El Paso IBC shall have signatory power for review and actions taken by the IBC. Electronic documents found in iRIS--including all finalized IBC minutes, approval documents, licenses, documents referenced in electronic letters, and official correspondence --have the full approval of the IBC Chair/designee and have the authority of signed documents. Handwritten signatures of the IBC Chair/designee are not required under this policy.

1.4.2 Responsibilities

The IBC shall ensure through the following actions that the Covered Work performed at the Institution meets all applicable safety, legal, and ethical requirements:

General:

- The IBC shall make recommendations to the VPR and develop proposals for policies regarding Covered Work that shall be reviewed and approved by the VPR prior to implementation.
- The IBC shall educate the Institutional community and other stakeholders regarding requirements relating to the Covered Work.
- The IBC shall maintain cooperative relationships with persons involved in the Covered Work.
- The IBC shall implement appropriate administrative procedures for regulating the Covered Work.
- The IBC shall ensure that the annual report containing the IBC roster is filed in a timely manner with National Institutes of Health/Office of Biotechnology Activities (NIH/OBA) by the OR as required under the NIH Guidelines.

Specific Covered Work:

- Work involving biological agents, including but not limited to, those defined in BMBL.
- The IBC shall implement, directly or through Department of Safety Services biosafety staff, and/or adopt by reference, institutional procedural guidelines to ensure the safe possession and use of biological agents.
- The IBC shall establish containment levels for protocols involving biological agents where formal containment levels have not been established.
- Recombinant DNA research.
- The IBC shall ensure that all research involving rDNA complies with the NIH Guidelines.

- Dual use research of concern.
- The IBC shall ensure that all dual use research of concern complies with guidance promulgated by the NSABB.

Oversight of the Select Agent work

- The IBC shall ensure that all experiments involving SAT comply with all SAT regulations.
- The IBC may review revisions to the laboratory safety/operations manuals, biosecurity plans, and emergency response plans for the SAT/BSL3 laboratories.
- The IBC shall make certain that, if applicable, the RO and ARO have the authority to ensure compliance with SAT regulations, and that to this end the RO and ARO conduct annual compliance audits of the laboratories authorized to possess, use, and store SAT. The Biological Safety Officer (BSO) shall perform such duties until the RO and ARO are assigned the official roles. The IBC shall ensure that any compliance deficiencies are corrected in a timely manner.
- The IBC shall ensure at least on an annual basis that the RO or ARO has registered all persons working with SAT as required by SAT regulations.
- The IBC shall ensure that the RO and/or ARO conduct annual training, to include an emergency/disaster drill, for all registered persons working with SAT as required by SAT regulations.
- The IBC shall ensure that the RO and/or ARO shall report immediately the release, loss, or theft of a SAT to the appropriate entities, including but not limited to the IBC Chair, DHHS, the Department of Public Health, as well as the Federal Bureau of Investigation (FBI) and the Institutional Police (if theft is involved) as mandated by the applicable regulations.

Specific responsibilities of the IBC:

- Implement institutional policy for the safe receipt, collection, handling, use, storage, transfer and/or disposal of biologically and chemically hazardous materials, including recombinant DNA;
- Advise the Institution/PI's on regulations and policies involving biologically and chemically hazardous materials, including recombinant DNA;
- Implement recognized standard procedures for research with biologically and chemically hazardous materials, including recombinant DNA;
- Advise the Institutional Animal Care and Use Committee (IACUC) and Institutional Review Board (IRB) on safe practices for work involving the use of biologically and chemically hazardous materials, including recombinant DNA;
- Certify to granting agencies, as requested, that facilities, procedures, and practices for handling biologically and chemically hazardous material, including recombinant DNA, have been reviewed and approved by the IBC, and certify that the training and expertise of personnel is sufficient and appropriate;

- Review reports from the laboratory safety division (TTUHSCEP Safety Services) of safety hazards in the laboratories at TTUHSC El Paso;
- Supervise the institutional educational programs on the use of biologically and chemically hazardous materials, including recombinant DNA;
- The IBC may review revisions to the laboratory safety/operations manuals, biosecurity plans, and emergency response plans for the laboratories;
- Review any protocols submitted to the IBC;
- Make recommendations to the VPR concerning the biohazards program;
- Enforce punitive measures, including lab closure, when necessary to safeguard employees, the public, and the environment.
- The IBC is also responsible for initially and periodically reviewing registrations for possession and/or use of biologically and chemically hazardous material, including recombinant DNA, for compliance with NIH Guidelines, the BMBL manual and Select Agent and Select Agent Toxins regulations, as applicable. As part of the review process, and in conjunction with the BSO and TTUHSC El Paso Department of Safety Services, the IBC shall:
- Conduct an independent assessment of the containment levels as required by Section II-A-3 of the NIH Guidelines,
- Conduct an assessment of the facilities, procedures, practices, training and expertise of personnel involved in research with biologically and chemically hazardous material, including recombinant DNA, and
- Ensure compliance with all surveillance, data reporting and adverse event reporting requirements set forth in the NIH Guidelines.

1.4.3 Registration with National Institutes of Health

In accordance with the National Institutes of Health Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines) the TTUHSC El Paso IBC is registered with the NIH Office of Biotechnology Activities (OBA). An annual report is filed with OBA by the Sr. Director of the Office of Research. The annual report includes an updated list of IBC members and a biosketch of each member. The OBA is also notified of any changes in IBC membership between annual reports by the Managing Director.

1.5 Confidentiality of Records

The TTUHSC El Paso IBC is a “medical committee” as defined under Texas Health & Safety Code chapter 161, and/or other applicable state and federal statutes. All documents generated by, submitted to, or for the purposes of fulfilling IBC committee duties are considered confidential and privileged as “medical committee documents”. Certain IBC documents are considered privileged and confidential records, not subject to disclosure, except to authorized TTUHSC El Paso representatives and federal regulatory officials. However, in accordance with the NIH Guidelines, TTUHSC El Paso shall, upon request, make available to the public all IBC meeting minutes and any documents submitted to or received from funding agencies, which the federal funding agencies are required to make available to the public. If public comments are made on IBC actions, the IBC Chair shall forward both the public comments and the IBC

response to the Office of Biotechnology Activities, National Institutes of Health, 6705 Rockledge Drive, Suite 750, MSC 7985, Bethesda, MD 20892-7985.

1.6 Relationship to other TTUHSC El Paso Compliance Committees

The TTUHSC El Paso IBC functions independently of, but in coordination with other TTUHSC El Paso Research and Safety Compliance Committees, including, but not necessarily limited to the following:

- Institutional Review Boards (IRBs)
- Conflict of Interest in Research Committee (COIRC)
- Institutional Animal Care and Use Committee (IACUC)

Subcommittees of the IBC may be appointed by the IBC Chairperson as deemed necessary to perform the work of the Committee. The Chairperson shall be an ex officio member of any such sub-committees.

1.7 Affiliated Entities

Generally, the IBC reviews only research conducted at and by TTUHSC El Paso employees. However, in the event that a sponsored study requires IBC approval for research activities that will take place at an affiliated entity, including, but not limited to receiving, collecting, handling, using, storing, transferring and/or disposing of chemical or biological agents, that does not have its own IBC, in which a TTUHSC El Paso faculty will be the PI of record, the TTUHSC El Paso IBC will be required to review and approve the research activities. This type of arrangement would require that a research agreement or memorandum of understanding (MOU) be in place.

1.8 Review and Approval of Bylaws

The bylaws shall be reviewed at least annually by the Chairperson of the Committee, the IBC Coordinator, the BSO, the IBC Senior Director, and the Managing Director of the Office of Research. Proposed changes to the bylaws will be presented to the full Committee for review and comment. The IBC Chairperson has authority to provide final approval of the Bylaws.

1.8.1 Amendment of Bylaws

The bylaws may be modified or amended as needed at the request of the VPR or designee in consultation with the IBC Chairperson.

CHAPTER 2 INSTITUTIONAL BIOSAFETY COMMITTEE STRUCTURE AND FUNCTION

2.1 Organization of the IBC

There is one registered TTUHSC El Paso IBC

2.2 Membership

2.2.1 Composition of IBC

The membership shall consist of a minimum of five TTUHSC El Paso faculty members. Attempts will be made to include representation from each TTUHSC El Paso School whose faculty conduct basic and/or clinical laboratory research. Efforts will also be made to include faculty with expertise in research with animals, genetic research, and research with microorganisms. A single Committee member may serve multiple roles. Membership will also include appropriate recombinant and synthetic nucleic acid expertise, plant and animal experts, a BSO, and at least two members not affiliated with the institution.

2.2.2 Member Education

All new IBC members are required to successfully complete two online courses offered through the University of Miami's Collaborative Institutional Training Initiative (CITI) Program. These include a) IBC Members and Staff, and b) Conflicts of Interest. All members must also submit a Research Financial Disclosure form on at least an annual basis, or within 30 days of a change in significant financial interests. The annual disclosure form is accessed through iRIS via the Conflict of Interest Module under "My Workspaces" at the top left of the iRIS dashboard. IBC members are encouraged to participate in ongoing continuing education. A stipend may be available to IBC members to help defray costs of attending a regional/national meeting that may benefit their role on this committee.

2.2.3 Liability Coverage

IBC members who act in the course and scope of their role and responsibilities as an IBC member in good faith without malice and in the reasonable belief that the action or recommendation is warranted by the facts known by that person have civil immunity pursuant to the Texas Tort Claims Act and Sections 160.010 of the Texas Occupations Code and 161.033 of the Texas Health & Safety Code.

2.2.4 Appointment

The VPR or designee shall appoint the members of the Committee for a two-year term. Generally, regular terms will begin on September 1, but may be made as needed. Confirmation letters will be sent to each member, along with confidentiality statements, to be signed and returned before appointment is official. As deemed necessary throughout the year, the Committee may vote to nominate new members for appointment by the VPR.

Members with more than three (3) unexcused absences per year may be removed from the Committee. A committee member may be removed at any time upon written notice by the VPR or designee.

2.2.4.1 Officers

The officers of the Committee shall be a Chairperson and Vice- Chairperson. These officers shall perform the duties prescribed by the bylaws and by the parliamentary

authority adopted by the Committee. The IBC Chair is appointed by the VPR from among the IBC members. The IBC Chair shall be an experienced scientific investigator with regard to issues related to biosafety, especially as it pertains to working with recombinant DNA. The IBC Chair shall preside over the IBC meetings to review protocols and acts as a liaison between the academic community and the IBC.

The IBC Chair may appoint a Vice-Chairperson to act in his/her absence. The Vice-Chair and designated IBC members shall serve as primary reviewers for all proposals submitted to the IBC, as preliminarily determined by the IBC Chair. The IBC Chair is responsible for making sure that IBC members are appropriately trained. The chairperson and vice-chairperson are considered voting members of the IBC for purposes of establishing the quorum.

2.2.4.2 BSO

The BSO has the following duties:

- Conduct periodic inspections of research laboratories to verify that laboratory standards are vigorously followed;
- Report to the IBC and VPR any significant problems, violations of the NIH Guidelines, state and federal regulations, and institutional policies, and any significant research-related accidents or illness, related to the receipt, collection, handling, use, storage, transfer, and/or disposal of biologically and chemically hazardous materials, including recombinant DNA, of which the BSO becomes aware of unless the PI has already filed a report;
- Provide advice on laboratory biosecurity; and
- Provide technical advice to PI's and the IBC on research laboratory safety procedures.
- Provide inspection reports and reports resulting from assessments and investigations regarding suspected noncompliance

2.2.4.3 Unaffiliated Members

Unaffiliated members are individuals who represent the interests of the surrounding community with respect to the environment and public health. They have no ties to the parent entity, its staff, or faculty.

2.3 Meetings

The Committee will meet every month in which there is business to conduct. The regular meetings of the Committee shall be held on the third Tuesday of each month, unless the Chairperson makes another arrangement. At a minimum, the Committee shall meet once every fiscal quarter. The agenda, draft minutes from previous meeting, and all appropriate material will be available for review by all voting members. Members should review the materials before each meeting, and within one week of being assigned, to allow for full review of the proposed protocol.

Staff of the Office of the Vice President for Research will provide administrative support for the IBC.

2.3.1 Public Notice

Prior notice of each meeting is available in iRIS and appropriately posted for the public on the website at http://www.elpaso.ttuhsc.edu/research/committees/ibc/submission-deadlines.aspx. Except where necessary to protect privacy and proprietary interests, the rDNA portion of the IBC meetings shall be open to the public.

2.3.2 Attendance

The importance of IBC member attendance cannot be overstated. Member absences may affect the quorum and therefore the ability to conduct business. Notification of an expected absence is required. Members absent more than 3 times in a fiscal year may be removed from the committee.

2.3.3 Quorum

An IBC meeting shall only be convened when a quorum is present. Quorum for this committee to conduct business is defined as a majority of the voting members present, including at least one officer, the BSO, and one member. Quorum for convened meetings may include video or teleconferencing, provided that the members participating from remote sites have access to all necessary materials required for review. A quorum is not present when a sitting member who is required (example: officer in attendance) must recuse him/herself for any reason. If a quorum is lost at any time during the meeting, no further action shall be taken by the IBC until a quorum is attained.

2.3.4 IBC Member COI

When an IBC member has a conflict of interest as defined by Institutional policy relating to a matter before the IBC, he/she shall make the conflict known and recuse him/herself from the consideration of that matter. Further, the iMedRIS software system used by the TTUHSC El Paso IBC does not permit any IBC member who is listed as study personnel on a particular protocol to access the IBC review comments or meeting discussions for that protocol.

2.3.5 Considerations for Review

The IBC shall consider in its deliberations and base its decisions relating to the Covered Work on the BMBL, the NIH Guidelines, SAT regulations, NSABB documents, the TTUHSC El Paso LCBM, and other relevant external and internal reference documents.

2.3.6 Expedited Subcommittee

In special circumstances determined by the Chair, a subcommittee review may be conducted to review a new application, renewal of an established protocol, or an amendment, if a grant transfer or grant award is pending, and approval must be granted prior to the next scheduled IBC meeting. The Chair, Safety Services member, and one additional committee member is required to approve the protocol under review. Business conducted for this review is available in iRIS and reported to the full committee at the next scheduled meeting.

2.3.7 Minutes

TTUHSC El Paso IBC meeting minutes are created by the IBC administrative staff through the iRIS system based on the information provided in written reviews of all IBC submissions since the last convened meeting, as well as from documented discussion that takes place during a convened meeting of the IBC. Meeting minutes will be distributed for review by the IBC administrative staff prior to the next convened IBC meeting. At each convened meeting, members will vote to approve the minutes from the previous review period. Documentation of approval of meeting minutes will be noted on the agenda and in the next review period's meeting minutes.

Minutes of IBC meetings shall be completed in sufficient detail to demonstrate the following:

- Date, time and location of the meeting,
- Attendance at the meetings and presence of a quorum,
- Actions taken by the IBC regarding each agenda item, including motions and votes, and prior meeting minutes,
- Notation of members who were not present during deliberations and voting due to a conflict of interest,
- The basis for requiring changes or disapproving any initial review or renewal of any research protocol, and
- Major points of discussion of research related issues and their resolution,
- When possible, and consistent with protection of privacy and proprietary interests, the institution shall make the IBC meetings open to the public.

Meeting minutes will be retained for three years following the meeting. Any printed or electronic documents related to a protocol will be retained for three years following termination of the protocol.

2.4 PI Responsibilities

The PI promotes good laboratory practices to provide valid and reproducible scientific results, prevent contamination, and improve overall laboratory safety and security, according to federal and state regulations and guidance documents.

2.4.1 Risk Assessment

A PI who wishes to receive, collect, handle, use, store, transfer, and/or dispose of biologically and chemically hazardous materials, including recombinant DNA, must make an initial risk assessment of the biohazardous materials based on the Risk Group (RG) of the agent in order to establish the proper physical and biological containment level. This risk assessment shall be in accordance with Section II-A of the NIH Guidelines. "Risk" implies the probability that harm, injury, or disease will occur. The primary focus of a risk assessment is to prevent or reduce the risk of laboratory-associated infections or accidental or unintentional release of potentially biohazardous agents into the environment. The initial risk assessment is made from review of Appendix B in the NIH Guidelines Governing Recombinant DNA Research.

2.4.2 Risk Group Classification

Agents are classified into four Risk Groups according to their relative pathogenicity for healthy adult humans as follows:

- **Risk Group 1 (RG-1)** agents are not associated with disease in healthy adult humans,
- **Risk Group 2 (RG-2)** agents are associated with human disease which is rarely serious and for which preventive or therapeutic interventions are often available,
- **Risk Group 3 (RG-3)** agents are associated with serious or lethal human disease for which preventative or therapeutic interventions may be available, and
- **Risk Group 4 (RG-4)** agents are likely to cause serious or lethal human disease for which preventive or therapeutic interventions are not usually available.

The NIH Guidelines serve as a reference in determining the risk level of a particular agent.

2.4.3 Consideration of Agent Factors and Intended Research Use

The agent's Risk Group is one component in assigning the appropriate level of physical and biological containment to reduce the risk of exposure to an agent. In addition, the following factors should be considered in assessing the risk and determining the level of physical and biological containment for the agent(s):

- Pathogenic virulence
- Operations in proposed research
- Route of transmission (e.g. parenteral, airborne, ingestion)
- Stability of agent
- Infectious dose of agent/communicability
- Concentration
- Quantity
- Origin of the material
- Data from animal studies
- Availability of immunization or vaccine or treatment
- Gene product effects (e.g., toxicity, physiological activity, and allergenicity)

When working with DNA of pathogens, any strain that is known to be more hazardous than the wild type parent (original) strain should be considered for handling at a higher containment level. Certain attenuated strains or strains that have been demonstrated to have irreversibly lost known virulence factors may qualify through an IBC review for a reduction of the containment level compared to the Risk Group assigned to the parent strain. See NIH Guidelines Section V-B, Footnotes and References of Section I-IV.

In addition to the above factors, consideration should be given to the types of manipulation planned for some higher Risk Group agents. Also, the PI should consult the Occupational and Health Administration (OSHA) regulation (29 FCR 1910.1030), and OSHA publication 3127 (1996 revised) when working with HIV, HBV, blood-borne pathogens, other blood-contaminated clinical specimens, body fluids, and tissues from all humans, or from HIV- or HBV-infected or inoculated animals.

2.4.4 Biosafety Level

The PI must also make an initial assessment of the proposed biosafety level for biohazardous agents with which s/he will be working. The final assessment of risk, based on the agent's Risk Group and other risk factors, should be utilized to determine the appropriate Biosafety Level (BL-1 to BL-4). The Biosafety Level describes the degree of physical and/or biological containment required to confine biohazardous materials and to reduce the potential for exposure of laboratory workers, person outside the laboratory, and the environment. Physical containment can be divided into two categories: (i) a set of standard practices that are generally used in microbiological laboratories; and (ii) special procedures, equipment, and laboratory installations that provide physical barriers that are applied in varying degrees according to the estimated biohazard. A third category of containment is the application of highly specific biological containment. The NIH Guidelines, Appendix I: Biological Containment, provides additional information.

Note: TTUHSC El Paso does not have any laboratories certified for BL-4. Therefore, no use or possession of recombinant DNA materials requiring BL-4, is allowed in any TTUHSC El Paso laboratory.

The following is a general description of the acceptable biosafety levels, which are described in more detail in the NIH Guidelines, Appendix G: Physical Containment.

- **Biosafety Level 1 (BL-1)**: This containment level is suitable for work involving materials of a minimal potential biohazard to laboratory personnel and the environment.
- **Biosafety Level 2 (BL-2)**: This containment level is suitable for work involving materials of a moderate potential biohazard to personnel and the environment. The biohazardous materials are associated with human disease which is rarely serious and for which preventive or therapeutic interventions are often available.
- **Biosafety Level 3 (BL-3)**: This containment level is suitable for work involving biohazardous materials that are associated with human disease which may have serious or lethal consequences or that has a potential for aerosol transmission.
- **Biosafety Level 4 (BL-4)**: This containment level is suitable for work involving biohazardous materials that pose a high risk of life threatening disease, aerosol transmission, or related agents with unknown risk of transmission.

These biosafety levels are determined by various criteria including pathogenicity, route of transmission, stability, infectivity, infectious dose, concentration, origin of sample, and availability and effectiveness of vaccine.

There are specific biosafety levels for work with biohazardous agents involving plants or animals. Additional information can be found in the NIH Guidelines, Appendices P (plants) and Q (animals) as well as the BMBL.

The Biosafety Level may be equivalent to the Risk Group classification of the agent, or it may be raised or lowered based on a comprehensive risk assessment.

If you have any questions regarding the risk assessment or appropriate containment level, you may consult with the IBC Chair, the BSO, or any member of the IBC. Except for certain defined recombinant DNA experiments whose biosafety level is established by the NIH, the IBC makes the final determination as to the appropriate Biosafety Level.

2.4.5 Other PI Responsibilities

Specific responsibilities include:

- maintaining a current, up-to-date curriculum vitae
- maintaining current licensure to practice, if applicable
- providing the sponsor and IBC with documentation of credentials, as requested
- demonstrating the proper education, training and experience to conduct the laboratory procedures
- signing the protocol, as required
- documenting the financial aspects, as appropriate
- disclosing conflicts of interest as described in the regulations
- complete institutional mandated research training as required
- NOT initiating or modifying any research involving biologically and chemically hazardous materials, including recombinant DNA, subject to IBC approval under these IBC Policies or NIH Guidelines until the research or proposed modification has been approved by the IBC. This includes any changes to procedures, location or personnel working on a previously approved protocol,
- Immediately reporting any significant problems or any significant research-related accidents and illnesses **in writing** to the BSO, the IBC Chairperson, the VPR, and any other TTUHSC El Paso committee that has reviewed and approved the research activity,
- Being adequately trained in good laboratory practice regarding the use of biologically and chemically hazardous materials, including recombinant DNA,
- Providing and maintaining documentation of material-specific training to all research personnel related to protocols registered through the IBC,
- Adhering to TTUHSC El Paso IBC approved emergency plans for handling accidental spills and personnel contamination, and
- Complying with shipping requirement for biologically and chemically hazardous materials, including recombinant DNA. For technical guidance, PI's may consult the NIH Guidelines, Appendix H "Shipment for recombinant

DNA" or contact the TTUHSC El Paso Office of Safety Services Safety Services OP 75.13 (http://elpaso.ttuhsc.edu/opp/_documents/75/op7513.pdf).

- Ensuring proper permits are obtained when needed. Ex: When importing and Transferring Animal Pathogens/ Biological Materials. USDA requires this for certain pathogens https://www.aphis.usda.gov/animal_health/downloads/organisms_and_vectors/vsregulatedlivestockpoultrypathogens_partial%20list.pdf.
- Working with the Office of Sponsored Programs to ensure a Materials Transfer Agreement (MTA) is approved when transferring biological material between TTUHSC El Paso and other academic, non-profit or industrial institutions for research purposes. An MTA is not required when transferring material within TTUHSC El Paso.

Each PI is responsible for compliance with all federal regulations and institutional policies when conducting research involving biohazardous or chemically hazardous materials and with the NIH Guidelines when conducting research with recombinant DNA. The PI is responsible for ensuring that reporting requirements under the NIH Guidelines for recombinant DNA are fulfilled. Additional information and guidance can be found in the NIH Guidelines or by contacting the IBC Chair.

2.4.6 Prior to Initiation of Research Involving Recombinant DNA Materials

The NIH Guidelines are applicable to all recombinant DNA research conducted in the United States, regardless of funding source. All recombinant DNA research that takes place at a TTUHSC El Paso facility must comply with NIH Guidelines. If a PI has questions about whether the experiments are covered by NIH Guidelines (Section III), they may contact the Chair of the IBC to ensure that the research or proposed modification meets all requirements.

Prior to initiation of research involving recombinant DNA materials, as appropriate for the materials being used, each PI shall:

- Obtain approval from the IBC (and other relevant TTUHSC El Paso review committees, such as the IRB, IACUC, Radiation Safety Committee, etc.)
- Review applicable guidelines and regulations and become familiar with the safety procedures and requirements related to the materials involved in the research activity,
- In conjunction with Safety Services, ensure that all research personnel have received training on Laboratory Safety Essentials,
- Instruct laboratory personnel on the potential hazards associated with the research, the necessary precautions to prevent exposures and the exposure evaluation procedures,
- Instruct and train laboratory staff in practices and techniques required to ensure safety and the procedures for dealing with laboratory accidents,
- Inform laboratory staff of where and how to obtain emergency medical treatment for any laboratory accidents which may occur.

2.4.7 During the Conduct of Research Involving Recombinant DNA Material

As appropriate for the materials being used, each PI shall:

- Limit or restrict access to the laboratory when work with the recombinant DNA material is in progress,
- Provide personal protective equipment required for work with specific hazardous material. See the TTUHSC El Paso Chemical Hygiene plan and the product SDS for guidance,
- Report any significant problems pertaining to the operation and implementation of containment practices and procedures in writing to the BSO, the IBC Chairperson, and the VPR. These officials will determine whether a report to the NIH Office of Biotechnology Activities is necessary,
- Report any adverse events in connection with the use of recombinant DNA materials in writing to the IBC, and
- Be proactive in monitoring the environment to prevent work errors or conditions that may lead to adverse events or significant problems with containment practices.

2.4.8 Experiments Requiring Submission to NIH/OBA

The PI, with assistance from the IBC Chair shall:

- Submit information to the NIH Office of Biotechnology Activities for certification of new host-vector systems (NIH Guidelines, Section IV-B-7-b-(1)),
- Petition NIH/OBA , with notice to the IBC, for proposed exemptions to the NIH Guidelines (NIH Guidelines, Section IV-B-7-b-(2)),
- Petition NIH/OBA with concurrence of the IBC, for approval to conduct experiments specified in NIH Guidelines Sections III-A-1, Major Actions Under the NIH Guidelines and Section III-B, Experiments that Require NIH/OBA and IBC approval before initiation, and
- Petition NIH/OBA for determination of containment for experiments requiring case-by- case review (NIH Guidelines, Section III-B), or which are not explicitly covered by the NIH Guidelines.

2.4.9 Reporting laboratory accidents and exposures

All adverse events, illnesses, or significant accidents leading to or potentially leading to an illness or any event that is environmentally dangerous to humans, animals or plants, must be reported within 24 hours to the IBC through iRIS using the Incident Report Form. The form must be completed in its entirety and include the following information:

- Name and description of the recombinant DNA material(s) and hazardous materials involved,
- Name(s) of personnel involved,
- A description of the adverse event or significant research related accident/illness, and

- A description of the immediate corrective actions taken and any long-term actions which would prevent future occurrences.

After the report has been received and reviewed by the IBC Chair and BSO, a decision will be made as to whether the NIH/OBA must be notified. The incident report will be placed on the agenda for review by the IBC. The IBC will notify the PI through iRIS about what further actions, if any, are to be taken.

2.4.10 Access to Laboratories

PI's shall allow access to their laboratories to members of the IBC conducting business on behalf of the IBC, to the BSO, to the VPR or designee, or to the Director of Safety Services for routine or for-cause laboratory inspections. In the event of a significant laboratory accident or exposure, additional personnel shall be given laboratory access. This may include, but is not limited to, law enforcement or medical personnel as necessary to ensure the safety of faculty, staff, students, volunteers or the environment.

2.5 IBC Submission Process

2.5.1 Principal Investigator (PI) Sign-off

Initial review, annual status reports and three year renewal submissions must be signed by the PI electronically in iRIS prior to the IBC receiving the submission. In signing the submissions, the PI is indicating that s/he has reviewed the information in the submission. Prior to submitting an initial review, the signature of the PI indicates an understanding and agreement with the following:

- The research will be conducted by the PI or under his/her close supervision;
- Will make available to all laboratory/research staff the protocols that describe the potential biohazards and the precautions to be taken;
- Will instruct and train laboratory/research staff in: (i) the practices and techniques required to ensure safety, and (ii) the procedures for dealing with accidents;
- Will inform the laboratory/research staff of the reasons and provisions for any precautionary medical practices advised or requested (e.g. vaccinations or serum collection);
- Will supervise the safety performance of the laboratory/research staff to ensure that the required safety practices and techniques are employed;
- Will report any significant problems pertaining to the operation and implementation of containment practices and procedures in writing to the BSO, IBC, NIH, OSP, and other appropriate authorities, if applicable;
- Will correct work errors and conditions that may result in the release of recombinant or synthetic nucleic acid molecule materials;
- Will ensure the integrity of the physical containment (e.g. biological safety cabinets) and the biological containment (e.g. purity and genotypic and phenotypic characteristics);

- Will comply with reporting requirements for human gene transfer experiments conducted in compliance with the NIH Guidelines, if applicable.
- Significant financial interests have been reported and financial conflicts have been managed as required by regulations and internal policies.

Before approval or during the course of conduct of any protocol, the IBC may ask for verification from the PI that any of these requirements is, in fact, being met.

2.5.2 Department Signatory Sign-off

In addition to the PI, a Departmental designated authority is required to electronically sign all initial reviews prior to the IBC receiving the submission. In providing an electronic signature, the designated authority is attesting that:

- The protocol's goals are consistent with TTUHSC El Paso's research mission.
- The PI is qualified to conduct the research protocol.
- Adequate facilities and resources to conduct the research will be provided;

The IBC may request documentation from the Department Signatory authority regarding review and approval of any of these requirements. In cases where the PI is the department chair/dean, sign off by the President will be required.

2.5.3 Submission through web-based program

A PI who wishes to complete an initial application shall submit their request via the iRIS system. Delays in the approval of initial applications include the absence of adequate detail for the IBC to evaluate the study's purpose and/or procedures. Investigators are required to provide specific information on all research procedures. The more complete the initial description, the less likely that time will be spent with correspondence back and forth between the PI and the IBC. IBC administrative staff is available to respond to questions by email or telephone.

Approvals will result in the issuance of a Biohazardous/Hazardous Material Use License, also referred throughout as a registration. This is a document from the IBC describing the authorized use and registration of chemicals, biologicals, approved laboratory space(s), and recombinant DNA by authorized personnel, as well as any unique restrictions or limitations.

A license will be needed if one is receiving, collecting, handling, using, storing, transferring and/or disposing of chemical or biological agents at any of the Institution's facilities or affiliated entities, or transporting specimens between buildings on or off campus. The license is to be displayed prominently in the research laboratory or approved area, listing all approved personnel.

A PI will only hold one approved license, which will cover all related research activities.

No one shall obtain or use any materials subject to registration with the IBC until the registration request has been approved by the IBC, or after approval of the amendment form, if it applies to an existing registration previously approved by IBC. Modification of any previously approved registration shall not be put into effect until the modification has been approved by the IBC in accordance with TTUHSC El Paso policy.

2.5.4 Required Documents

The following documents should be submitted during the initial review process:

- Complete IBC application form, which includes the addendum;
- Summary of research or aims page, as applicable;
- Documentation of approval by other TTUHSC El Paso institutional committees, as applicable;
- Curriculum Vitae of PI uploaded under their account.

Materials for initial review shall be submitted by the established deadlines available at http://www.elpaso.ttuhsc.edu/research/committees/ibc/submission-deadlines.aspx

2.5.5 Submission Screening

IBC administrative staff will prescreen all IBC submissions. If the submission is incomplete or otherwise not fully prepared for review, it will be returned to the PI for completion. Appropriate training will be verified to ensure that it has been completed by all research personnel listed. When the submission is adequately prepared, it will be placed on the agenda and assigned to an IBC member or members for review.

2.5.6 Agenda

The IBC agenda consists of all IBC submissions that have been prescreened by IBC administrative staff, and acknowledged or assigned. IBC staff, in consultation with the IBC chair as necessary, make assignments based on an initial assessment of whether the submission requires administrative, expedited or full committee review. Because reviews of submissions that are to be acknowledged or receive expedited review take place on a continual basis, the agenda is an evolving document until finalized at the time of the convened meeting.

The agenda serves as the working document to inform IBC members of all submissions that have been acknowledged or have received expedited review since the last convened meeting of the IBC. The agenda provides an up-to-date reference of the review status of each submission.

2.5.7 Reviewers

Each submission to be reviewed at a convened meeting will be assigned to a primary and secondary reviewer. Efforts will be made to make the assignments primarily on the basis of reviewer expertise or knowledge. All study materials are available to all IBC members for review through the iRIS system.

The Primary Reviewer will review the application for completeness, with a special emphasis on safety concerns relevant to the application. This will include a review of the materials to be used, the investigator's plans for safe use and disposal of the materials, and a brief review of the studies in which the materials will be used. The secondary reviewer will also review and provide commentary, as appropriate, in the iRIS system. All comments and questions will be included in the "Review Checklist and Comments" section of the iRIS system.

The PI will be notified via iRIS regarding the need for clarifications or corrections to the application prior to the IBC meeting, in order to expedite the review process.

At the IBC meeting, the Primary and Secondary Reviewers will present a summary of the submission and then open the meeting up for discussion. Once the review is complete, the IBC will vote on the application.

2.5.8 Notifications to Investigators

All IBC decisions are communicated to the PI and designated research team members via the iRIS system. This includes but is not limited to approval, disapproval, terminations, clarifications, or modifications to secure approval. Generally IBC decisions will be communicated within 1 business day of the IBC's determination.

2.6 IBC Actions

2.6.1 Approval Requirements

In conducting the review of proposed research, the IBC must obtain information in sufficient detail to make the determinations required under federal and state regulations and institutional policies. This review may be conducted administratively for protocols that meet criteria for acknowledgment or expedited review, or at a convened meeting of the IBC.

2.6.1.1 Approval

The IBC must determine that all requirements are satisfied in order to approve a proposed research protocol.

2.6.1.2 Additional Information Required; Approval Recommended

The IBC (for research reviewed at a convened meeting) or experienced IBC member (for research reviewed by expedited procedure) may request additional information prior to approval of a submission in order to make all of the determinations required for approval

The IBC/experienced IBC member may request clarifications, protocol modifications, or revisions to other supporting documentation. In iRIS, these requests are entitled "Stipulations." Stipulations must be satisfactorily addressed before approval is effective. Investigator response(s) to minor modifications may be reviewed using expedited or administrative procedures

Responses to stipulations in iRIS are due within 30 days of the date of the request for additional information unless otherwise specified. If no response has been received after 30 days, the study will be administratively closed by the IBC and further review of the study will require a new application to be submitted to the IBC. If a PI's response will be delayed due to extenuating circumstances, arrangements should be made with the IBC Coordinator.

2.6.1.3 Additional Information Required; Return to the Full Committee for Review

The IBC (for research reviewed at a convened meeting) may request additional information prior to approval of a submission in order to make all of the determinations required for approval

The IBC may request clarifications, protocol modifications, or revisions to other supporting documentation. In iRIS, these requests are entitled "Stipulations." Stipulations must be satisfactorily addressed before approval is effective. Investigator

response(s) are considered to be substantive and modifications must be reviewed at a subsequent convened IBC meeting. Submission deadlines apply. If a PI's response will be delayed due to extenuating circumstances, arrangements should be made with the IBC Coordinator.

2.6.1.4 Table/Defer

The IBC may table or defer an item, remove from committee consideration at a convened meeting, due to various reasons.

- Numerous changes are required;
- Incomplete submission;
- IBC member/consultants not available for review;
- Loss of quorum;
- Necessary documentation from other pertinent TTUHSC El Paso committees (e.g. Conflict of Interest Committee) has not been provided.

Note: All studies that are tabled at a full committee meeting will require subsequent full committee review.

IBC administrative staff will send a written notice to the investigator to describe the reason(s) for table/deferral. If additional information is required, stipulations will be stated. Responses to stipulations in iRIS are generally due within 30 days of the date of the request for additional information unless otherwise specified. If no response has been received after 30 days, the study may be administratively closed by the IBC and further review of the study will require a new application to be submitted to the IBC. If a PI's response will be delayed due to extenuating circumstances, arrangements should be made with the IBC Coordinator.

2.6.1.5 Disapproval

When the IBC disapproves new research, it is rejecting oversight of the protocol as submitted, and the research is not allowed to proceed. When the IBC disapproves a change in research, the change cannot be implemented, and it is expected the research will continue as previously approved by the Committee. Disapproval may occur for a variety of reasons, most of which involve safety and/or scientific validity. The IBC cannot disapprove a submission that has previously been approved. Disapproval is only valid when the Committee is considering an item that is not yet approved.

The written disapproval notification to the PI will include reasons for the decision of the IBC. The PI may request reconsideration of the decision of the IBC via iRIS within 10 days of the date of notice. The PI shall provide a rationale for the request to reconsider and any other relevant supporting documentation to the IBC and the submission will be placed on the agenda for review by the IBC. The PI may also address the IBC in person at the next scheduled IBC meeting.

The IBC shall notify the PI in writing of its decision after reconsideration and the reasons for its decision. No further request for reconsideration by the PI is permitted following the final decision by the IBC made on reconsideration.

2.7 Modifications to Approved Registrations

PI's shall not initiate or implement any changes or modifications of IBC approved registrations without the prior review and approval of the IBC. This includes, but is not limited to, a change in the types of materials, changes in personnel or location, or changes that increase the risk of the protocol and/or the Biosafety Level. An Amendment form must be completed, signed and submitted through iRIS by the submission deadline in order to be considered for the following month's meeting.

2.7.1 Minor Changes

- Minor changes to the protocol, such as personnel changes, for which appropriate training has been verified, and/or removal of locations, are reviewed and processed administratively by the IBC Coordinator. Other minor changes, such as addition of room locations, are reviewed and processed by expedited review through the BSO. Minor changes related to certain biological agents and RDNA materials, such as commercially available plasmids without any oncogene or toxins, can be expedited at the discretion of the IBC Chair. All modifications must be submitted through iRIS on an amendment form, along with a revised study application. All submissions processed throughout the month are available on the agenda for review by all IBC members, but no discussion or vote will be required for items that have been processed in this manner. Outcome letters and updated licenses will be sent to the PI once the submission is approved.

2.7.2 Major Changes

Major changes to the protocol (including changes in recombinant DNA materials) require review and approval at a convened meeting of the IBC. All modifications must be submitted through iRIS on an amendment form, along with a revised study application. The amendment form will be placed on the next available agenda for review.

2.8 Continuing Review of Approved Registrations

2.8.1 Annual Status Reports

Annual status report forms are required for PI's who want to retain their registration for another year. The PI is responsible for completing the form and submitting it through iRIS, prior to the expiration date. The deadline is indicated on the initial approval letter and is also available in iRIS. The PI will receive courtesy reminder notices of the upcoming required registration via iRIS approximately 75 days, 60 days, 45 days and, 30 days before the expiration date; however, it is the responsibility of the PI to ensure that the ASR is submitted by the required time. ASR's for which appropriate training has been verified, are reviewed and processed administratively by the IBC Coordinator.

All submissions processed throughout the month are available on the agenda for review by all IBC members, but no discussion or vote will be required for items that have been processed in this manner. Outcome letters and updated license will be sent to the PI once the submission is approved.

2.8.1.1 Submission of ASR Materials after Expiration Date

Once IBC approval expires, the IBC will not immediately inactivate the study, pending an ASR, if the PI submits the ASR materials to the IBC for review at the next meeting. Extensions to the 30-day deadline will be made on a case-by-case basis. If the PI fails to submit the annual status report within 30 days after the expiration date and has not communicated with the IBC regarding extenuating circumstances, the study will be closed administratively by the IBC. Studies that are administratively closed by the IBC are no longer approved for any research activity. An investigator who wishes to reinitiate a research protocol that has been inactivated must submit the protocol as an initial application.

2.8.2 Three Year Renewal

All continuing IBC-approved protocols require a detailed renewal after three years, i.e., a three year renewal form must be submitted, along with a revised study application, via iRIS. The PI will receive courtesy reminder notices of the upcoming required registration via iRIS approximately 75 days, 60 days, 45 days, and 30 days before the expiration date. Requirements for registration renewal are identical to those for initial review of the protocol. It is the responsibility of the PI to be aware of this requirement and to submit the appropriate documentation by the required time.

2.8.2.1 Submission of Three Year Renewal Materials after Expiration Date

Once IBC approval expires, the IBC will not immediately inactivate the study, pending a three year renewal, if the PI submits the three year renewal materials to the IBC for review at the next meeting. Extensions to the 30-day deadline will be made on a case-by-case basis. If the PI fails to submit the materials within 30 days after the expiration date and has not communicated with the IBC regarding extenuating circumstances, the study will be closed administratively by the IBC. Studies that are administratively closed by the IBC are no longer approved for any research activity. An investigator who wishes to reinitiate a research protocol that has been inactivated must submit the protocol as an initial application.

2.8.3 Termination of a Protocol/Registration

PI's who will be leaving TTUHSC El Paso or who will no longer be using materials under a protocol for which they have received an IBC license are required to notify the IBC through iRIS of their intent to terminate their registration(s), using the Termination request form. Please note that an IBC license may not be transferred to a different PI. The investigator should also work with the IBC and Safety Services to ensure that any materials in the lab are properly destroyed or transferred to a different TTUHSC El Paso laboratory as approved by the IBC. These terminations will be processed throughout the month and will be available on the agenda for review by all IBC members. Investigators who are closing a laboratory for any reason should also refer to the TTUHSC El Paso Lab Close-Out Policy: http://elpaso.ttuhsc.edu/opp/_documents/73/op7310.pdf.

2.8.4 Full or Partial Transfer of Materials to another TTUHSC El Paso Laboratory

PI's who wish to transfer materials to another faculty member must notify Safety Services of their intent to transfer the materials. If the investigator who is to receive the transferred

materials has an existing license, he/she will be responsible for submitting an amendment with a revised application to the IBC for review and approval prior to the transfer of the materials. If there is no existing license, an initial application will need to be submitted. No materials shall be transferred until IBC approval has been granted for the submission(s) related to the requested transfer. Investigators may also need to refer to HSC EP OP 73.02 Ownership and Transfer of Externally Sponsored Protocols and Research Records.

2.9 Compliance Oversight

The IBC has the authority to monitor research involving hazardous chemical and biological materials, including rDNA, approved by the IBC pursuant to the responsibilities that fall under the NIH Guidelines, the BMBL, and Select Agents and Select Agent Toxins regulations. The ORR shall be responsible for compliance activities on behalf of the IBC and VPR, including audits and monitoring of IBC approved research.

The IBC has the authority to inspect research facilities, obtain records and other relevant information related to the use of hazardous chemicals and biological materials used in research. The IBC takes such actions that are in its judgment necessary to enforce compliance with applicable federal and state law, regulations, or guidelines, including action to suspend or terminate approval of research that is not being conducted in accordance with IBC requirements or that has been associated with unexpected serious harm to others.

In addition, routine and random inspections of the approved research areas are conducted by Safety Services. This information is reported to the IBC and discussed at the committee meetings.

There are varying degrees of non-compliance, as well as an escalation process and relevant disciplinary action(s), pertaining to PI's, research personnel, and their respective IBC protocols.

2.9.1 Non-Compliance

A situation, event or process in research activities that is inconsistent with Federal, state, and/or local regulations applying to research involving hazardous chemical and biological materials, including rDNA, under the jurisdiction of the TTUHSC El Paso IBC, or TTUHSC El Paso policies and procedures governing research involving hazardous chemical and biological materials, including, rDNA, or the research activities as approved by the TTUHSC El Paso IBC.

2.9.2 Minor Non-Compliance

Non-compliance that is neither serious nor continuing. Unplanned or unforeseen changes in the implementation of an IBC-approved protocol. Generally refers to a modification of procedures that has already occurred for a single procedure; they are not intended to modify the protocol. Examples of minor protocol violations may include the following, but is not limited to:

- Failure to report a change in personnel.
- Hazardous shipment was sent out without prior inspection from Safety Services.
- Failure to properly label licensed chemicals.

2.9.3 Serious Non-Compliance

Non-compliance that is a divergence from the protocol that materially (a) reduces the quality or completeness of the data, (b) impacts safety, rights, or welfare. Examples of serious protocol violations may include, but are not limited to the following:

- Failure to obtain IBC approval prior to initiating research involving hazardous chemical and biological materials, including rDNA, or to deviate from methods and procedures of an approved IBC protocol prior to approval (e.g., addition of biohazardous/hazardous materials or procedures that increase the risks).
- Failure to acquire the appropriate export, import or collection permits for applicable research activities.
- Failure to report work related accident(s)/exposure(s) and illnesses to Safety Services and IBC.
- Failure to instruct, train, and document training of personnel in the procedures and techniques consistent with safety practices and procedures for dealing with reporting accidents.
- Failure to correct laboratory safety deficiencies noted during inspections within one month.
- Instances demonstrating that biohazardous material, including rDNA, was not appropriately contained, inactivated, or disposed of properly.
- Failure to report any significant problems and/or violations of the NIH Guidelines, Select Agent Regulations, Federal and State regulations, or TTUHSC El Paso policies.
- Failure to demonstrate and document the correction of work errors and conditions that may have resulted in the release of biohazardous materials.
- Failure to adequately keep records
- Failure to report a change in protocol.
- Intentional deviation from protocol or regulations by study personnel or Principal Investigator

2.9.4 Continuing Non-Compliance

A pattern of repeated non-compliance which continues:

- After initial discovery and after IBC approval of corrective action plan and suggests that non-compliance will continue if there is no intervention, or
- Increases the risk of serious non-compliance, or
- If continued, could significantly increase risks to, or jeopardize the safety, welfare, and/or rights of others, or
- If continued, could decrease the scientific integrity of the research.

2.10 Compliance Corrective Action

2.10.1 Reporting Non-Compliance

TTUHSC El Paso is committed to operating with integrity and in full compliance with all institutional policies, state laws, and federal regulations. The ORR encourages the reporting of non-compliance by the PI, members of research staff, employees, students, volunteers or the general public. Reports of non-compliance can include but are not limited to, protocol deviations, unanticipated events involving risks to others, complaints regarding treatment by research staff, issues of data integrity, or any other compliance concerns. When potential non-compliance is reported by someone other than the PI, efforts will be taken to maintain confidentiality. The name of the reporter will not be disclosed to the individuals involved in the complaint, unless disclosure is required to reconcile the situation.

Safety Services, the IBC, or the OR may receive an allegation of non-compliance by any means including, but not limited to:

- Voluntary notification by the PI or research staff, through iRIS or direct communication with the research compliance officer, IBC, Safety Services or OR staff,
- Information given by other staff of the institution,
- Information given by other members of the research staff, including students and volunteers,
- Safety Services inspections,
- Anonymous reports to the Ethics Point.

Initial assessment of minor deficiencies found during an inspection may be corrected on site and a summary will be provided in the monthly BSO report reviewed by the IBC.

Initial assessment of the validity of an allegation will be made by Safety Services in consultation with the Senior Director of OR, the IBC Chairperson, and/or the OR Director. This initial assessment will generally be conducted within one business day.

If the initial assessment indicates that the allegation has no basis in fact or does not need to be investigated given the information received, the BSO will document this and no further action will be taken. A summary of this assessment will be provided in the monthly BSO report reviewed by the IBC.

If the initial assessment indicates that an investigation is warranted, then Safety Services will initiate an investigation to gather facts to allow determination of the nature and extent of the concern, whether individuals are in immediate risk, and if the concern involves non-compliance with institutional policy or federal regulations. The involved PI(s) may be informed by the IBC of the non-compliance investigation that is being conducted by Safety Services. If Safety Services, in consultation with the IBC Chair, concludes that that the noncompliance is serious, a subcommittee may be appointed to conduct the investigation by the IBC Chair.

The following considerations are evaluated during the investigation of the suspected noncompliance:

- Whether the reported actions resulted in potential harm to the involved personnel.

- Whether humans, animals, or plants were at risk of harm by the non-compliance.
- Whether a significant negative environmental or agricultural impact has occurred or has the potential to occur.
- Whether the reported violations constitute serious or continuing non-compliance with institutional policies or federal regulations.

2.10.2 When the Investigation deems that Minor Non-Compliance has occurred

Safety Services will gather the investigation and provide a report to the IBC. The report shall include:

- A description of the minor non-compliant violation and whether the violation resulted in any adverse events.
- A summary of the records and evidence reviewed during the investigation.
- Identification of the institutional policies or federal violations under which noncompliance occurred.

Disciplinary action may include:

A letter from the IBC sent to the PI, which should include corrective actions to be implemented immediately to avoid non-compliance in the future and an appropriate date by which the corrective action(s) should be implemented, usually within 30 days. Follow up training will also be required within 15 business days.

A follow up report will be provided to the IBC, at the following month's meeting.

2.10.3 When the investigation deems that serious non-compliance has occurred

When Safety Services and the IBC chair determine that a violation of institutional policies or federal regulations has occurred, the IBC Chair will appoint a subcommittee to further investigate the violation. In cases where the noncompliance is ongoing, and/or represents a safety issue, or to prevent further risk to the safety or health of personnel, or to the institution itself, the IBC chair will suspend the research activity until the subcommittee has reported their findings to the full committee and the full committee makes a determination. An official notice will be sent to the PI through iRIS.

After the subcommittee has reported their findings to the full committee, a corrective action plan will be requested from the PI, as a notice through iRIS. The PI will have a timeline in which the corrective actions must be implemented, not to exceed 60 days. The PI will have the opportunity to work with the IBC, Safety Services and the IBC Chair to modify the corrective actions, if deemed appropriate by the IBC. The OVPR, institutional committees, TTUHSC El Paso representatives, and other regulatory bodies may be notified of the noncompliance violation, as appropriate.

Examples of Corrective Actions after Determination of Serious Noncompliance:

- Requiring specific training or retraining for involved individuals and those conducting research.
- Changes in procedures used in research to mitigate the risks
- Additional monitoring by the IBC, Safety Services, or delegated individuals, of research activities that pertain to the noncompliance violation.
- Requiring submission and approval of a modification to an already approved IBC protocol prior to continuation of the research for which noncompliance was reported.
- Restricting or limiting the activities that the individual(s) may engage in.
- Suspending approval or terminating an approved IBC protocol.

2.10.4 Procedures for Suspending Research

If at any time during the investigation it is determined that either institutional policies or federal regulations have been violated, which pose a threat to individuals, the institution, or the environment, the IBC chair will have the authority to suspend the activity. Safety Services will take control of any biohazardous materials present in the facility or laboratory (if needed), and/or other actions as needed.

The IBC may determine to not permit the research to continue until the appropriate corrective actions have been instituted and reinstatement has been approved by the full committee.

In extreme cases, the IBC may determine that a serious noncompliant violation poses such a risk that the lab is closed, activity is indefinitely suspended, vote to revoke an approved IBC protocol, or subsequently refer the matter to the Vice President for Research.

2.10.5 Continued Non-Compliance

All cases of continuing non-compliance will be reported to the VPR and handled on a case-by-case basis.

2.10.6 Reporting to NIH

The IBC shall report any significant problems with or violations of the NIH Guidelines or any significant research-related accidents or illnesses related to recombinant DNA to the VPR and the TTUHSC El Paso ORR within 30 days. These reports will be sent by the VPR to NIH/OBA at the following address:

Office of Biotechnology Activities National Institutes of Health
6705 Rockledge Drive, Suite 750, MSC 7985
Bethesda, MD 20892-7985

CHAPTER 3 RESEARCHER AND RESEARCH STAFF INFORMATION

3.1 Introduction

The purpose of this chapter is to provide guidance to research investigators and personnel on the safe, legal, and ethical use of hazardous chemical and biological materials, including rDNA, in its facilities in accordance with applicable laws, regulations and TTUHSC El Paso policies and procedures. All research involving hazardous chemical and biological materials, including rDNA, conducted at or in affiliation with TTUHSC El Paso must be reviewed and approved by the TTUHSC El Paso Institutional Biosafety Committee (IBC) prior to beginning the Covered Work.

In addition to the information found in this Manual, investigators and research staff or those who wish to learn more about the TTUHSC El Paso IBC can find more information at the TTUHSC El Paso Institutional Biosafety Committee website. Contact information for IBC administrative staff, current IBC roster, IBC deadlines and meeting dates, as well as links to other helpful information can be found at the site.

3.2 Prerequisites for all personnel involved in biosafety research activities

3.2.1 Educational Requirements

All PIs and research personnel are required to receive training on hazardous chemical and biological materials, and financial conflict of interests prior to beginning any biohazard research-related activities. This training will be verified prior to iRIS access being granted. Initial approval of IBC submissions will be withheld until all research personnel have been verified as having completed/updated training and financial disclosure reports.

3.2.1.1 Laboratory Safety Training

All PIs and research personnel are required to receive training regarding laboratory safety prior to conducting any work in any TTUHSC El Paso laboratory or approved area. The currently approved training is Laboratory Safety Essentials (LSE). It is an online training course through ACME that is assigned by Safety Services. Contact information is available : Laboratory (ttuhsc.edu). In addition, yearly, in-person and/or online, refresher training specific to approved agents will be required and conducted by Safety Services.

3.2.1.2 Hazmat Shipping Training

All PIs and research personnel who handle, transport off campus, and cause hazardous materials to be transported off campus are required to complete this training. Training is available at: https://news.mayocliniclabs.com/2021/06/15/dangerous-goods-training-2/. Additional Information is available at: http://elpaso.ttuhsc.edu/safety/hazmatinfo.aspx

3.2.1.3 On/Off Campus Transport Training

TTUHSCEP OP 75.34 requires all those that may transport material between campus buildings do so safely and in compliance with OP 75.34. Training is through ACME and access to this training is obtained through Safety Services by emailing:

Jacqueline.lomeli@ttuhsc.edu.

3.2.1.4 Select Agent Training

All PIs and research personnel are required to receive this training if involved with the procurement, possession, storage, use, transfer, disposal, training, and security of exempt quantities of select agent toxins. Information is available at: http://elpaso.ttuhsc.edu/safety/lab.aspx. All personnel working with select agents will also be required to obtain FBI clearance before beginning any work.

3.2.1.5 Additional Training

Additional training may be required if working in BSL2 or BSL3 areas of the Laboratory Animal Resources Center (LARC). Information is available at: http://elpaso.ttuhsc.edu/safety/lab.aspx.

3.2.1.6 Conflict of Interest Training

All PIs and research personnel involved in research activities must complete conflict of interest training every 4 years. New protocols may not be submitted or approved without up to date training for all research personnel. Additionally, approval of annual status reports and/or three year renewals may be denied if training of any research personnel has lapsed. The training is available through the University of Miami at www.citiprogram.org.

3.2.1.7 Financial Disclosure

All research staff must have a current Annual Financial Disclosure statement on file with the ORR in accordance with TTUHSC El Paso OP 73.09 Financial Conflicts of Interest in Research. The link to the Financial Disclosure form is available at http://elpaso.ttuhsc.edu/research/financial-disclosure.aspx.

3.2.2 CITI Instructions

Registration: To begin the on-line course, go to the CITI website and select "Register". Next, enter "Texas Tech University Health Sciences Center-El Paso" as your organization affiliation. Continue through the multiple step process to establish your Username and Password. On the CITI registration page you will need to select the **Conflict of Interest Course.** You will then have access to the required modules. TTUHSC El Paso personnel must use their TTUHSC El Paso email address for registration. More information on CITI Training can be found at the CITI Program Support Center.

Course Completion: Upon successful completion of the course, you will be able to download a course transcript. TTUHSC El Paso is also notified of your successful completion of the course. You will be required to achieve an overall score of at least 80% to successfully complete the courses.

3.2.3 Investigator Conflicts of Interest

All TTUHSC El Paso investigators and study personnel are bound to the policies set forth in TTUHSC El Paso OP 52.06 Standards of Conduct and Ethics, TTUHSC El Paso OP 10.05 Conflicts of Interest and Commitment and TTUHSC El Paso OP 73.09 Financial Conflicts of Interest in Research. Unaffiliated investigators may also be bound to these policies if their own institutions do not have internal conflict of interest policies. Failure of any PI and associated research personnel to comply with these policies may result in suspension of submission

privileges. In accordance with the TTUHSC El Paso Conflict of Interest in Research Policy, all research personnel are required to disclose any financial conflicts of interest as outlined in the policy. These disclosures are to be made at least annually, and are to be updated more frequently as circumstances change.

If a protocol is submitted for IBC review and it is determined that a financial conflict of interest exists, the issue must be referred to the Conflict of Interest in Research Committee (COIRC) established by TTUHSC El Paso OP 73.09 Financial Conflicts of Interest in Research. The IBC will not continue the review of a submission until the COIRC has met and made its recommendations, and the investigator has adequately addressed these.

Non-financial conflicts of interest (conflicts of commitment, nepotism, etc.) may also interfere with objective conduct of research activities. Such conflicts will be addressed as indicated in TTUHSC El Paso OP 10.05 Conflicts of Interest and Commitment and TTU System Regents' Rules, Chapter 10.

3.2.4 iRIS Access

All submissions to a TTUHSC El Paso IBC must be submitted using the Internet Medical Research Information System (iRIS) software. In order to gain access to the system, all users must first complete required training. Investigators may request an iRIS account at the iRIS website: https://ttuep.imedris.net/

3.3 Who is eligible to be a TTUHSC El Paso PI?

Faculty status is required for all PIs. Exceptions may be granted on a case-by-case basis by the VPR. Details may be found in TTUHSC El Paso OP 73.08 Requirements for PI Status.

3.4 Non-Salaried Appointments

Personnel with a Non-Salaried faculty appointment may not be PIs on TTUHSC El Paso IBC applications, but may be listed as coinvestigators. If listed as participants in a protocol, non-salaried faculty must comply with all TTUHSC El Paso policies and procedures.

3.5 Non-TTUHSC El Paso Research Personnel

Non-TTUHSC El Paso personnel who will be conducting research activities on campus will first need to submit an application to be processed as a research volunteer. This is done through the OR and includes completion of safety training courses, HIPAA training, a criminal background check, orientation, and an immunization review. Additional information can be found at: Research Volunteers (ttuhsc.edu). Successful completion of the prerequisites will allow the personnel to obtain an iRIS account once research training has been completed.

3.6 PI Responsibility for Research Activities

The PI retains ultimate responsibility for the conduct of all research activities as specified in the IBC-approved protocol and for submission of all required documents including the application,

protocol, forms, responses to stipulations, revisions, reports, and any other documentation, including those made by authorized research personnel in accordance with TTUHSC El Paso IBC Policies and Procedures. While duties related to the conduct of the research may be delegated to other members of the research team, the authority for and conduct of research remain with the PI.

3.7 Notice of Absence

PIs shall notify the IBC in writing as soon as possible prior to any employment change, extended absence, or faculty development leave during which the PI will be engaged in research (See TTUHSC El Paso OP 60.02 Faculty Development Leaves of Absence). The PI shall submit information and/or an amendment to the IBC designating an investigator responsible for any active research study during PI's absence. Notice and/or amendments shall be made in accordance with local IBC submission requirements.

CHAPTER 4 GLOSSARY

ADDITIONAL INFORMATION REQUIRED A request made by the IBC for changes or clarifications to protocols it has reviewed.

ADMINISTRATIVE REVIEW Review of minor modifications that do not require review by the IBC and are completed by the IBC Administrative staff.

AMENDMENT Changes or clarifications made in writing to the original protocol.

ANNUAL STATUS REPORT Annual review of a protocol to document that it continues to meet regulatory and institutional requirements.

APPROVAL The IBC has reviewed the protocol and made a determination that the protocol has met all requirements. Research procedures may begin.

APPROVAL RECOMMENDED The IBC has reviewed the protocol and made a determination that the protocol may be approved, pending minor modifications/clarifications.

AUDIT A systematic and independent examination of research related activities, procedures and documents to determine whether the evaluated research related activities, procedures, and documents were conducted, and the data were recorded, analyzed, and accurately reported according to the protocol, and the applicable regulatory requirement(s).

BIOHAZARDOUS/HAZARDOUS MATERIAL USE LICENSE A document from the IBC describing the authorized use and registration of chemicals, biologicals, approved laboratory space(s), recombinant DNA in a research laboratory by authorized personnel, as well as any unique restrictions or limitations. The License is to be displayed prominently in the research laboratory, listing all approved personnel. A license will be needed if one is receiving, collecting, handling, using, storing, transferring, and/or disposing of biologically and chemically hazardous materials, including recombinant DNA, or transporting specimens between buildings on or off campus. A PI will only hold one approved license, which will cover all related research activities. Exceptions will be reviewed on a case by case basis.

BIOLOGIC Any therapeutic serum, toxin, anti-toxin or analogous microbial produce applicable to the prevention, treatment, or cure of diseases or injuries.

BIOLOGICAL SAFETY OFFICER A TTUHSC El Paso staff person who is trained as a Biosafety Officer and who is responsible for oversight of laboratory safety training, laboratory inspections, reviewing inventories and records and other duties as outlined in the NIH Guidelines, IV.B.c. The BSO will serve as a member of the IBC.

CLINICAL TRIAL A research study to answer specific questions about vaccines or new therapies or new ways of using known treatments. Clinical trials are used to determine whether new drugs or devices are safe and/or effective.

CLINICALTRIALS.GOV IDENTIFIER (NCT NUMBER) A unique identification code is given to each clinical study registered on ClinicalTrials.gov. Because the format is "NCT" followed by an 8-digit number (for example, NCT00000419), this identifier is also known as the NCT Number.

CO-INVESTIGATOR An individual involved with the PI in the scientific development or execution of a protocol. A coinvestigator typically devotes a specified percentage of time to the protocol and is considered research personnel. A coinvestigator may also be designated as responsible when the principal investigator is unavailable or absent, if he/she has the adequate training and certification to serve in this capacity, and is named on the study application

COMPLIANCE Adherence to all the research related requirements and the applicable regulatory and institutional requirements.

CONFLICT OF INTEREST A conflict of interest refers to a situation in which an Employee's financial, professional, or other personal considerations may directly or indirectly affect, or have the appearance of affecting, the Employee's judgment in exercising any duty or responsibility, including the conduct or reporting of research, owed to the Institution.

CONFLICT OF INTEREST IN RESEARCH COMMITTEE See TTUHSC El Paso OP 73.09 Financial Conflicts of Interest in Research. The Conflict of Interest Committee is appointed by the VPR to review and oversee the management of financial conflicts of interest in research.

CONTINUING NON-COMPLIANCE A pattern of repeated non-compliance, which continues:

- After initial discovery and after IBC approval of corrective action plan and suggests that non-compliance will continue if there is no intervention, or
- Increases the risk of serious non-compliance, or
- If continued, could significantly increase risks to, or jeopardize the safety, welfare, and/or rights of others, or
- If continued, could decrease potential benefits (the scientific integrity of the research).

CORRECTIVE AND PREVENTIVE ACTION (CAPA) An effective CAPA program will include incident identification, investigation of incident causality, development of an action plan based on root cause analysis, action plan verification and validation, action plan implementation, effectiveness checks and closure.

DISAPPROVAL The IBC has reviewed the protocol and determined that it is not approved and may not receive further review. This only applies to protocols that have not previously been approved.

DOCUMENTATION All records, in any form (including, but not limited to, written and electronic) that describe or record the methods, conduct, and/or results of a protocol, the factors affecting a protocol, and the actions taken.

DRAFT Status of a research protocol that has not been submitted to the IBC.

DUAL USE RESEARCH OF CONCERN (DURC) Life sciences research that, based on current understanding, can be reasonably anticipate 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 or other plants, animals, the environment, material or national security.

EXPEDITED REVIEW Review of proposed research by the IBC Chair or a designated voting member or group of voting members rather than by the entire IBC.

EXPERIMENTAL Term often used to denote a therapy (drug, device, procedure) that is unproven or not yet scientifically validated with respect to safety and efficacy. A procedure may be considered "experimental" without necessarily being part of a formal study (research) to evaluate its usefulness.

FULL COMMITTEE REVIEW Review of proposed research at a convened meeting, at which a majority of the voting membership of the IBC is present, including at least one unaffiliated member. For the research to be approved, it must receive the approval of a majority of those voting members present at the meeting.

GOOD LABORATORY PRACTICE (GLP) a set of principles intended to assure the quality and integrity of non-clinical laboratory studies that are intended to support research or marketing permits for products regulated by government agencies.

GRANT Financial support provided for research study designed and proposed by the principal investigator(s). The granting agency exercises no direct control over the conduct of approved research supported by a grant.

IBC RECORDS IBC records include but are not limited to: all minutes of IBC meetings, a copy of all proposals reviewed including all submission forms, any supplemental information, all correspondence, and IBC membership with a resume/biographical sketch for each member.

IBC REGISTRATION MANAGEMENT SYSTEM (IBC RMS REGISTRATION) The system that supports online submission of IBC registrations and annual registration updates to the NIH Office of Science Policy (OSP).

INCIDENT Any incident or problem involving biohazards.

INFECTIOUS BIOLOGICAL AGENTS Biological agents and biologically derived materials that present a risk or potential risk to the health of humans or animals, either directly

through infection or indirectly through damage to the environment. Categories of potentially infectious biological materials include the following:

- Human, animal, and plant pathogens (bacteria, parasites, fungi, viruses),
- All human blood, blood products, tissues, and certain body fluids (excluding routine use of human blood and body fluid for clinical purposes).
- Cultured cells and potentially infectious agents these cells may contain, and
- Any Biosafety Level 2 or higher recombinant DNA materials.

INITIAL REVIEW Submission of a new protocol for review by the IBC. Applicable federal regulations must be met prior to IBC approval of a protocol. No research activities that fall under the scope or authority of the TTUHSC El Paso IBC may commence prior to IBC approval of the protocol. In no case will the TTUHSC El Paso IBC grant "retroactive" approval to a research protocol where procedures have begun prior to approval.

INSTITUTIONAL REVIEW BOARD (IRB) A specially constituted review body established or designated by an entity to protect the welfare of human subjects recruited to participate in biomedical or behavioral research. At TTUHSC El Paso, the IRB is deemed to be a medical committee.

INTERNET MEDICAL RESEARCH INFORMATION SYSTEM (iRIS) The software through which all IBC applications, reviews and approvals are submitted and through which information is communicated between investigators and the IBC.

MATERIALS TRANSFER AGREEMENT (MTA) a legal contract required for the transfer of biological material between TTUHSC El Paso and other academic, non-profit or industrial institutions for research purposes.

MINOR NON-COMPLIANCE Non-compliance that is neither serious nor continuing. May include unplanned or unforeseen changes in the implementation of an IBC-approved protocol. Generally refers to a modification of procedures that has already occurred for a single procedure; they are not intended to modify the protocol. Examples of minor protocol violations may include the following, but is not limited to:

- Failure to report a change in protocol or personnel.
- Hazardous shipment was sent out without prior inspection from Safety Services.
- Failure to report single work related accident/exposure or illness to Safety Services and/or the IBC.

NATIONAL INSTITUTES OF HEALTH (NIH) Agency within DHHS that provides funding for research, conducts studies and funds multi-site national studies.

NON-COMPLIANCE A situation, event or process in research activities that is inconsistent with Federal, state, and/or local regulations applying to biohazardous research under the jurisdiction of the TTUHSC El Paso IBC, or TTUHSC El Paso policies and procedures governing biohazardous research, or the research activities as approved by the TTUHSC El Paso IBC.

OFFICE OF RESEARCH (OR) Office responsible for the oversight and direction of the biohazardous research program at TTUHSC El Paso, which includes administrative oversight of the IRB, IBC, the TTUHSC El Paso Research Compliance Program, and TTUHSC El Paso educational requirements for all research related activities.

OPEN Status of an IBC approved research protocol that is currently active.

PENDING–SUBMITTED FOR INITIAL REVIEW Status of a research protocol that has been submitted to the IBC for review. This status label remains until a final decision regarding the protocol is made by the IBC. Decisions by the IBC may include a request for additional information, or may be approved, tabled, or not approved.

PRINCIPAL INVESTIGATOR (PI) A TTUHSC El Paso faculty member who is full-time, compensated, and with an appointment indicated under HSCEP OP 73.08. The PI has ultimate responsibility for the design and conduct of a research protocol, including supervision of the research personnel, and under whose immediate direction the laboratory research procedures are being carried out.

PROTOCOL The formal design or plan of an experiment or research activity; specifically, the plan submitted to an IBC for review and to an agency for research support. The protocol includes a description of the research design or methodology to be employed with the use of potentially hazardous materials, the location where the procedures will be performed, the techniques/procedures used to contain hazardous materials to protect personnel and the environment, and the proposed methods of analysis that will be performed on the collected data.

QUORUM A majority of the voting members appointed to the IBC membership. A quorum must include at least an Officer, one unaffiliated member, and a Safety Services representative. A quorum must be established, recorded, and maintained for the deliberation and vote on all matters requiring a vote.

RECOMBINANT OR SYNTHETIC NUCLEIC ACID MOLECULES (RDNA)
In the context of the *NIH Guidelines*, recombinant and synthetic nucleic acids are defined as:

- Molecules that a) are constructed by joining nucleic acid molecules and b) that can replicate in a living cell, i.e., recombinant nucleic acids;
- 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
- Molecules that result from the replication of those described in (i) or (ii) above.

REQUEST FOR ADDITIONAL INFORMATION A request made by the IBC for changes or clarifications to protocols it has reviewed.

RESEARCH A systematic or clinical investigation, including research development, testing and evaluation, designed to contribute to generalizable knowledge.

RESEARCH LABORATORY Any laboratory or other approved (excluding accredited space occupied by the Laboratory Animal Resources Center) space occupied by the PI in which biological, chemical, recombinant or synthetic DNA materials are received, collected, handled, used, stored, transferred and/or disposed of. All research laboratories conducting this type of work require IBC protocol review and approval before such work may begin.

RESEARCH PERSONNEL Any person, including, but not limited to faculty, staff, students or volunteers, working in a laboratory in which biological or chemical materials are received, collected, handled, used, stored, transferred and/or disposed of.

RESTRICTED ACCESS Limitation of access for only authorized personnel to an area because of the nature or type of use of hazardous materials stored in that area.

REVIEW (OF RESEARCH) The oversight of research on a periodic basis by the IBC.

SERIOUS NON-COMPLIANCE Non-compliance that diverges from the protocol and that materially (a) reduces the quality or completeness of the data, or (b) impacts safety, rights, or welfare. Examples of serious protocol violations may include, but are not limited to the following:

- Failure to obtain IBC approval prior to initiating research that utilizes biohazardous materials or to deviate from methods and procedures of an approved IBC protocol prior to approval (e.g., addition of biohazardous/hazardous materials or procedures that increase the risks of the research).
- Failure to acquire the appropriate export, import or collection permits for applicable research activities.
- Failure to frequently report work related accident(s)/exposure(s) and illnesses to Safety Services and IBC.
- Failure to instruct, train, and document training of personnel in the procedures and techniques consistent with safety practices and procedures for dealing with reporting accidents.
- Failure to correct laboratory safety deficiencies noted during quarterly inspections within at one month.
- Instances demonstrating that biohazardous material was not appropriately contained, inactivated, or disposed of properly.
- Failure to report any significant problems and/or violations of the NIH Guidelines, Select Agent Regulations, Federal and State regulations, or TTUHSC El Paso policies.
- Failure to demonstrate and document the correction of work errors and conditions that may have resulted in the release of biohazardous materials.
- Failure to adequately keep records
- Intentional deviation from protocol or regulations by study personnel or Principal Investigator

SPECIMEN Any biological material obtained from or derived from patients or human research subjects. This includes, but is not limited to: fixed, frozen or fresh pathology or

autopsy specimens; blood; urine; saliva; CSF; semen; breast milk; and any purified DNA, RNA, proteins, cell lines or clones.

SPONSOR A person or other entity that initiates a clinical investigation, but that does not actually conduct the investigation, i.e., the test article is administered or dispensed to, or used involving, a subject under the immediate direction of another individual. A person other than an individual (e.g., a corporation or agency) that uses one or more of its own employees to conduct an investigation that it has initiated is considered to be a sponsor (not a sponsor-investigator) and the employees are considered to be investigators.

STUDY STATUS Label assigned to a study signifying subject enrollment, treatment and/or activity. Labels include: Draft, Pending-Submitted for Initial Review, Open, Completed, Not approved, Suspended, Terminated, and Withdrawn.

SUSPENDED Protocol status assigned to research protocols that have been previously approved and the IBC has made a determination that approval is suspended. The PI will be instructed regarding the extent of the suspension. Instructions may include cessation of all research activities pending final IBC determination in writing.

TABLED Protocol status assigned when the IBC has reviewed the research protocol and determined that extensive changes are necessary. The protocol will be reviewed at a convened meeting of the IBC once changes have been made and submitted.

TERMINATED Study status assigned to protocols that have been permanently closed.

TERMINATION REPORT A form that is filed when the PI is no longer engaged in the research for which a specific license has been issued.

THREE-YEAR RENEWAL Review of a protocol to document that it continues to meet regulatory and institutional requirements.

UNAFFILIATED MEMBERS Member of an IBC who has no ties to the parent entity, its staff, or faculty. This individual is usually from the local community (e.g., minister, business person, attorney, teacher, homemaker, or others).

WITHDRAWN Study status assigned to a research protocol that was submitted for IBC review and for various reasons the PI decides to withdraw the submission from further consideration by the IBC.