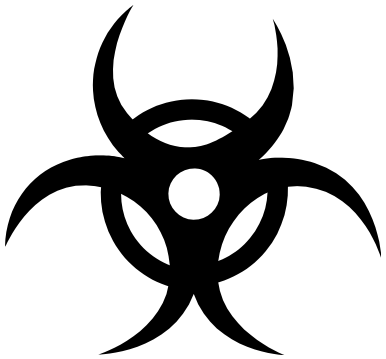
TARLETON
STATE UNIVERSITY
Member of The Texas A&M University System

Institutional Biosafety Committee (IBC)
General Operations Manual (GOM)



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Tarleton State University
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General Operations Manual (GOM)

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List of Abbreviations

BMBL	"*Biosafety in Microbiological and Biomedical Laboratories"*
BSC	Biosafety Cabinet
BSL	Biosafety Level
BSO	Biological Safety Officer
CDC	Center for Disease Control
IACUC	Institutional Animal Care and Use Committee
IBC	Institutional Biosafety Committee
IO	Institutional Official
IRB	Institutional Review Board
NIH	National Institute of Health
NIH guidelines	*NIH Guidelines for Research Involving Recombinant DNA Molecules*
NIH OSP	NIH Office of Science Policy
OHS	Occupational Health and Safety
ORI	Office of Research and Innovation
OSHA	Occupational Safety and Health Administration
PI	Principal Investigator
PPE	Personal Protective Equipment
RCC	Research Compliance Coordinator
rDNA	Recombinant DNA
RG	Risk Group
RMC	Risk Management and Compliance
SOP	Standard Operating Procedure
TAMUS	Texas A&M University System
TSU	Tarleton State University

Section 1: Introduction

1.0 Purpose and Scope of Manual

Tarleton State University (TSU) is responsible for providing suitable orientation, appropriate materials, adequate resources, and training to enable research faculty and staff and Institutional Biosafety Committee (IBC) members to carry out their respective duties. The IBC's duty is to review, approve, and oversee the use of recombinant DNA (rDNA), biohazardous agents, biohazardous materials, or toxins in all research and teaching activities conducted by Tarleton State University research personnel or at Tarleton State facilities. *The Institutional Biosafety Committee Policies and Procedures Manual* provides a review of the relevant regulatory and local requirements.

The IBC policies apply to all personnel engaged in research or teaching involving rDNA, biohazardous agents, biohazardous materials, and toxins that are:

- Sponsored by Tarleton State
- Conducted by Tarleton State research personnel.
- Conducted using Tarleton State property and facilities
- Received, stored, used, transferred, or disposed of at any Tarleton State facilities
- Research at other institutions conducted on behalf of Tarleton State

1.0.1 Research

Many of the items covered by the IBC are used in medical research, biological research, and agricultural research. Review is required even if the activity does not seem to qualify as "true research" (e.g., when the results are not intended for publication, when the work will not advance work in another area, or the work will not contribute to generalizable knowledge).

1.0.2 Teaching

The use of biohazardous items in educational settings is subject to IBC review. Examples include using biologically hazardous materials, toxins derived from biologically viable organisms and/or rDNA to teach techniques or biological procedures.

1.0.3 Research Conducted by "Affiliated Faculty"

Research conducted by "affiliated faculty"—those who hold clinical or adjunct appointments—is subject to the institution's guidelines for biologically hazardous materials, toxins derived from biologically viable organisms and/or rDNA use must be submitted for IBC review. Any research project that is conducted by or under the direction of any employee or agent of the institution, in connection with his or her institutional responsibilities, requires IBC approval.

1.1 IBC Mission Statement

Tarleton State University's IBC will safeguard human health and the environment by maintaining an adherence with the *NIH Guidelines for Research Involving Recombinant DNA Molecules* (*NIH Guidelines*) and the CDC/NIH "Biosafety in Microbiological and Biomedical Laboratories" (BMBL) 5th Ed. The IBC will oversee all aspects of TSU's biosafety in teaching and research activities. The IBC will review, approve, and maintain a registry of research projects and/or proposals involving the use of recombinant DNA, biohazardous agents, biohazardous materials, or toxins at Tarleton State University. The IBC will inspect research facilities and laboratories, and oversee trainings and educational programs. The IBC will serve as a resource and provide guidance for faculty, investigators, technicians, students, staff, and administration.

1.2 Charge and Authority of the IBC

The IBC has been charged in the planning and implementation of the campus Biosafety program with a purpose to ensure the health and safety of all personnel working with rDNA and biohazardous materials, biohazardous agents, or toxins. Such activities performed under the auspices of Tarleton State University, including cooperative research conducted with one or more public or private entities, must be reviewed and approved by the IBC prior to initiation. It is the responsibility of the IBC to ensure that biologically hazardous materials, toxins derived from biologically viable organisms and/or rDNA are used safely and in compliance with federal and state laws, regulations and guidelines. Tarleton State University IBC assures compliance with Texas A&M University System policy 15.99.06 and Tarleton State University policy 15.99.06.T1 "Use of Biohazards in Research, Teaching and Testing", The Centers for Disease Control and

Prevention/National Institutes of Health "Biosafety in Microbiological and Biomedical Laboratories" (BMBL) 5th ed., the *NIH Guidelines for Research Involving Recombinant or Synthetic DNA Molecules*, USDA regulations controlling the use of biohazardous materials and rDNA, and the latest Select Agents Regulations (42 CFR Part 73, 7 CFR Part 331, and 9 CFR Part 121). In the case of conflict between requirements of the regulatory agencies, the more protective regulations shall prevail, as appropriate.

Members of the IBC shall be appointed by the Institutional Official (IO) and the committee shall be structured according to the *NIH Guidelines*. The committee is charged with review, approval and oversight of research involving rDNA and biohazardous materials, biohazardous agents, or toxins in research and teaching activities. The IBC is responsible for establishing and implementing policies that provide for the safe conduct of research or teaching involving rDNA and biohazardous materials, biohazardous agents, or toxins. The IBC has the authority to approve, require modifications to secure approval, disapprove, suspend, or terminate research or teaching activities as required to assure adherence to the appropriate regulations and guidelines. The IBC advises the IO of the status of the institution's compliance and establishes plans and schedules for correction of deficiencies necessary to either maintain or achieve compliance. The IBC also makes recommendations to the IO regarding any aspect of the institution's biosafety program including facilities and personnel training.

The IBC's authority to review and approve permits is independent of the IO, who may not over-rule an IBC decision to withhold approval of a permit. If the IBC approves a permit, however, the institution is not required or obligated to conduct the research activity. The institution may also subject permits to additional institutional review (e.g., Risk Management, Occupational Health & Safety, department head, Animal Care and Use Committee, Institutional Review Board, etc.).

1.3 Committee Compositions

The IBC is composed of no fewer than five regular voting members. Required membership as laid out by the *NIH Guidelines* included: a Biological Safety Officer (BSO), two members that are not-affiliated with the institution, a plant/plant pathogen/plant pest containment expert, and an animal containment expert. The IBC may use consultants as necessary during review discussion. Some IBC members fulfill specific regulatory requirements; others have unique roles by virtue of their

position. There are no specific prohibitions regarding individuals filling more than one role on the IBC.

1.3.1 Biological Safety Officer Role and Responsibility. The *NIH guidelines* mandate the appointment of a BSO at the institutions who serves on the IBC. The BSO will serve as the chair of the IBC. The BSO's duties include:

- Inspecting laboratory to ensure standards are followed
- Report to the IBC and institution: problems, violations of the *NIH Guidelines*, and significant research-related accidents
- Develop emergency plans in regards to spills, personnel contamination, and laboratory accidents
- Investigate laboratory accidents involving recombinant or synthetic nucleic acid molecule research
- Advise on laboratory security
- Provide technical advice on research safety procedures to PI's and the IBC

The BSO (IBC chair) can appoint a vice-chair to serve in the chair's capacity as necessary.

1.3.2 Non-affiliate Members Role and Responsibility. The nonaffiliated members represent general community interests. Neither they, nor their immediate family, have an affiliation with TSU. These members have equal status to every other committee member and are provided the opportunity to participate in all aspects of IBC functions.

1.3.3 Plant, Plant Pathogen, or Plant Pest Containment Expert Role and Responsibility. When the institution conducts recombinant or synthetic nucleic acid molecule research that requires Institutional Biosafety Committee approval in accordance with Appendix P of the *NIH Guidelines*, the IBC shall contain at least one individual with expertise in plants, plant pathogens, or plant pest containment.

1.3.4 Animal Containment Expert Role and Responsibility. When the institution conducts recombinant or synthetic nucleic acid molecule research that requires Institutional Biosafety Committee approval in accordance with Appendix Q of the *NIH Guidelines*, IBC shall contain at least one individual with expertise in animal containment principles.

1.4 Federal Registrations

The IBC is registered with the NIH Office of Science Policy (OSP) for purposes of rDNA research. For more information visit https://osp.od.nih.gov/biotechnology/biosafety-and-recombinant-dna-activities/

An annual report is filed with OSP, which includes an updated list of IBC members indicating the role of each member along with CV's, resumes, or biosketches for each member. The OSP is notified of any changes in IBC membership when changes occur. Such notice shall include a revised list of members, contact information and a CV or resume for each new member. The Office of Research and Innovation (ORI) notifies OSP of changes in IBC membership and submits an annual report on behalf of TSU.

TSU does not currently work with any select agents as defined by HHS or USDA guidelines. Before embarking on any research involving such agents, TSU will have a certificate of registration for Select Agents and Select Agent Toxin with the Centers for Disease Control (CDC) for the possession, use, receipt, or transfer of listed select agents or select agent toxins.

Section 2: Responsibilities

2.1 Institutional Official Responsibilities

The responsibility for the Biosafety Program at Tarleton State University rests with the Associate Vice President for Research. The IO:

- Appoints members to the IBC.
- Annually evaluates allocation of resources to research compliance and the IBC and adjusts as necessary.

The IO has charged the IBC (See Section 1.2) to review, approve and provide oversight and guidance to research and teaching personnel who seek to use rDNA and biohazardous materials, biohazardous agents, or toxins in experiments. Any possession and/or use of rDNA and biohazardous materials, biohazardous agents, or toxins at TSU must be conducted with appropriate safeguards and in accordance to with Tarleton State University policies and federal guidelines and regulations.

2.2 Responsibilities of the IBC

The responsibilities of the IBC include, but are not limited to, the following:

- Review, approve, and monitor research and teaching activities that involve rDNA, biohazardous materials, biohazardous agents, or toxins in accordance with the criteria outlined in the most current versions of the *NIH Guidelines*, select agent regulations, the BMBL, state and federal regulations and laws, and university rules and procedures.

  As part of the review process, the IBC will do the following:

  - Conduct an independent assessment of the containment levels (BSL-1 to BSL-3), as required by the *NIH Guidelines* or the BMBL.
  - Conduct an assessment of the facilities, procedures, practices, training, and expertise of personnel conducting research involving rDNA and/or biohazardous materials, biohazardous agents, or toxins.

  - Ensure adherence with all surveillance, data reporting, and adverse event reporting requirements set forth in the *NIH Guidelines* for rDNA research and the select agents and toxins regulations.

- Review and approve all activities involving the use of rDNA and/or biohazardous materials.
- Notify investigators in writing of the committee's decision to approve, withhold approval, or required modifications to secure approval of activities related to the use of biohazardous materials.
- Inspect at least once a year all of TSU's facilities using the BMBL as a basis for evaluation.
- Assess training of personnel involved in research utilizing rDNA and/or biohazardous materials, biohazardous agents, or toxins.
- Annually review all approved research and teaching involving the use of rDNA and biohazardous materials, biohazardous agents, or toxins.
- Direct development of appropriate procedures as required by NIH/OSP, CDC, and USDA regulations to oversee the possession and/or use of rDNA and biohazardous materials, biohazardous agents, or toxins.
- Review concerns involving the use of biohazards at TSU and if necessary suspend or terminate permit approval for the possession or use of rDNA and/or biohazardous materials, biohazardous agents, or toxins that poses undue risk to research personnel or a threat to the health and safety of the community.
- Periodically review the IBC's policies and procedures and modify them as necessary to ensure appropriate biosafety measures and adherence with federal and state requirements.
- Make written recommendations to the IO regarding any aspect of the institution's biosafety program, facilities, or personnel training.
- Report any significant problems with or violations of the *NIH Guidelines* and/or any significant research-related accidents or illnesses to the research compliance coordinator (RCC) and the IO who will report to the NIH/OSP.

2.2.1 Conflict of Interest

The *NIH Guidelines* state that no IBC member "may be involved (except to provide information requested by the IBC) in the review or approval of a project in which he/she has been or expects to be engaged or has a direct financial interest."

All investigators, consultants, and/or IBC members are required to disclose any conflicts of interest. An investigator or IBC member is said to have a conflict of interest whenever that person, his or her spouse, or dependent child falls under any of the following conditions:

- Is an investigator or sub-investigator on the permit (IBC members only, not applicable to PIs).
- Has entered into a financial arrangement with the sponsor or agent of the sponsor, whereby the outcome of the study could influence the value of the economic interest.
- Acts as an officer or a director of the sponsor or an agent of the sponsor.
- Has an equity interest in the sponsor of $5,000 or greater.
- Has received payments or other incentives from any sponsor that when aggregated for the investigator or member, spouse, or dependent children, total $5,000 or greater.
- Has identified him or herself for any other reason as having a conflict of interest.

Other possible examples of conflict of interest include cases where:

- A member is involved in a potentially competing research program;
- Access to funding or intellectual information may provide an unfair competitive advantage;
- A member's personal biases may interfere with his or her impartial judgment;

If the investigator submitting a permit believes that an IBC member has a potential conflict, the investigator may request that the member be excluded. The Chair (or in his/her absence, the Vice-Chair) will present the declared conflict and the Committee will determine whether a conflict exists. Should an IBC member declare involvement in any way in a research permit under review by the IBC, or state a conflict of interest with the research permit, then the member(s):

- May remain in the meeting room to provide information requested by the IBC;
- Leave the meeting room for discussion and voting; and
- Are not counted towards quorum.

2.2.2 Confidentiality

During the process of review of an activity (including, but not limited to, any annual reviews or permit amendments), material provided to the IBC and the Office of Research and Innovation (ORI) (administrative office that supports the IBC) shall be considered privileged information and the IBC shall assure the confidentiality of the data contained therein.

2.3 IBC Chair Responsibilities

The IBC Chair's responsibilities include:

- Serving as one of the contacts for all regulatory agencies.
- Acting as a liaison between research personnel and the IBC.
- Reviewing permits prior to official committee decisions made at the convened meeting.
- Approving the agenda for the convened meeting of the IBC.
- Calling the meeting to order, directing the meeting deliberations, requesting motions and seconds, and closing the meeting once it has concluded business.
- Reviewing initial biosafety concerns and determining the course of action required.
- Notifying the IO of received biosafety concerns.

2.4 Responsibilities of the Principal Investigator

All research or teaching utilizing biologically hazardous materials, toxins derived from biologically viable organisms and/or rDNA that is conducted at TSU must be under the direct supervision of a member of TSU faculty. Generally, faculty members are considered to be sufficiently knowledgeable to supervise and/or conduct research as determined by their appointment. The IBC, however, may at its discretion determine that a faculty or member lacks sufficient expertise to carry out any particular research project based on their relevant training and experience.

Research conducted by non-faculty, academic support staff, post-doctoral fellows, staff appointments, graduate students, or undergraduate students must be under the direction of a faculty member, as defined above. In such cases, the faculty member shall be considered the Principal Investigator (PI). The PI may delegate the performance of any or all components of the research

to non-faculty if they certify to the IBC that the individuals are sufficiently trained to perform the functions assigned.

Individuals that do not meet any of the above criteria may, by demonstrating sufficient cause and necessary expertise, petition the Associate Vice President for Academic Research for permission to submit an application for approval of an IBC permit. Such agreement shall be in writing and require the individual to comply with all relevant IBC and TSU policies for the conduct of research involving biologically hazardous materials, toxins derived from biologically viable organisms and/or rDNA.

2.4.1 General Responsibilities

The PI is responsible for full compliance with the policies, practices, and procedures set forth by TSU, the *NIH Guidelines,* BMBL, and select agents and toxins regulations. This responsibility extends to all aspects of biosafety involving all individuals who enter or work in the PI's laboratory or collaborate in carrying out the PI's activities. Although the PI may choose to delegate aspects of the Biosafety Program in his/her laboratory to other laboratory personnel (laboratory directors or supervisors) or faculty, this does not absolve the PI of their ultimate responsibility. The PI remains accountable for all activities occurring in their laboratory. Documentation of training and compliance with appropriate biosafety practices and procedures are essential. The PI is responsible for ensuring the appropriate safety training of employees and students and for correcting unsafe working conditions.

As part of general responsibilities, the PI shall:

- Develop, implement, and make available written laboratory-specific biosafety procedures that are consistent with the nature of current and planned activities. The PI shall ensure that all laboratory personnel, including other faculty members, understand and comply with all laboratory-specific biosafety procedures.
- Delay initiation of projects until the IBC has approved a permit detailing the activities to be carried out.
- Ensure all laboratory personnel, maintenance personnel, and visitors who may be exposed to any biohazardous agents are informed in advance of their potential risk and of the behavior required to minimize that risk. It is essential that everyone who may have potential

exposure to biohazardous agents be informed of such hazards and appropriate safety practices be taken before entering or working with such hazards.

- Ensure all maintenance work in, on, or around contaminated equipment is conducted only after the equipment is properly decontaminated by the laboratory staff or PI.
- Ensure materials are properly decontaminated before disposal and that all employees are familiar with the appropriate methods of waste disposal.
- Report any significant problems or violations of the policies, practices, and procedures to the RCC as soon as reasonably possible.
- Notify the RCC and IO immediately if the following occurs:
    - A laboratory-acquired infection is known or suspected.
    - A spill of any quantity involving an agent infectious to humans, plants, or animals occurs in a public area.
- Receive training in standard microbiological techniques.
- Ensure all personnel are appropriately trained in biosafety and receive appropriate medical surveillance when needed.
- Coordinate and develop emergency plans for handling accidental spills and personnel contamination.
- Create and foster an environment in the laboratory that encourages open discussion of biosafety issues, problems, and violations of procedure. The PI will not discipline or take any adverse action against any person for reporting problems or violations to the IBC, ORI, Risk Management and Compliance (RMC), or state or federal agencies.
- Comply with shipping requirements for biohazardous agents and select agents. The PI should contact RMC to ensure that all applicable transportation safety regulations are met prior to shipping microbiological cultures, tissues (human or animal), or body fluids. These materials are often regulated for shipment and must only be shipped by personnel who have been properly trained and authorized by TSU to ship such materials on its behalf.

2.4.2 Responsibilities during permit submission

During submission of a permit the PI shall:

- Make an initial determination of the required levels of physical and biological containment in accordance with the requirements set forth by the *NIH Guidelines* and the BMBL as applicable.
- Select appropriate microbiological practices and laboratory techniques to be used for the research project, diagnostic lab, or lab course.
- Complete and submit IBC permit application to the IBC using the most current forms.

2.4.3 Responsibilities prior to project initiation

Prior to initiation of a project the PI shall:

- Make available to all laboratory staff and involved facilities staff (such as animal care staff) the permits that describe the potential biohazards and the precautions to be taken.
- Instruct and train all personnel in:
    - Identification of the biohazard(s) present,
    - Practices and techniques required to ensure safety and reduce potential exposure, and
    - Procedures for dealing with accidents, spills, and exposures.
- Inform the laboratory staff of the reasons and provisions for any precautionary medical practices advised or requested (e.g., vaccinations or serum collection).
- Ensure collaborators are made aware in advance of any biohazardous agents sent to them and comply with all applicable packaging and shipping requirements.
- Maintain a formal inventory of all biological material received and sent. Logs should include the approximate quantity of the materials and where it is stored in the laboratory.

2.4.4 Responsibilities during the conduct of the project

During the active stages of a project the PI shall:

- Supervise the performance of the laboratory staff to ensure required safety practices are employed.

- Submit any changes in a given project to the IBC for review using the amendment form.
- Investigate and report in writing to the IBC any significant problems pertaining to the operation and implementation of containment practices and procedures.
- Immediately notify RMC of any laboratory spills, accidents, containment failures, or violations of biosafety practice that result in the release of biohazardous agents and/or the exposure of laboratory personnel (or the public) to infectious agents.
- Correct work errors and conditions that may result in the release of biohazardous agents.
- Ensure the integrity of all containment systems used in the project, lab, or course.
- Restrict access as required by the laboratory-specific biosafety practices and procedures and the biosafety containment level approved by the IBC.
- Immediately notify the IBC and RMC if a select agent has been isolated and confirmed from environmental and/or diagnostic specimens.

2.4.5 Required Principal Investigator Certification

By submitting an IBC permit application, to the IBC for review, the PI is certifying the following:

- I attest that the information contained in this registration is accurate and complete.
- I agree to comply with all Texas A&M University System and Tarleton State University IBC requirements regarding research involving biohazardous and/or recombinant materials.
- I agree not to initiate any research subject to IBC approval until I have received such approval.
- I agree to notify the IBC immediately of incidents involving biohazardous and/or recombinant agents
- I have read and agree to comply with the *NIH Guidelines for Research Involving Recombinant DNA* (*NIH Guidelines*). I acknowledge my responsibility for the conduct of this research in accordance with Section IV-B-7 of the *NIH Guidelines*.
- I have the knowledge and training required to safely handle the materials described.
- I agree to train all of my laboratory personnel in required procedures.
- Entry doors to the laboratory will be closed and locked when the laboratory is unattended.

- I agree to provide all personnel working in the laboratory notification, information, and training on the hazards, laboratory security and emergency policies and procedures associated with working in my laboratory.
- I agree to inform all personnel working in the laboratory that potentially all microorganisms can be pathogens under certain conditions. When necessary, work procedures and protocols are in place to prevent aerosols and exposure to microorganisms.
- I assure that all personnel are provided training in sterile technique, the use of automatic pipettors, and the proper disposal of biohazardous materials.
- I assure that all personnel are advised that if they are in an immunocompromised/ immunosuppressed condition that they are at risk for infection from the general environment and susceptible to infections that would normally not be a problem for an immunocompetent individual.
- I assure that all personnel are further advised that working in a laboratory that conducts experiments using live microorganisms could increase their risk of infection and be hazardous to their health.

It is implicit upon submission of a permit to the IBC that the PI has read and agrees to abide by the above obligations.

2.5 Responsibilities of the Office of Research and Innovation

The Office of Research and Innovation (ORI) will provide overall administrative support and will coordinate IBC reviews and meetings. Responsibilities of the ORI include, but are not limited to, the following:

- Provide the necessary liaison between the research personnel, the IBC, federal agencies, and regulatory agencies.
- Serve as the office of record for documentation involving the IBC.
- Provide all necessary documentation, forms, regulatory guidelines, and regulations to Principal Investigators.
- Maintain IBC registration forms and records.
- File annual updates and other reports with the NIH/OSP.

- Communicate with the IRB or IACUC when permits involve human subjects or animals.
- Schedule and assist with annual laboratory inspections.
- Draft revised policies and procedures to remain in compliance with those regulations by monitoring Federal and state regulations.
- Provide administrative support for the IBC by scheduling meetings, arranging for meeting space, and taking meeting minutes.

Section 3: Permit Submission, Modification, and Review

3.1 Permit Submission

The IBC is responsible for overseeing and evaluating all aspects of biosafety, and is charged with reviewing permits that involve biologically hazardous materials, toxins derived from biologically viable organisms, and/or rDNA to ensure that the criteria established in the *NIH Guidelines* and the BMBL are implemented. In its review of proposals, the IBC's primary goal is to facilitate compliance with applicable laws, regulations, and policies.

IBC permit submissions, modifications, or renewals, must be submitted to the Office of Research and Innovation (ORI) by the PI for review and IBC approval. No research or teaching involving rDNA, biohazardous materials, biohazardous agents, or toxins can be initiated until the PI has received the approval of the IBC. Modifications to approved permits shall not be implemented until approved by the IBC. Classroom teaching activities will be submitted and approved in a permit separate from a PI's research activities.

Experiments involving biologically hazardous materials, toxins derived from biologically viable organisms and/or rDNA that are subject to review by the IBC prior to initiation include, but are not limited to:

- Recombinant nucleic acid studies that are potentially exempt from the *NIH Guidelines.*
- The deliberate transfer of a drug resistance trait to microorganisms that are not know to acquire the trait naturally.
- The deliberate transfer of rDNA or nucleic acids derived from rDNA into human research participants.
- The deliberate formation of rDNA containing genes for the biosynthesis of toxin molecules.
- The use of RG-2 or RG-3 agents as host vector systems.
- The use of human etiologic and animal viral etiologic agents.
- The cloning of DNA from RG-2 or greater agents into non-pathogenic prokaryotes or lower eukaryotic host-vector systems.

- Whole animals in which the animal's genome has been altered by stable introduction of rDNA or DNA derived into the germ-line (transgenic animal).
- Viable rDNA-modified microorganisms or cell lines tested on whole animals.
- Genetically engineered plants produced by rDNA methods.
- More than 10 liters of rDNA cultured in a single vessel.
- The formation of rDNA molecules containing one-half or more of the genome of a eukaryotic virus or a virus from the same family.
- Experiments using BSL-1, BSL-2 or BSL-3 containment.
- The use of biological toxins or bioactive derivatives/subunits of toxins.
- Non-recombinant research using biohazardous materials, biohazardous agents or toxins.
    - The growth/culturing of any microorganism (bacteria, virus, fungi, parasite) that may be infectious to humans, animals, or plants.
    - Research collecting, analyzing, or culturing animal cell lines, human cell lines, or non-human primate cell lines.
    - Research collecting or analyzing human or non-human primate tissues, body fluids, or other potentially infectious materials. Body fluids include but are not limited to: blood, urine, saliva, mucus, semen, cerebrospinal fluid, blood plasma, tears, bile, pus, feces.
    - Research involving the use of arthropods as vectors
    - Researching involving arthropods not indigenous to the region

3.2 New Submissions

IBC permits must be accurately completed and submitted to ORI for review and IBC approval. Permits to be reviewed must be received at least 2 weeks prior to the next scheduled meeting to be put on the agenda (meeting schedule is available at the website below).

The IBC permit application is available online at:

https://www.tarleton.edu/osp/compliance/ibc.html

Once a permit application has been received by ORI, a permit number will be assigned and used to reference the study. The permit will undergo an administrative review by the RCC to ensure all appropriate sections of the permit are completed. The RCC will also ensure that all individuals listed on the permit have completed the required trainings. Training requirements are described in Section 5 of this manual. After completion of the clerical review and missing/incomplete items have been addressed the permit will be pre-review by the IBC Chair and another assigned member of the committee (described in Section 3.6). It may be necessary for the PI to submit additional information if requested to ensure a complete application for review by the full committee. The PI will be notified of the IBC decision. All laboratories were work with biohazardous materials or rDNA is conducted are required to be inspected prior to initiation of work. Additionally, BSL-2 and BSL-3 laboratories must develop a Lab Biosafety Manual and have it approved by the IBC.

3.3 Monitoring of Approved Permits

3.3.1 Annual Permit Renewal

The *NIH Guidelines* require periodic review of recombinant or synthetic nucleic acid molecule research (IV-G-2-b-(5)). The IBC is required to regularly review approved research, teaching, and other activities at intervals appropriate to the degree of risk but no less than once per year.

PI's are required to complete an Annual Permit Renewal form. In doing so, the PI verifies that completed activities were conducted in accordance with the approved permit, describes any proposed departures from the approved permit, and solicits information about activities projected for the upcoming year.

When Annual Permit Renewals are submitted to the ORI prior to the permit's first and second anniversary, the permit is considered active and experiments can be conducted while the annual report is under review. Annual Permit Renewals cannot be submitted after a permit's anniversary date. If the PI fails to submit the annual permit renewal by the first and second anniversary, the permit is considered expired and a new permit application is required for consideration. The study must cease at the original expiration date and cannot be continued until a new permit is approved.

The purpose of continuing review is primarily threefold:

- to inform the IBC of the current status of the project;

- to ensure continued compliance with the *NIH Guidelines,* the BMBL, institutional requirements, regulations, and laws; and
- to allow for re-evaluation of the use of biologically hazardous materials, toxins derived from biologically viable organisms and/or rDNA at appropriate intervals.

Federal requirements, research ethics, and moral obligations of the scientific community to society demand that IBCs conduct appropriate and meaningful reviews of ongoing permits in the same responsible manner that initial reviews are done. This means that the IBC will not "rubber stamp" a previously approved permits during continuing review just because it has undergone a thorough initial review.

3.3.1a Review of BSL-1 Annual Permit Renewals

Annual Permit Renewals submitted for work approved at BSL-1 will be reviewed by no fewer than two IBC members. The Chair through the Research Compliance Coordinator, will designate qualified members to review the annual permit renewal documents. These designated members have authority to approve, require modifications (to secure approval), or request full committee review of the annual renewal. A designated reviewer may not withhold approval; this action may only be taken if the review is conducted using the full committee method of review.

When an Annual Permit Renewal is received it will undergo a clerical review by the Research Compliance Coordinator and then be provided to each Committee member. Members will then be given five business days to review the Annual Permit Renewal documents and respond, either allowing the review of the permit by designated members or to hold the renewal for the next full committee meeting. Failure to respond within the 5 day period will be considered as an approval to use designated members review. Responses will be sent directly to the Research Compliance Coordinator via email. If any one member votes

to hold the protocol until the next IBC meeting, then the protocol is placed on the agenda for the next IBC meeting. Otherwise, the protocol is reviewed by designated members.

3.3.1b Review of BSL-2 and Higher Annual Permit Renewals

Annual Permit Renewals submitted for work approved at BSL-2 will be reviewed by full-committee. IBC member will be provided with a copy of the Annual Permit Renewal documents from the ORI at least one week prior to the next scheduled meeting. The Annual Permit Renewal will then be reviewed in the same manner as initial Permit Review described in Section 4.2 of this document.

3.3.2 The Third-Year Resubmission

IBC permits must be re-submitted once every three years. The three-year period begins on the actual date of IBC approval; the IBC may not administratively extend approval beyond the three years. Since the permits approval period cannot be extended, investigators must be cognizant of the permits approval period. To aid investigators, the ORI shall attempt to provide adequate warning of pending permit expiration. It is the ultimate responsibility of the PI to submit the third-year resubmission by the appropriate deadline for a scheduled review, prior to permit expiration. The IBC requires a Third Year Resubmission be submitted as a new permit, using the most recent version of the application.

3.4 Modifications to Approved Permits

Amendments are required to be submitted to the ORI on the approved IBC amendment form when there are changes to an approved permit.

3.4.1 Significant Changes

Significant changes to an IBC-approved permit must be reviewed and approved by the IBC before they occur. The institution interprets significant changes to mean those that have the potential to impact safety consequences.

Examples of significant changes include, but are not limited to, changes:

- in the objectives of a study;
- in the Principal Investigator;
- that impact personnel safety;
- in location of the work.

Proposed significant changes require IBC review (and approval) prior to initiation. The IBC may determine that the significant change proposed requires submission of a new permit to accurately capture all required information to ensure the safety and well-being of personnel.

3.4.2 Non-Significant Changes

Non-significant changes are those that do not have the potential to impact substantially and directly on the health and well-being of personnel or the environment. Amendment/modification applications to existing permits that involve certain changes not considered significant can be reviewed (and approved) administratively.

Examples of non-significant changes include, but are not limited to, changes:

- in the funding source;
- in personnel (other than the PI).

Proposed non-significant changes require administrative review (and approval) by the Research Compliance Coordinator (RCC) prior to initiation.

3.5 Permit Termination

The PI will notify the ORI when the research covered by an approved permit is completed or no longer active. The IBC shall contact the PI if there are any questions or concerns regarding termination of approved permits. Failure to renew a previously approved IBC permit, described in Section 3.3, will result in termination of the permit. Issues of non-compliance with institutional and federal regulations, policies and guidelines or requirements of the IBC may initiate permit termination. Instances of non-compliance will be evaluated by the IBC to determine if permit termination is appropriate.

3.6 IBC Pre-Review of Permits

All new permit submissions, requests for modification, and annual renewals will be reviewed by the IBC Chair and a member of the committee prior to being brought to full committee.

The pre-review by the chair will consist of:

- Reviewing research submittal for completeness.
- Determining overall risk assessment.
- Setting appropriate containment levels.
- Requesting clarifications or changes.
- Recommending additional conditions.

The committee member will be responsible for:

- Reviewing research submittal for completeness.
- Determining overall risk assessment.
- Setting appropriate containment levels.
- Requesting clarifications or changes.
- Recommending additional conditions.
- Presenting an overview of the permit at the convened IBC meeting.

3.7 Controlled Substance Notification

Upon submission of an IBC permit that utilizes a controlled substance, controlled substance analogue, or chemical precursor, the Office of Risk Management will be notified of the work by the RCC. Once approval has been granted to an IBC permit that contains the use of a controlled substance, controlled substance analogue, or chemical precursor, the approval documents will be provided to the PI, the PI's department head, the PI's Dean, the Office of Risk Management, and the Associate Vice President of Research by the RCC. This notification is to ensure all parties are aware of the work and respective responsibilities. The PI is responsible for following all Federal, State, and University laws, regulations, and policies for the substance to be used. The PI

holds this responsibility, unless the PI's department has a Texas Controlled Substance Registration Certificate, then the responsibilities fall to the individual listed on this document.

Section 4: Meeting Processes

4.1 Quorum Requirements

A permit is approved only if a quorum is present and if more than 50% of the quorum votes in favor of permit approval. TSU defines a "quorum" as more than half of the IBC voting members. For reasons other than conflict of interest, abstentions from voting do not alter the quorum or change the number of votes required. For example: If the IBC has 9 voting members, at least 5 members must be present at a convened meeting to constitute a quorum. Approval of a permit would require a minimum of three votes whether or not there were abstentions. Members are expected to attend the convened meetings unless the research compliance coordinator (RCC) has been notified ahead of time that they are unable to do so. Members failing to attend meetings on a regular basis may be removed from the committee. Members who are on the Stephenville campus are expected to attend the meeting in person. Members who are based off of the main campus can request to attend meetings by Zoom, but must ensure confidentiality is maintained during the meeting.

4.2 Permit Review

In order to approve proposed research projects or proposed significant changes in ongoing research projects, the IBC shall conduct a review of those components related to the use of biologically hazardous materials, toxins derived from biologically viable organisms, and/or rDNA. The committee will determine that the proposed research projects are in accordance with the *NIH Guidelines* and the BMBL.

If the IBC does not have the scientific and technical expertise to evaluate all aspects of a permit, it may bring in outside expert consultants to provide information. Such consultants should not have a conflict of interest with the research activity and will not vote on any matters pertaining to the permit. In all cases, the onus should be on the investigator to justify and explain his or her proposed experiments to the satisfaction of the IBC.

Permits to be reviewed at a meeting must be received at least 2 weeks prior to the next scheduled meeting to allow time for the pre-review process. 5 business days prior to a meeting, the RCC distributes copies of the permits being presented and any other items of discussion to each IBC member. Review and approval of permits requires a convened meeting of a quorum of the IBC

members. Proposals reviewed by the committee must receive the approval vote of a majority of the quorum present in order to receive approval.

The IBC may contact investigators with questions or concerns about their proposal (e.g., documentation, lab practices, containment, training, equipment, personal protective equipment, facilities, etc.).

4.2.1 Range of IBC Actions

Upon review of permits, the IBC may take one of the following actions depending upon the findings of the committee: approval, modifications required (to secure approval), or withhold approval. The IBC may also defer or table the review of a permit. The IBC will notify investigators and the institution in writing of its decision to approve, withhold approval, or require modifications (to secure approval) of a permit.

Approval

When the IBC has determined that all review criteria have been adequately addressed by the investigator, the IBC may approve the project, thus granting the investigator permission to perform the experiments or procedures as described. The approval is valid for 3 years contingent upon completion of annual permit renewals.

The IBC-approved proposal may be subject to further review and approval by institutional officials due to financial, policy, facility, or other institutional or administrative considerations. Those officials, however, may not approve an activity if it has not been approved by the IBC.

Modifications required (to secure approval)

The IBC may require modifications to a permit before granting approval. If the IBC determines that a permit is approvable contingent upon receipt of a very specific modification(s), or clarification of a specific point, the IBC may handle these modifications or clarifications as administrative details that any member, such as the Chair, could verify prior to granting approval. The member that will verify the modifications should be selected at the time the permit is being reviewed by the committee.

If a study is unusually complex or involves untried or controversial procedures, the IBC may wish to impose restrictions. If such modifications represent significant departures, the

IBC can ask the investigator to revise the permit to reflect the modifications imposed by the IBC.

If a permit is missing substantive information necessary for the IBC to make a judgment, or the IBC requires extensive or multiple modifications, then the IBC can require that the permit be revised and resubmitted.

Withhold approval

When the IBC determines that a proposal has not adequately addressed all of the requirements of the *NIH Guidelines* and the BMBL, as applicable, or the described activities represent an inappropriate use of biologically hazardous materials, toxins derived from biologically viable organisms, and/or rDNA, the Committee may withhold approval.

As indicated previously, a higher institutional authority may not administratively overrule an IBC decision to withhold approval of a proposal. If approval is withheld, the IBC must provide the reasons for its decision and give the investigator an opportunity to respond.

Defer or table review

If the permit requires significant clarification in order for the IBC to make a judgment, Committee members with certain expertise are not present, the IBC wishes to seek external consultation, or any of a number of other reasons prevent the IBC from conducting its review, then the IBC may wish to defer or table review until a future meeting.

4.2.2 Notification of Review Outcome

The ORI will notify investigators of the IBC's decision to approve or withhold approval of those activities related to the use of biologically hazardous materials, toxins derived from biologically viable organisms and/or rDNA. ORI will also notify investigators of the modifications required to secure IBC approval. The procedure to notify investigators of the IBC's decisions regarding permit review are as follows:

- Upon completion of the review process, each Principal Investigator (PI) receives a written notification of review decisions (approved, modifications required (to secure approval), approval withheld, or tabled) and whether any special monitoring provisions

will be required. Records of communication are maintained electronically within the IBC permit files.

4.3 Meeting Minutes

Review of permits by the IBC invokes a deliberative process, and the IBC minutes should document the fulfillment of the review and oversight responsibilities described in Section IV-B-2-b of the *NIH Guidelines*.

Recorded minutes from IBC meetings are intended to reflect the substantive discussion of permits. Minutes are intended to contain sufficient information that a reasonable person could understand the nature of the discussion. Meeting minutes are not intended to provide a verbatim transcript of discussion nor to reiterate shared knowledge of the Committee such as recent discussions about a permit in previous minutes. Historical evidence of compliance or non-compliance would be recorded in the minutes if it were germane to the discussion. Minutes may include reference to historical discussion by the IBC from members who have served on the Committee and observed the procedures being proposed, served as reviewers for permits involving similar procedures (where their questions were answered), or participated in past IBC discussions about the procedures.

Minutes of each meeting are recorded in writing and include:

- Date and place of meeting
- Record of attendance
    - Generally a member is marked as either present or absent, if the member arrives late or leaves during a meeting the time is noted in the minutes. An exception would be when the IBC member leaves the meeting room during discussion of a permit on which that member is a participant. If a member recuses themselves due to a conflict of interest this is noted in the meeting minutes. If the temporary absence of a member drops the number of members present below the quorum, no official actions may take place and this will be noted in the minutes.
- Activities and deliberations of the Committee

  - A deliberation of the Committee refers to the discussion and reasons based on *NIH Guidelines* Section II and III leading to particular IBC decisions. Minutes should include, as a minimum, a summary of the key points discussed prior to a committee decision.
  - Activities of the Committee include, but are not limited to, corrections or approval of previous minutes; presentation of program, policy, facility, and compliance reports; and decisions on policies, permits, and amendments.

- Permits reviewed (identified by permit number and permit title)
- Time meeting is adjourned

Completed minutes are distributed to all IBC members. Minutes are reviewed at a subsequent convened meeting of the IBC and the Committee votes on approval. A copy of the approved meeting minutes is then provided to the IO. This informs the IO of all actions taken by the IBC.

4.4 Meeting Frequency

Convened meetings of the IBC are scheduled once a month. Permits to be reviewed at a meeting must be received at least 2 weeks prior to the next scheduled meeting to be put on the agenda.

The Chair may call an emergency meeting of the IBC as necessary to address such issues as noncompliance or serious and/or unexpected events involving rDNA, biohazardous materials, biohazardous agents, and toxins.

4.5 Attendance of Non-Members

IBC meetings are considered open and members of the TSU community and the public at large may request to attend an IBC meeting. The RCO must be made aware as soon as possible of additional attendees in order to schedule a room of appropriate size.

4.6 Reports and Recommendations to the Institutional Official

Copies of minutes, reports of laboratory incidents/accidents/spills, potential or actual exposure to infectious or biohazardous materials, incidents of non-compliance, permit suspensions, and terminations will be available for review by the IO. The IO will be consulted on any reports required and filed with the NIH OSP or other agencies.

The IBC will make written recommendations to the IO regarding any aspect of the institution's biosafety program, facilities, or personnel training. The procedures for making recommendations to the IO are as follows:

1. Recommendations regarding any aspect of the TSU's biosafety program, facilities, or personnel training are formulated at convened meetings of the IBC.
2. Recommendations are prepared in writing by the RCC, the IBC Chair (or in his/her absence, by the Vice-Chair), and/or any IBC member. A copy of these recommendations are reviewed by the IBC. Any minority views are noted and included in the final report.
3. The IBC Chair or his/her designee (generally the RCC) submits recommendations, including minority views that are approved by the IBC to the IO.

Section 5: Training

5.1 Introduction to Biosafety Laboratory Training

Laboratory personnel must possess certain skills to ensure their safety in the laboratory and the integrity of the research being conducted. Prerequisites for laboratory staff to reduce the inherent risks associated with hazardous agents include: training, experience, knowledge of the agent and procedure hazards, good habits, caution, attentiveness, and concern for the health of coworkers. Not all workers who join a laboratory staff will have these prerequisite traits even though they may possess excellent scientific credentials. Therefore, it is important all staff receive training to gain the necessary skills needed for working in a laboratory setting.

Training has numerous components including general safety practices and safety theory that progresses to task specific safety practices such as: SOPs, entry and exit procedures, room and suite specific procedures, use of PPE and equipment, animal handling, incident and accident reporting, etc. Components also include training under normal operating conditions, during emergencies, systems failures, and in the event of a suspect or known exposure. Training is often conducted in a layered approach to include a review of manuals and SOPs, classroom training, as well as hands-on training with a skilled and knowledgeable mentor that may start with less hazardous organisms, progress to a "watch one, do one" approach, and culminate in demonstration of competency.

5.2 PI and Laboratory Personnel Training Requirements for Biosafety

BSL-1 and BSL-2 PI's, researchers, and laboratory personnel must complete the CITI "Intro to Biosafety" and CITI "Responsible Conduct of Research" training courses. These course training will expire 3 years after the completion date. Additionally, if individuals are working in a BSL-2 lab the Traintraq course for working at the BSL-2 level will be required. The BSL-2 Traintraq course will expire 3 years after the completion date.

When submitting an IBC permit, training must be up to date. If training is valid at time of permit submission, training will remain valid until there is a change requested for the permit through submission of an amendment or the next annual protocol renewal is submitted.

All PI elgilble faculty will receive annual notification from the ORI notifying them of the types

of projects requiring IBC approval, as well as contact information for who to contact with questions.

The IBC permit application form now contains the Statement of Informed Consent that is designed for PIs to communicate hazards to laboratory workers, guide discussion of worker immunocompetence, and document completion of the online Biosafety Training. The informed consent page should be filled out for each individual listed on the permit and should document all biohazardous that the personnel may come into contact within the lab, not just what is described on the permit. PIs are responsible to train new staff in practices to the point where aseptic techniques and safety precautions become second nature.

5.3 Education and Training for IBC Members

Training for IBC members will occur not less than once annually. The objective of the training will be to increase their knowledge, understanding, and awareness of current laws and regulations, new directives, best practice guidelines, and institutional policies. These trainings will be presented by the TAMUS chief RCO, guest speakers, webinars, or other training programs of interest to the IBC. The trainings will be recorded to allow for distribution of material to individuals to satisfy requirements for members who were unable to attend the in person training.

5.4 Occupational Health & Safety Program

5.4.1 Description and Purpose

Tarleton State University is committed to providing a safe, secure, and healthy environment for all faculty, staff, students, and visitors. Any employee who, based on job function and risk assessment or named on an IBC permit, may be exposed to occupational health risks, may participate in the Occupational Health and Safety (OHS) Program. Students not employed by TSU but who encounter health risks due to their academic or research activities are also eligible to participate. The program focuses on occupations and research activities involving exposure to animals and those who handle biological materials or chemicals or are exposed to other health risks.

5.4.2 Enrollment Requirements

All faculty, staff, and students who are, or will be, working with biological materials or chemicals are required to enroll in the OHS Program. Through communication with PI and Employee

Services, the ORI will verify enrollment of all relevant personnel. No personally identifiable health information will be accessed by the ORI. The OHS enrollment is valid for one year and must be updated annually. When submitting an IBC permit application, OHS enrollment must be up to date. If the enrollment is valid at time of permit application submission, it will remain valid up to the next annual renewal and progress report or until submission of an amendment.

5.4.3 Opting Out or Declining Participation

After completing the enrollment process through the ORI individuals may elect to opt out or decline the medical surveillance portion of the program. The requirement to complete the online evaluation process prior to declination is to ensure that employees are fully informed about risks associated with their work activities and to be informed of the services available through the program.

5.4.4 Administration of Program

The OHS Program is administered by the ORI. The OHS Program facilitates awareness of, and appreciation for, safe conduct of work and research activities so that accidents and occupational injuries and illnesses will be minimized. The OHS Program, in conjunction with the Department of Risk Management and Compliance, shall identify and control, to the extent possible, any safety, public health, and environmental hazards presented by work and research activities.

5.5 Personal Health Status

Personal health status may impact an individual's susceptibility to infection and ability to receive immunizations or prophylactic interventions. Therefore, all laboratory personnel and particularly women of childbearing age should be provided with information regarding immunocompetence and conditions that may predispose them to infection. Lab workers who have an autoimmune or chronic disease (no matter how well managed), heart disease, are taking immune suppressing medications (e.g., chemotherapy, systemic steroids), are a female of childbearing age or are pregnant or planning conception, should be encouraged to discuss with the PI any additional safety concerns, extra medical surveillance, or supplementary PPE.

5.6 Medical Surveillance

The potential exists for lab workers exposed to volumes and concentrations of microorganisms not typically found in nature to present with atypical signs and symptoms. TSU does not have a medical surveillance plan at this time. Individuals working with pathogenic microorganisms should have adequate medical insurance and should inform their primary care physician of their routine laboratory activities. If applicable, proof of vaccination must be provided by any employee working with designated pathogens. Any necessary vaccinations or surveillance tests must be received through the costs of the laboratory worker or the PI or a declination of vaccination form must be filled out. All medical surveillance and vaccination requirements specific to laboratory research are listed on the IBC permit application for review by the IBC at the time of registration.

5.7 Safety Plan

Each IBC permit must include a detailed safety plan indicating proper containment, spill control procedures, and disposal of intended biological materials. Availability of biological safety cabinets and autoclaves are also to be indicated as part of the PI's safety plan. A copy of the safety plan will be reviewed by the Office of Risk Management and Compliance (RMC) as well as the IBC.

5.8 Exposure Control Plan for Bloodborne Pathogens

Any research, diagnostic, or teaching activity conducted with material derived from humans including blood, body fluids, tissues, primary or established cell lines requires the PI to indicate "Bloodborne Pathogens" on their safety plan and complete the appropriate section of the IBC permit. In addition, an Exposure Control Plan must also be adopted to meet Occupational Safety and Health Administration (OSHA) regulation 1910.1030 for Bloodborne Pathogens in the workplace, available at:

https://www.osha.gov/pls/oshaweb/owadisp.show_document?p_id=10051&p_table=STANDARDS

Any faculty, staff, and/or student included on an IBC permit is required to complete the annual TAMUS Bloodborne Pathogen Safety course on TrainTraq. If training is valid at the time of permit submission, training will remain valid until there is a change requested for the permit through submission of an amendment or the next annual protocol renewal is submitted.

Section 6: Facility Inspections

6.1 Facility Inspections

The facility inspections are a physical inspection of all buildings, rooms, and areas that are used for research involving biologically hazardous materials, toxins derived from biologically viable organisms and/or rDNA. The IBC must have reasonable access to these areas for the purpose of verifying that activities involving biologically hazardous materials are being conducted in accordance with the proposal approved by the IBC.

The IBC inspects at least once every year all of the TSU's biohazard facilities using the BMBL and *NIH Guidelines* as a basis for evaluation. The IBC procedures for conducting annual facility inspections are as follows:

1. Every year, the RCC and IBC Chair organizes the inspection schedule of the research facilities located on campus. These inspections are conducted using the *BMBL* and *NIH Guidelines* as a basis for evaluation. All IBC members are invited, and encouraged, to attend the facility inspections.
2. The PI is notified, in writing, of any minor or significant deficiency identified in his/her laboratory, facility, or designated space. PI's are required to promptly provide a response to the deficiency notification with a description of how the deficiency has been corrected or to submit a written plan with a timeline outlining how the deficiency will be corrected.
3. Findings from the Facility Inspections are compiled by the RCC and IBC Chair and prepared for IBC review following the inspections. The RCC requests additional comments and minority views from all members present.

6.1.1 Categories to be inspected

It is helpful for the inspection team to use a list of categories such as:

- Standard microbiological practices
- Special practices
- Safety Equipment (Primary Barriers and Personal Protective Equipment)
- Laboratory facilities (Secondary Barriers)

The IBC may determine whether the supervisory personnel of various facilities should be notified of the date and time of an inspection. Advance notification allows individuals to be available to answer questions; an unexpected visit may show the facility during usual operations but also may result in a visit having to be rescheduled if key individuals are not available. Although advance notification is not required, the IBC usually provides reasonable notice to investigators of the dates, times, and locations of inspections.

6.1.2 Performing Inspections

Adherence to the following recommendations will assist the IBC in performing inspections:

- An updated list of all facilities to be inspected should be maintained by the IBC.
- All proposals submitted to the IBC should specify locations where biohazard work will be performed.
- A list of all facilities including room number, function of the room, species, and deficiencies identified during the previous inspection.
- For facilities with multiple rooms, a floor plan can assist the inspectors.
- If a subcommittee is performing the inspection, a blend of Committee members who last inspected the area with members who did not participate in the last review can improve the process.
- Apparent deficiencies should be discussed with the person in charge of the facility to ensure that the team's perception of the situation is accurate.
- Use of a checklist provides consistency and helps document that all categories were assessed.

6.2 Deficiency Correction Schedule

All deficiencies identified during the Facility Inspection must have a reasonable and specific plan with scheduled dates for correction, typically 30 days will be given for all corrections. If the PI feels this is not a reasonable timeline they may submits a written plan with a timeline outlining how the deficiency will be corrected. All individuals to be involved in the corrections should be consulted to ensure that the plan is realistic.

Section 7: Biosafety and Biohazards Noncompliance Investigation

7.1 Purpose

To help ensure the safety of laboratory personnel as well the public, the Institutional Biosafety Committee (IBC) must review and address all biosafety concerns. Procedures are established to ensure that concerns are communicated to the IBC. The Committee or its designees must review each concern in a timely and systematic manner and when necessary take prompt and appropriate corrective actions.

7.2 Reporting Suspected Noncompliance

To facilitate communication, there are a number of options available to communicate concerns about biosafety at TSU, or to report instances of suspected non-compliance with laws, rules, regulations and policies. The names of contact persons including the IBC Chair and Research Compliance Coordinator (RCC) are listed on the IBC website. EthicsPoint (www.ethicspoint.com), a Risk, Fraud, & Misconduct Hotline established by the Texas A&M University System, may also be utilized when reporting concerns.

Although written concerns are more convenient to handle, complainants may not be willing to submit them in this manner. In such cases, the individuals who receive concerns should document them fully to ensure that the issues are clear and to prevent misunderstandings.

Requests for anonymity should be honored to the extent possible. This includes protecting the confidentiality of those who report concerns as well as anyone against whom allegations are directed, while allegations are under investigation. The policy of TSU is to prohibit unlawful retaliation against employees as a consequence of good faith actions in the reporting of, or the participation in an investigation pertaining to, allegations of wrongdoing.

7.3 Investigation of Suspected Noncompliance

7.3.1 Initial Evaluations

Concerns may include situations or activities ranging from those in which individuals are reported to be in immediate, actual, or perceived jeopardy to those in which violations are alleged to be

occurring but individuals are not in apparent danger. They may also focus on allegations of past policy and procedure violations or permit non-compliance.

The course of action taken by the IBC should be driven by the potential significance of the alleged situation. For example, conditions that reportedly jeopardize the health or well-being of individuals should be evaluated immediately. To cope promptly with such situations, the IBC chair, who is also the BSO, is authorized to halt procedures which they believe do not comply with institutional policies until the IBC can be convened and consider the matter formally. Similarly, situations that may involve potential criminal activity or human safety should be reported promptly to the institution's law enforcement or occupational health and safety officials. Allegations of other ongoing policy or procedural matters may not require such same-day attention, but should not be dealt with merely as a matter of convenience. Emergency meetings may be necessary in these cases to ensure prompt consideration of concerns.

7.3.2 The Role of the IBC Chair

Upon receipt of a concern, the Chair will review the complaint and notify the Associate Vice President for Research Grants and Sponsored Projects. The Chair will determine whether the concern requires further investigation and immediate action, further investigation but no immediate action, or no action.

If the concern requires further investigation, the Chair will assign a subcommittee, notify the IBC, and convene an IBC meeting once the investigation subcommittee has completed their report.

If immediate action is warranted because animal or human welfare may be compromised, the Chair may halt biohazard activities until such time as the IBC committee may investigate, and make a determination. Medical intervention, suspension of a research activity, and/or notification of appropriate safety, occupational health, or other officials, are examples of actions that may be taken immediately to protect animal or human welfare. If an activity is suspended, the Chair shall report that action to any federal agency funding that activity.

If no action is required, the concern will be added to the agenda, and discussed at the next convened IBC meeting. After meeting and reviewing the concern, the IBC may assign a subcommittee as described above.

In the event of a conflict of interest with the Chair, the IBC Vice-Chair will perform the duties outlined in place of the conflicted party. If both parties are conflicted, the Associate Vice President for Research Grants and Sponsored Projects will assign the duties to an IBC member.

7.3.3 Investigation

The Chair should charge a designated person or group with its requirements for information gathering as well as constructing a report of the investigation and impose a completion date. The assigned completion date will depend on the IBC's determination of whether immediate remedial action may be required. The nature of the information required will vary depending on the circumstances, but often involves:

- interviewing complainants (if known), any persons against whom allegations were directed, and pertinent program officials;
- reviewing any pertinent records.

The report presented to the IBC should review:

- the concern(s),
- the results of interview(s),
- the condition of the laboratory
- the results of records and other document reviews.

The report reviewed should also contain:

- any supporting documentation such as correspondence, reports, and records,
- conclusions regarding the substance of the concerns vis-à-vis requirements of the BMBL, institutional policies and procedures,
- recommended actions, if appropriate.

7.3.4 Outcomes and Final Actions

Upon receipt and evaluation of the report, the IBC may request further information or find that:

- there was no evidence to support the concern or complaint,
- the concern or compliant was not substantiated, but

  - related aspects require further review or
  - other institutional programs may require review, or

- the concern or complaint was valid.

7.4 Non-Compliance with IBC Permit, Policies, Procedures, or Decisions

Permit non-compliance occurs when procedures or policies approved by the IBC are not being followed. When faced with permit noncompliance, the IBC's first step, if possible, should be to find a way to bring the work into compliance.

If allegations of non-compliance are verified, the IBC can apply corrective actions to ensure the safety of all individuals. If, in the opinion of the IBC, corrective actions are not appropriate, they need not be applied. A clearly minor and unintentional misinterpretation of an IBC policy that has created no additional risk for an individual is an example of where a verified allegation of non-compliance might lead to an explanation, not a corrective action.

7.5 Consequences of Non-Compliance

Subsequent actions of the IBC may include:

- implementing measures to prevent recurrence;
- notifying the Associate Vice President for Research Grants and Sponsored Projects of its actions;
- notifying funding or regulatory agencies, as required;
- notifying the complainant, any persons against whom allegations were directed, and pertinent program officials (appropriate supervisory and management staff, the public affairs office, TAMUS attorneys, TAMUS Office of Research Compliance, etc.).

7.6 Incident Reporting to NIH

The following incidents must be reported to NIH's Office of Science Policy (OSP) within 30 days. Guidelines for incident reporting are available at http://osp.od.nih.gov/office-biotechnology-activities/biosafety/institutional-biosafety-committees/incident-reporting.

- Any significant problems or violations of the NIH Guidelines (e.g., failure to adhere to the containment and biosafety practices in the guidelines); and

- Any significant research-related accidents and illnesses (e.g., spill or accident leading to personal injury or illness or a breach in containment, escape or improper disposition of a transgenic animal).

The following incidents require immediate reporting to NIH OSP:

- Spills or accidents involving rDNA requiring BSL-2 containment resulting in an overt exposure (e.g. needle-stick; splash in eyes, nose, mouth; or accidental Aerosolization/inhalation).

Minor spills of low-risk agents, contained and properly disinfected, generally don't need to be reported, but researchers should consult the IBC or NIH OSP if uncertain. Any incident reports to the NIH OSP should be submitted by the IBC chair. The report should include the nature of the spill, the response made to mitigate the problem, and all steps taken to preclude its reoccurrence.

Section 8: Recordkeeping

8.1 Maintaining IBC Records

The Office of Research and Innovation is responsible for maintaining:

- minutes of IBC meetings;
- minority IBC views;
- documentation of permits reviewed by the IBC, and proposed significant changes to permits;
- IBC annual facility inspections, including deficiencies identified and plans for correction; and
- accrediting body determinations.

All records are to be kept for a minimum of three years, with the exception of records that relate directly to permits, which must be kept for the duration of the activity and for an additional three years after completion of the activity.

Permits and standard operating procedures (SOPs) that have been submitted for review but have not been acted on by the PI will be terminated after 45 days of inactivity. Terminated permits and SOPs will require resubmission, and be received as new submissions. These new submissions will receive a new permit number, and begin the review process anew.

8.2 Principal Investigator

Principal Investigators are required to:

- Keep copies of research records for a period of three (3) years after the termination of a permit study.
- Keep accessible all records for inspection and copying by authorized representatives.
- Maintain a copy of the laboratory Biosafety Plan in the laboratory. All research personnel should review and document the review.
- Maintain documentation of all safety related training for research personnel

8.3 Use of Electronic Mail (Email) for Official Correspondence

Electronic mail (email), like postal mail, is a mechanism for official TSU communication. The IBC will exercise the right to send email communications to all laboratory users and the IBC will expect that email communications will be received and read in a timely manner.

This policy applies to all faculty, staff, students, or any other person listed on any biosafety permits submitted to the IBC for review and approval. Official communications using email can include email to a group, or an email message to only one person.

8.4 Door Placard for BSL-1 and BSL-2

The laboratory entryway signs are generated by ORI. For BSL-1 laboratories they are generated or updated after completion of the annual facility inspection. BSL-2 door placards are generated at the initial completion or update of the BSL-2 certification process or if there is an update to the permit with work in the location. Sign information contains the biohazard symbol, biosafety level, as well as the office and after-hours contact numbers for the PI and the second person in charge of the laboratory in the PI's absence.

8.5 Autoclave Performance Verification

Each load of biohazardous waste processed in an autoclave must meet the following operating conditions and be tested:

- A biological challenge with *Bacillus stearothermophilis* will be performed with a standard load on a monthly basis. The biological challenge needs to be incubated for 48 hours. Test results will be documented in a log book to be kept next to the autoclave and will include the following: date tested, initial of person doing test, test results. Review of the log book will occur at annual facility inspections.