15.99.05.W1.03AR **Recombinant DNA and/or Infectious Biohazards in Teaching and Research**

Approved: August 15, 2010
Last Revised: October 4, 2023
Next Scheduled Review: October 4, 2028

Procedure Summary

Environmental Health and Safety at WTAMU is composed of two distinct but integrated environmental safety departments that report to the Vice President of Research and Compliance. Academic and Research Environmental Health and Safety (AR-EHS) is responsible for research and academic related compliance, which includes laboratory and academic research and the associated compliance committees. Fire and Life Safety (FLSEHS) is responsible for fire related compliance and conducts fire and life safety inspections of campus buildings and assists with the testing of all fire detection and suppression systems.

Table of Contents

1. Purpose

The West Texas A&M University Institutional Biosafety Committee (IBC) is responsible for the review of research and teaching activities that involve biological agents, toxins, or recombinant DNA (rDNA). This review process ensures that all University activities comply with government regulations set forth by the National Institutes of Health (NIH) and the Centers for Disease Control and Prevention (CDC). The IBC shall consist of University faculty and community representatives as set forth by the *NIH Guidelines*, and will meet monthly, or on an as-needed basis, to review faculty research proposals that involve biological agents, toxins, or rDNA and biosafety issues at the University. Other than compliance with federal agencies, the main goal of the IBC is to minimize risks to faculty, staff, students, facilities, the community, and the environment while using rDNA and biohazardous materials. The IBC also ensures compliance with laws and regulations regarding the receipt, use, storage, and transfer/shipping of biohazardous materials. The IBC policies outline the processes that must be followed when obtaining, using, storing, transferring, or destroying biohazardous or potentially biohazardous materials and all IBC policies should be used in conjunction with other pertinent University policies and procedures.

2. Operating Procedure

The Vice President for Research and Compliance is the designated Institutional Official and is ultimately responsible for the compliance of the policies and procedures described here. The IBC will review and approve or reject all required activities involving any known or potential rDNA/biohazardous materials unless those materials are exempt under federal regulations and the procedures set forth in this operating procedure.

3. Scope

This policy applies to all activities, teaching and research, that involve rDNA and/or biohazardous materials as defined in Section 5, below, that are:

- Conducted by university employees and students;
- Conducted using property and/or facilities owned by the university; and/or
- Stored at any university owned facility.

The IBC policies and procedures apply to all faculty, staff, students, visitors, and agents (and their employees) that are engaged in teaching or research activities involving rDNA and/or biohazardous materials.

4. IBC Registration with the National Institutes of Health

The IBC will maintain active registration with the NIH Office of Biotechnology Activities (OBA) for purposes of rDNA research. A report will be filed with the OBA at the beginning of each fiscal year that includes an updated list of IBC members, which indicates the role, contact information, and biosketches of each member. The OBA will be notified immediately upon a change in IBC membership, and this notice will include a revised list of members, contact information, and biosketches. It is the responsibility of the IBC Chair to notify the OBA of changes in IBC membership and for submitting the annual report on behalf of the university.

5. Definitions of rDNA and/or Biohazardous Materials

5.1 Recombinant DNA (rDNA)

The *NIH Guidelines for Research Involving Recombinant DNA Molecules* define rDNA molecules as either (1) molecules that are constructed outside living cells by joining of natural or synthetic DNA segments to DNA molecules that can replicate in a living cell, or (2) molecules that result from the replication of those

described in (1) above. Synthetic DNA segments that have the potential to produce harmful or potentially harmful polynucleotides or polypeptides (e.g. toxins, pharmacologically active agents) are considered equivalents to their natural DNA counterparts.

5.2 Infectious Biological Agents

Infectious biological agents include biological agents and/or biologically derived materials that present or potentially present a risk to the health and welfare of humans or animals whether directly through infection or indirectly through damage to the environment. Categories of potentially infectious biological materials include:

- Human, animal, and plant pathogens (bacteria, parasites, fungi, viruses, prions);
- All human and non-human primate blood, blood products, tissues, and bodily fluids;
- Cultured cells and potentially infectious agents that may contain or can support the proliferation of unfixed clinical specimens, and infected or potentially infected animals and animal tissues.

5.3 Select Agents and Toxins

The Department of Health and Human Services (HHS), Centers for Disease Control and Prevention (CDC), and the United States Department of Agriculture (USDA) have identified select agents and toxins that have a high potential to pose a major threat to public, animal, or plant health. These agents are subject to protocol and regulatory oversight by these agencies. The HHS/CDC list of select agents and toxins (including those that overlap with the USDA) are identified at 42 CFR 73.3 (HHS list) and 42 CFR 73.4 (Overlap list). The USDA list of select agents and toxins are identified at 9 CFR 121.3.

Because WTAMU does not have a permit of registration with the CDC or USDA the receipt, use, or storage of select agents and toxins will be reviewed on an individual basis.

6. Risk Assessment and Selection of Appropriate Safeguards

Teaching or research activities that involve rDNA and/or biohazardous materials are classified on the basis of potential risk to humans. Risk classification determines the type of biological and physical containment level(s). There are no facilities currently at the university certified to conduct Biosafety Level 3 (BSL-3) or BSL-4 research or teaching. The primary investigator (PI), course instructor (CI), or course coordinator (CC) have the primary responsibility to conduct initial risk assessments and determine the appropriate level of risk and biological/physical containment level prior to the possession or usage of rDNA and/or biohazardous material.

The initial level of risk and biological/physical containment levels for rDNA and/or biohazardous materials is submitted to the IBC, and is subject to review and approval by the IBC. The Institutional Biological Safety Officer (BSO) and/or Director of Academic and Research Environmental Health and Safety (AR-EHS) may make risk and biological/physical containment level recommendations to the IBC for all teaching or research involving rDNA and/or biological hazards.

6.1 Risk Group Classification

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

- Risk Group 1 (RG-1) – Agents that are not associated with disease in healthy adult humans.

- Risk Group 2 (RG-2) – Agents that are associated with human disease which is rarely serious and for which preventative or therapeutic interventions are *often* available.
- Risk Group 3 (RG-3) – Agents that are associated with serious or lethal human disease for which preventative or therapeutic interventions *may* be available.
- Risk Group 4 (RG-4) – Agents that are likely to cause serious or lethal human disease for which preventive or therapeutic interventions are *not usually* available.

The following resources are available for reference when determining the risk group of a particular rDNA and/or biohazardous agent:

- *NIH Guidelines*, Appendix B, *Classification of Human Etiologic Agents on Basis of Hazards*.
- BMBL, Section VII, Agent Summary Statements.
- Canadian Laboratory Biosafety Guidelines.
- World Health Organization Biosafety Guidelines.
- American Biological Safety Association's Risk Group Classification for Infectious Agents.
- American Tissue Culture Collection.

6.2 Factors Used in Determining Risk Groups

In addition to the Risk Group of the respective agent, the following factors should also be considered in assessing risk and determining the level of physical and biological containment:

- Pathogenicity of the biohazardous material – Disease incidence and severity.
- Virulence – The relative pathogenicity of the agent and any virulence factors.
- Operations – The method by which the agent will be utilized during the teaching or research.
- Route of transmission – The potential for aerosol transmission.
- Stability of the agent – Factors such as desiccation, exposure to sunlight or UV light, or exposure to chemical disinfectants.
- Infectious dose and communicability of the agent – The range from the healthiest immunized individual to the individual with the least resistance.
- Concentration of the agent – The concentration of the agent and the activities planned.
- Origin of the biohazardous materials – Factors such as geographic location, host, and nature of the source.
- Availability of data from animal studies – Can be useful in the absence of data from studies involving humans.
- Established availability of immunizations/vaccines and/or treatment – The unavailability or limited supply of immunizations/vaccines and/or treatment may impact the risk involved in the use of biohazardous materials.
- Gene product effects such as toxicity, physiological activity, and allergenicity
- Any strain that is known to be more hazardous than the wild-type strain should be considered for handling at a higher containment level. Certain attenuated strains, or strains that have lost certain

virulence factors, may qualify for a reduction in the containment level compared to the wild-type strain. See *NIH Guidelines*, Section V-B, and Sections I-IV.

6.3 Biological and Physical Containment (Biosafety Level)

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 (BSL-1 or BSL-2) for the rDNA and/or biohazardous materials. Note that West Texas A&M University does not have facilities for BSL-3 or BSL-4 containment, and no teaching or research involving the use or possession of agents requiring these levels of containment will be permitted in or on any university-owned property. The level of biosafety describes the degree of physical and biological containment required to contain rDNA and/or biohazardous materials in order to reduce or eliminate the potential for exposure of all personnel whether inside or outside of the facility, as well as the environment.

Following is a general description of the acceptable biosafety levels at West Texas A&M University:

- Biosafety Level 1 (BSL-1) – Suitable for work involving biohazardous materials of a minimal potential hazard to personnel and the environment.
- Biosafety Level 2 (BSL-2) – Suitable for work involving biohazardous materials of a moderate potential hazard to personnel and the environment. The biohazardous materials are associated with human disease which is rarely serious and for which preventative or therapeutic interventions are often reliable.

There are specific biosafety levels for work with rDNA and/or biohazardous agents involving plants or animals. Additional information on these can be found in the BMBL and the *NIH Guidelines* Section III and Appendix P (plants) and Q (animals). Following is a general description of the acceptable plant and animal biosafety levels at West Texas A&M University:

- Plant Biosafety Level 1 (BSL-1P) – Suitable for work with plants that have low environmental risk and no evidence of harmful impact, survival, or spread.
- Plant Biosafety Level 2 (BSL-2P) – Suitable for work with plants that could live in the environment with negligible impact, or impact could be readily managed. Includes transgenics capable of interbreeding with weeds/related species, transgenics that use the entire genome of an indigenous infectious agent/pathogen, and plant-associated, indigenous or exotic microbes that are potentially harmful, but harm could be managed.
- Animal Biosafety Level 1 (ABSL-1) – Suitable for work involving well characterized agents that are not known to cause disease in immunocompetent adult humans, and present minimal hazard to personnel and the environment.
- Animal Biosafety Level 2 (ABSL-2) – Suitable for work involving laboratory animals infected with agents associated with human disease and pose moderate hazards to personnel and the environment.

7. Biosafety Regulations and Guidelines

These IBC policies are based upon the following regulations and guidelines:

- *NIH Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines):* If the university conducts or sponsors rDNA teaching or research covered by the *NIH Guidelines*, it is responsible for

ensuring that such teaching or research is conducted in compliance with these guidelines. This requires a combined effort of the PI, CI, or CC along with the IBC, AR-EHS, BSO and University Official(s). This document provides guidelines for constructing and handling rDNA molecules and organisms containing rDNA molecules and is available online.

- *Biosafety in Microbiological and Biomedical Laboratories* (BMBL): This document is published by the CDC and NIH and contains guidelines for microbiological practices, safety equipment, and facilities that constitute the four biosafety levels, and is considered to be the standard for biosafety. This document is available online.

8. Responsibilities

The responsibility for biosafety in teaching and research ultimately lies with the Vice President of Research and Compliance who oversees the IBC, AR-EHS, the BSO, and faculty and staff who obtain, possess, or use rDNA and/or biohazardous materials. It is the role of the IBC to review, approve/reject, and provide oversight and guidance to individuals at the university or that use property owned by the university that seek to use or possess rDNA and/or biohazardous materials for teaching and research. Regardless, the possession and/or use of rDNA and/or biohazardous materials at the university or in conjunction with the university must be conducted with safeguards in place to protect against environmental release.

8.1 General PI, CI, or CC Responsibilities

The PI, CI, or CC shall:

- Not initiate or modify any teaching or research involving rDNA and/or biohazardous materials subject to IBC approval under these IBC policies or *NIH Guidelines* until the proposed teaching or research modification(s) has been approved by the IBC.
- Immediately report any significant problems or accidents and illnesses to the AR-EHS safety officer, the BSO, the IBC Chair, and any other university committee that has reviewed and approved the research activity (e.g. IACUC, IRB, radiation).
- Comply with all local, state, and federal requirements when teaching or research involves rDNA and/or biohazardous materials.

8.2 PI, CI, or CC Responsibilities Prior to Initiation of Teaching or Research Involving rDNA and/or Biohazardous Materials

Prior to initiation of teaching or research involving rDNA and/or biohazardous materials, the PI, CI, or CC must do the following:

- Review all applicable guidelines and regulations and become familiar with all safety procedures and requirements related to the rDNA and/or biohazardous materials involved.
- Develop Standard Operating Procedures (SOPs) incorporating biosafety procedures and a biosafety manual prepared specifically for the teaching or research classroom or laboratory. Each manual must include the protocol submitted to the IBC which describes the potential biohazards and the precautions to be taken (e.g. hazards and risks, immunizations, personal protective equipment, decontamination, storage and disposal, and spill procedures). Copies of this manual must be located in each teaching and research classroom or laboratory and made readily accessible to all personnel including the IBC Chair and safety officer.

- Establish policies and procedures to limit access to only those individuals who have been properly advised on all potential hazards and meet specific entry requirements (e.g. immunization, training on use of protective clothing/gear).
- Instruct all personnel and students on the potential hazards associated with the teaching or research activities, the necessary precautions to prevent exposures, and exposure evaluation procedures. Ensure that all personnel receive annual training updates or additional training as necessary for all procedural and/or policy changes.
- Instruct personnel and students in aseptic techniques and in the biology of the organisms or agents used so that potential biohazards are understood and appreciated.
- Instruct and train personnel and students in the practices and techniques required to ensure safety and the procedures for dealing with and reporting accidents, spills, and illnesses.
- Comply with all required occupational health requirements including ensuring that all personnel know the reasons and provisions for precautionary medical practices implemented and ensure they are offered, at no cost, appropriate immunizations or tests for the biohazardous materials handled or potentially present.

8.3 PI, CI, or CC Responsibilities During the Conduct of Teaching or Research Activities Involving rDNA and/or Biohazardous Materials

During teaching, research or any other use of rDNA or biohazardous materials, the PI, CI, or CC must:

- Limit or restrict access to the teaching or research laboratory or classroom when work with the rDNA and/or biohazardous materials is in progress, including a determination of who may be at increased risk.
- Provide personal protective equipment required for work with the respective rDNA and/or biohazardous material.
- Supervise the safety performance of the teaching or research staff and personnel to ensure that the required safety practices and techniques are employed.
- Correct work errors and conditions that may result in the release of rDNA and/or biohazardous materials.
- Ensure the integrity of the biological and physical containment (biosafety level).
- Ensure the security of rDNA and/or biohazardous materials at all times.

8.4 Specific Responsibilities Regarding rDNA

The *NIH Guidelines* are applicable to all rDNA research conducted within the United States. It is the responsibility of the university to ensure that rDNA teaching or research conducted at or sponsored by the university, irrespective of the funding source, complies with the *NIH Guidelines* as a condition for NIH funding of such teaching or research at the university. All rDNA teaching or research conducted at this university, regardless of the funding source, must comply with the *NIH Guidelines*.

8.5 General PI, CI, or CC Responsibilities Regarding rDNA Teaching or Research

In addition to all responsibilities discussed above, the PI, CI, or CC must:

- Not initiate or modify any rDNA research which requires prior IBC approval prior to initiation, until that research or the proposed modification(s) has been approved by the IBC and has met all other requirements of the *NIH Guidelines*.
- Determine whether experiments are covered by Section III-E, *Experiments that Require Institutional Biosafety Committee Notice Simultaneous with Initiation*, of the *NIH Guidelines*, and ensure that all appropriate procedures are followed.
- Report any significant problems with the *NIH Guidelines*, or any significant teaching or research related accidents and illnesses to the BSO, the IBC Chair, Research Compliance Officer (RCO; as appropriate), and any other appropriate university committees that have approved the research.
- Report any new information bearing on the *NIH Guidelines* to the IBC and to the NIH OBA.

8.6 PI, CI, or CC Responsibilities for Submissions to the NIH OBA

As per Section IV-B.7b of the *NIH Guidelines*, the PI, CI, or CC must:

- Submit information to the NIH OBA, with notice to the IBC, for certification of new host-vector systems.
- Petition the NIH OBA, with notice to the IBC, for proposed exemptions to the *NIH Guidelines*.
- Petition the NIH OBA, with notice to the IBC, for approval to conduct teaching or research specified in *NIH Guidelines* Section III-A-1, *Major Actions under the NIH Guidelines*, and Section III-B, *Experiments that Require NIH OBA and Institutional Biosafety Committee Approval before Initiation*.
- Petition the NIH OBA, with notice to the IBC, for determination of containment of experiments requiring case-by-case review.
- Petition the NIH OBA, with notice to the IBC, for determination of containment for experiments not covered by the *NIH Guidelines*.

8.7 PI, CI, or CC Responsibilities Regarding Access to Teaching or Research Facilities

All teaching and research facilities are property of the university and subject to university rules on access. All faculty, staff, and personnel are required to allow access to their facilities that are registered for rDNA and/or biohazardous materials to the IBC, BSO, AR-EHS, and the RCO director for routine laboratory inspections.

8.8 Environmental Health, Safety, & Risk Management Duties

It is the responsibility of the Vice President of Research and Compliance and the Director of the Academic and Research Environmental Health and Safety Office to provide access to a Biological Safety Officer to aid in the protection from possession or use of rDNA and/or biohazardous materials. The safety officer's duties include, but are not limited to:

- Periodic (minimum of one per fiscal year) inspections of all laboratories and classrooms conducting rDNA and/or biohazardous research to ensure that proper standards are strictly followed;
- Reporting to the IBC Chair any significant problems, violations of *NIH Guidelines*, and any significant accidents or illnesses of which he/she becomes aware;
- Assist the PI, CI, or CC with the development of emergency plans for handling accidental spills and personnel contamination;

- Investigate accidents involving rDNA and/or biohazardous materials;
- Provide information on spills and incidents to the IO who will inform public health officials;
- Provide advice on laboratory security; and
- Provide advice to the IBC, faculty, and staff on safety procedures

9. IBC Responsibilities

According to the NIH OBA:

"Institutional Biosafety Committees (IBCs) were established under the *NIH Guidelines for Research Involving Recombinant DNA Molecules* to provide local review and oversight of research utilizing rDNA. Over time, many institutions have chosen to assign to their IBCs the responsibility of reviewing a variety of experimentation that involves biological materials (e.g. infectious agents) and other potentially hazardous agents (e.g. carcinogens). This additional responsibility is assigned entirely at the discretion of the institution."

The responsibilities of the IBC at the university include the following:

1) IBC Responsibilities as per NIH Guidelines Section IV-B-2-b:
   - Review and approval of teaching or research involving rDNA that is sponsored by or conducted at the University for compliance with the *NIH Guidelines*. This relates to initial and annual review of approval and modifications to all proposals and activities.
   - Assess facilities, procedures, practices, training, and expertise of personnel taking part in teaching or research involving rDNA.
   - Notify the PI, CI, or CC and RCO (as appropriate) of the IBC's review results, including approval or rejection.
   - Assess, modify and finalize containment levels for teaching or research involving rDNA.
   - Adopt and implement emergency plans set forth with the assistance of the safety officer for accidental spills and personnel contamination resulting from rDNA research.
   - Review and report, along with the BSO, any significant problems with or violations of the *NIH Guidelines*, accidents, or illnesses to the IO (the Vice President of Research and Compliance) and to the NIH OBA as per section IV-B-1-j of the *NIH Guidelines*.

2) Other IBC Responsibilities:
   - Develop appropriate procedures to supervise the possession and/or use of rDNA and/or biohazardous materials as required by the NIH and/or BMBL.
   - Suspend or terminate IBC protocol approval for any teaching or research involving rDNA and/or biohazardous materials immediately upon the finding of noncompliance or that such use or possession poses an immediate threat to the health and safety of the community.
   - Review the IBC policies and procedures and modify as necessary to ensure compliance with federal, state, and university requirements.
   - Review all teaching and research protocols that include the possession or use of rDNA and/or biohazardous materials for compliance with the *NIH Guidelines* and the BMBL. As part of this review process, the IBC will:

- Conduct an assessment of the containment levels (BSL-1 or BSL-2) as required by Section III-A3 of the *NIH Guidelines*.
- Conduct an assessment of the facilities, procedures, practices, training, and expertise of personnel involved in teaching or research using rDNA and/or biohazardous materials.
- Ensure compliance with the *NIH Guidelines* and BMBL for all surveillance, data reporting, and adverse event reporting requirements.

3) Teaching or research that requires IBC approval include those that involve:

- Pathogens and potential pathogens of humans, animals, or plants that are classified by the American Tissue Culture Collection (ATCC) as Biosafety Level 2 (BSL-2) or higher and/or are listed by the American Biological Safety Association (ABSA) as Risk Group 2 or higher (based on the *NIH Guidelines* and/or *BMBL*).
- Human-derived materials that contain or potentially contain human pathogens (including human blood, blood components, and unfixed tissue).
- Non-human primate-derived materials that contain or potentially contain human pathogens (including non-human primate blood, blood components, and unfixed tissues).
- Use of all cell lines, whether human or non-human primate, that are classified as BSL-2 or higher by the ATCC and/or as Risk Group 2 or higher by the ABSA (based on the *NIH Guidelines* and *BMBL*).
- Recombinant DNA and recombinant RNA including creation or use of transgenic plants and animals.
- Select agents and toxins (see List of Agents and Toxins) including strains and amounts exempted from the select agent regulations.
- Any material(s) (pathogenic or nonpathogenic) requiring a CDC import license or a USDA permit.
- The deliberate transfer of drug resistance trait(s) to microorganisms that are not known to acquire the trait naturally.
- The deliberate transfer of rDNA or DNA or RNA derived from rDNA into human research participants (human gene transfer).
- The deliberate formation of rDNA containing genes for the biosynthesis of toxin molecules lethal for vertebrates at an LD50 of less than 100 ng/kg.
- Using Risk Group 2 or Risk Group 3 agents as host-vector systems.
- The cloning of DNA from Risk Group 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 microorganism tested on whole animals.
- Genetically engineered plants by rDNA methods.
- More than 10 liters of culture (over the entire length of the project) and/or one liter in a 24-hour period.

- The formation of rDNA molecules containing two-thirds or more of the genome of a eukaryotic virus.

NOTE: Teaching or research requiring BSL-2 containment must be reviewed and approved prior to the initiation of experiments. Teaching or research involving select agents and/or select toxins will be reviewed on an individual bases, and that involving BSL-3 or BSL-4 containment will not be approved.

9.1 IBC Membership

Per the NIH OBA, the IBC is composed of at least five voting members who are appointed by the Vice President of Research and Compliance and will serve three-year terms. Members must represent the faculty and the community at large, and will have experience and expertise in rDNA and the ability to assess the safety of teaching and research involving rDNA and/or biohazardous materials. The committee will be able to identify potential risks to public health, animal and plant health or products, and the environment posed by possessing or using such materials. The IBC will be composed of the following:

- At least one individual with expertise in rDNA technology and/or biological safety and/or physical containment.
- At least one scientist with expertise in biological safety and physical containment.
- At least one individual with expertise in the use, storage, transfer, and disposal of biohazardous materials.
- At least one scientist with expertise in plant, plant pathogen, or plant pest containment principles.
- At least one scientist with expertise in animal containment principles.
- One individual representing laboratory technical staff.
- The Institutional Biological Safety Officer
- At least two members who are not affiliated with the university and who represent the interests of the surrounding community with respect to health and protection of the environment.

NOTE: A single member can represent more than one of the above criteria. The BSO must be affiliated with the university AR-EHS department. The IBC may invite consultants knowledgeable in community attitudes and the environment to its meetings as necessary to assist in the review process, but such consultants shall not vote.

9.2 IBC Chair Appointment

The IBC Chair is appointed by the Vice President for Research and Compliance and will serve a three-year term. The Chair shall be a tenured or tenure-track faculty member that is currently pursuing research involving rDNA and/or biohazardous materials.

9.3 IBC Chair Responsibilities

The Chair shall preside over the IBC meetings, serve as one of two contacts for all regulatory agencies (in addition to the BSO), and act as a liaison between the academic community and the IBC. The IBC members will vote on a member of the IBC to serve as Vice Chair in his/her absence. The Chair will divide the IBC into subcommittees that will review all submitted teaching or research protocols to determine their exempt or non-exempt status and provide details back to the entire IBC.

9.4 IBC Regular Meetings and Minutes

The IBC will publicly meet at least four times each fiscal year and more often as necessary to review and approve protocols and conduct continual review or approved protocols. Scheduled meetings of the IBC will be maintained on the IBC website under AR-EHS. Prior to each regular meeting, the IBC Chair will send every member of the IBC a copy of all materials to be reviewed at the meeting.

Minutes of IBC meetings will include the following:

- Attendance of members and guests.
- All IBC actions taken on each reviewed protocol and any required modifications for IBC approval.
- Record of members who were not present due to conflict of interest.
- The basis for rejecting any protocols that are reviewed.

The *NIH Guidelines* cite many items that the IBC should consider as appropriate with respect to the review of proposed rDNA teaching or research. These are described in Section II-A and Section III of the *NIH Guidelines*.

- Agent characteristics (e.g. virulence, pathogenicity, environmental stability).
- Types of manipulations planned.
- Source(s) of the inserted DNA sequences (e.g. species).
- Nature of the inserted DNA sequences (e.g. structural gene, oncogene).
- Host(s) and vector(s) to be used.
- Whether an attempt will be made to obtain expression of a foreign gene, and if so, the protein that will be produced.
- Containment conditions to be implemented.

An applicable section of the *NIH Guidelines* (e.g. Section III-D-1, Section III-E-1, etc.). IBC meeting minutes will include references for each of the above criteria, as appropriate, for each reviewed protocol. The intent of the minutes will be to provide sufficient detail about the discussions of these matters to document the committee's rationale for particular decisions. All minutes will be made publicly available by the university upon request.

9.5 Emergency Meetings

The IBC Chair may call an emergency meeting of the IBC as necessary to address noncompliance issues or serious/unexpected events involving biohazardous materials at the university.

9.6 Attendance and Quorum

Members are expected to attend the majority of all IBC meetings, whether regular or emergency meetings. Those that attend 50% or less of the total meetings in a fiscal year will be contacted by the IBC Chair to increase their attendance. Members who fail to attend on a regular basis will be removed from the committee.

In order to conduct business at any IBC meeting, a majority of voting members must be present. The final approval or rejection of non-exempt protocols involving rDNA and/or biohazardous materials requires a majority vote of present voting IBC members. Members who have a conflict of interest in the project (i.e.

are acting as the PI, CI, or CC, have a financial interest in the project, etc.) shall not be present during the IBC's initial or continuing review (deliberations and voting) of the protocol. Those with a conflict of interest are still required to submit any information requested by the IBC. If a quorum is lost at any time during the meeting, the meeting will be adjourned and no further action shall be taken by the IBC until a quorum is established.

9.7 IBC Records Retention

The following records will be retained by the IBC Chair for a minimum of three years after the completion of the research or teaching protocol:

- IBC meeting minutes
- All protocols and attachments
- List of all IBC members

All IBC policies will be maintained by the IBC on the AR-EHS websites. The IBC will maintain its original NIH OBA registration, and all correspondence, annual reports, and notices of new members until the IBC is no longer registered with NIH OBA.

9.8 Incident Reporting Requirements

Any and all teaching and/or laboratory incidents must be reported to the PI, CI, or CC. Any incident that exposes or has the potential to expose any individual, either directly or indirectly, to any uncontained agent, toxin or chemical must be immediately reported on the day of occurrence to AR-EHS, the BSO, and the IBC Chair. As per Section IV-B-2-b-(7) of the *NIH Guidelines*, registered IBCs are required to report on behalf of their institutions "any significant problems, violations of the *NIH Guidelines*, or any significant research [or teaching]-related accidents and illnesses" to the NIH OBA within 30 days of the occurrence of the event. In the case of exposure in a BSL-2 setting, all spills and incidents must be reported to the NIH OBA immediately. Significant problems that must be reported include, but are not limited to, any overt exposure or potential exposure such as a needle stick, splash, or contamination from equipment failure. Significant events may also occur due to a breach in containment that may be determined to exert an overt or potential exposure to any individual. Because rDNA is considered biohazardous, any and all incidents involving disposal of rDNA must also be reported. The University considers **ALL** rDNA and/or biohazardous incidents to be reportable to the BSO, IBC and AR-EHS, regardless of whether they have been determined to be exempt from the *NIH Guidelines*. A mandatory investigation and internal report will be completed for all incidents. If there is any doubt in what events should or should not be reported, consult with the BSO or the IBC Chair.

9.8.1 Method of Adverse Event Reporting

It is the responsibility of the PI, CI, or CC to be properly trained, and to train all personnel in proper safety methods and adverse event reporting. Any incident must be immediately reported to the BSO, whose contact information can be found on the AR-EHS website as well as the IBC chair. A phone call to the University Police Department will also result in contact of the safety officer and IBC Chair.

The BSO or IBC chair will report all significant incidents involving rDNA and/or biohazardous materials to the IBC via the Rapid Response Team (RRT). The RRT is a subcommittee of the IBC appointed annually by the IBC Chair. Permanent members of the RRT include the BSO, IBC Chair, RSO, and the Director of AR-EHS. The RRT will evaluate any incident that involves rDNA and/or biohazardous

materials within 24 hours of receiving the report, and immediately notify all members of the IBC, AREHS, and the IO.

It is preferred that all personnel submit the Adverse Event Form when submitting a report to the BSO and IBC chair, however, depending on the time of occurrence and severity of the event, this may not be the case. The RRT will use the Adverse Event Form to make a formal report to the IBC and IO, and in required instances to the NIH OBA. The IBC is responsible for review of all reported incidents provided by the RRT.

9.9 Compliance Oversight and Appropriate Actions Taken

The IBC has authority and is required to address all non-compliance issues with these University policies and procedures or the *NIH Guidelines*, the BMBL, or other state and federal requirements. Non-compliance of any type can result in the IBC taking one or more of the following actions:

- Suspending the use and/or storage of rDNA and/or biohazardous material.
- Termination of the IBC approved protocol for the rDNA and/or biohazardous material.
- Confiscation of the rDNA and/or biohazardous material.
- Destruction of the rDNA and/or biohazardous material.
- Any action necessary to protect the public and/or the university including transfer of locks on research labs and/or teaching classrooms/labs to suspend activity.
- Reporting to the NIH, CDC, USDA, and/or any other local, state, or federal agency.

10. IBC Review

Any faculty, staff, or personnel that desires to possess or use rDNA and/or biohazardous materials, including those whose protocols are deemed exempt by the *NIH Guidelines*, must submit a protocol permit registration document with the IBC. The IBC will review and approve any and all teaching and/or research activities involving (1) rDNA, (2) infectious agents capable of infecting humans, animals, or plants, (3) any other potentially biohazardous materials. Note that neither the university, nor the IBC, will approve any use or possession of select agents and toxins. Any questions on exemptions to the select agents and toxins should be directed to the IBC Chair. Some federal regulations allow exemption for some types of rDNA use, however, an application for all rDNA projects must be submitted to the IBC so that the IBC is aware of the activities and can verify that they are exempt.

No personnel will obtain or use rDNA and/or biohazardous materials as outlined in section 9.c. above until the respective protocol has been approved by the IBC. Modifications of approved protocols should not occur until approved by the IBC.

10.1 IBC Review of Teaching and/or Research Involving rDNA and/or Biohazardous Materials

Any teaching or research involving rDNA and/or biohazardous materials as outlined in section 9.c. above conducted on or in university owned property is subject to review and approval by the IBC. The PI, CI, or CC must submit an IBC Permit Registration form to the IBC Chair. Approval must be obtained before initiating any teaching or research involving rDNA and/or biohazardous materials.

If teaching or research involving rDNA falls into any of the conditions below, approval by the NIH, NIH OBA, and its committees, in addition to the IBC, is required:

- Experiments Requiring IBC Approval, RAC Review, and NIH Director Approval Before Initiation (See *NIH Guidelines*, Section III-A) – This includes experiments considered as Major Actions under the *NIH Guidelines* and experiments involving the deliberate transfer of a drug resistance trait to microorganisms that do not acquire the trait naturally, if such acquisition could compromise the use of the drug to control disease in humans, veterinary medicine, or agriculture.
- Experiments Requiring NIH OBA and IBC Approval Before Initiation (See *NIH Guidelines*, Section IIIB) – This covers experiments involving the cloning of toxin molecules with LD50 of less than 100 ng/kg body weight.
- Experiments Requiring IBC and IRB Approvals and RAC Review Before Research Participant Enrollment (See *NIH Guidelines*, Section III-C) – These experiments involve the deliberate transfer of rDNA, or DNA or RNA derived from rDNA, into human subjects (human gene transfer).
- Experiments Requiring IBC Approval Before Initiation (See *NIH Guidelines*, Section III-D) – Full board review and approval required before commencing research. This category covers the following subsections: (1) experiments using RG-2, RG-3, RG-4 or restricted agents as host-vector systems; (2) experiments in which DNA from RG-2, RG-3, RG-4, or restricted agents is cloned into nonpathogenic prokaryotic or lower eukaryotic host-vector systems; (3) experiments involving the use of infectious DNA or RNA viruses or defective DNA or RNA viruses in the presence of helper virus in tissue culture systems; (4) experiments involving whole animals and/or whole plants; and (5) experiments involving more than 10 liters of culture.
- Experiments Requiring IBC Notice Simultaneous with Initiation (See *NIH Guidelines*, Section III-E) – This includes experiments not included in *NIH Guidelines* Sections III-A, III-B, III-D, III-F, and their subsections. Under these IBC policies, IBC approval is required prior to initiation of the teaching or research.
- Exempt Experiments (See *NIH Guidelines*, Section III-F) – Refer to the list below for a list of rDNA molecules that are exempt from the *NIH Guidelines*. Under these IBC policies, protocol and approval of the exempt status by the IBC is required prior to initiation of the teaching or research. The IBC Chair has the authority to make this determination and provide information on all decisions made to the IBC through meeting agendas and minutes.

NOTE: If an rDNA experiment falls into *NIH Guidelines* Section III-F (Exempt) and into either Sections III-D or III-E as well, the experiment is considered exempt from the *NIH Guidelines*, but is still subject to approval of exempt status prior to initiation of teaching or research activities.

10.2 Notice of IBC Action

Upon review of the submitted IBC Permit Registration form, the IBC Chair will provide written notification of the IBC's decision (approved or rejected) to the PI, CI, or CC, and to the BSO and AR-EHS, as applicable. In some instances, the BSO, IBC and/or IBC Chair may require additional information to complete the review process. In such instances, the BSO or IBC Chair will contact the PI, CI, or CC to request further information, which must be submitted to the IBC before any further action will be taken regarding the IBC Permit Registration. If the requested information is not submitted to the IBC at least two weeks prior to the next scheduled IBC meeting, the respective IBC permit registration will be rejected, and the PI, CI, or CC will be required to resubmit their application.

10.3 Length of Approval of IBC Permits Involving rDNA and/or Biohazardous Materials

IBC approval of permits for rDNA and/or biohazardous materials is valid for three years. All IBC approvals must undergo an annual review, unless a shorter period is determined to be required by the IBC. The IBC will inform each PI, CI, or CC of the date upon which the annual review must be complete. Each PI, CI, or CC must submit the Annual Permit Renewal Form to the IBC at least one month prior to the next meeting of the IBC. The IBC Chair will notify the PI, CI, or CC of all decisions that are made.

10.4 Modifications to Approved Protocols

No changes or modifications to the approved IBC permit should be implemented without prior review and approval of the IBC. This includes, but is not limited to, modification of rDNA and/or biohazardous materials, procedure changes, changes in personnel, termination or transfer of the approved agents, or changes that increase the risk of the project and/or the biosafety level. An IBC Amendment Form must be submitted to the IBC for review and approval. The IBC Chair will notify the PI, CI, or CC, BSO and AR-EHS, as applicable, of all decisions that are made.

11. Record Retention

No official state records may be destroyed without permission from the Texas State Library as outlined in Texas Government Code, Section 441.187 and 13 Texas Administrative Code, Title 13, Part 1, Chapter 6, Subchapter A, Rule 6.7. The Texas State Library certifies Agency retention schedules as a means of granting permission to destroy official state records.
West Texas A&M University Records Retention Schedule is certified by the Texas State Library and Archives Commission. West Texas A&M University Environmental Health and Safety will follow Texas A&M University Records Retention Schedule as stated in the Standard Operating Procedure 61.99.01.W0.01 Records Management. All official state records (paper, microform, electronic, or any other media) must be retained for the minimum period designated.

12. Training

All personnel submitting an IBC Registration Permit, Annual Renewal, and/or Amendment, must complete both the Initial Biosafety Training module (valid for three years) and the Responsible Conduct in Research module (valid for one year) using the Collaborative Institutional Training Initiative (CITI) Program. Both modules must be successfully completed ***prior*** to submission of documents to the IBC. IBC documents will not be reviewed until training is completed.

West Texas A&M University Environmental Health and Safety will follow the Texas A&M University System Policy 33.05.02 Required Employee Training. Staff and faculty whose required training is delinquent more than 60 days will have their access to the Internet terminated until all trainings are completed. Only Blackboard and Single Sign-on will be accessible. Internet access will be restored once training has been completed. Student workers whose required training is delinquent more than 30 days will need to be terminated by their manager through Student Employment.

Cross Reference: *NIH Guidelines for Research Involving Recombinant DNA Molecules*; *Biosafety in Microbiological and Biomedical Laboratories* (BMBL); 42 CFR 73.3; 42 CFR 73.4; 9 CFR 121.3.

Forms: Permit Registration Form, Annual Renewal Form, Adverse Event Form, BSL2 SOP Template, BSL2 Manual Template, Amendment Form

---

Contact Office

WTAMU Environmental Health and Safety
(806) 651-2270