Angelo State University

Institutional Biosafety Committee Policy and Procedures

December 2020
Approved via IBC member email review

Angelo State University
Institutional Biosafety Committee
Policy and Procedures

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1. General Requirements and Procedures for Recombinant DNA Research, Biohazardous Research, Synthetic Nucleic Acids (As defined by NIH) and Activities, Use, and Handling of Extremely Toxic/Hazardous Substances

1.1. **The Biohazardous Use Protocol (BUP) is a registration document for an Institutional Biosafety Committee (IBC) Permit** and is required for laboratory research involving recombinant DNA, biohazardous, and/or synthetic nucleic acids, all biohazardous materials, and for clinical research involving human gene transfer. Obtaining an **IBC Permit** will help ensure that your research is conducted in compliance with recombinant DNA, biohazardous, and/or synthetic nucleic acids regulations (e.g., NIH, CDC, etc.) prior to possession or use of the material. Transfer of potentially biohazardous materials to or from other agencies may also require a materials transfer agreement.

1.2. The Center for Disease Control and Prevention (CDC) defines **Biohazardous Materials** as "infectious agents or hazardous biologic materials that present a risk or potential risk to the health of humans, animals, or the environment. The risk can be direct through infection or indirect through damage to the environment. Biohazardous materials include certain types of recombinant DNA, organisms and viruses infectious to humans, animals, or plants (e.g., parasites, viruses, bacteria, fungi, prions, and rickettsia), and biologically active agents (e.g., toxins, allergens, and venoms) that can cause disease in other living organisms or cause significant impact to the environment or community."

1.3. Research involving any of the agents listed below must be approved by the Angelo State University Institutional Biosafety Committee (IBC) prior to initiation:

A. Pathogens and potential pathogens of humans, animals or plants

B. Materials potentially containing human pathogens (including human blood, tissue, and cell lines and non-human primate blood, tissue, and cell lines)

C. Recombinant DNA (and RNA) including creation or use of transgenic plants and animals

D. Select agents and toxins including strains and amounts exempted from the select agent regulations

E. Any material requiring a CDC import license or a USDA permit

F. Any material that is considered extremely toxic or a hazardous substance

1.4. The Institutional Biosafety Committee (IBC), which is composed of academic and research faculty, staff, and outside community members (Appendix A), will perform a risk assessment of research experiments as described on the **BUP Registration Document** (Appendix B) and assign an appropriate level of biological safety containment to protect ASU faculty, staff, students, the surrounding community, and the environment. An **IBC Permit** is required and must be approved prior to the use of biohazardous materials.

1.5. A Self-Assessment Checklist is provided in Appendix C to assist you in (1) determining whether an IBC Permit applies to your activity or research and (2) assessing your compliance regarding the requirements outlined in OP 34.29, this Policy, and the applicable guidelines, regulations, and laws.

1.6. General requirements for Biosafety are included in the following Operating Procedures and Safety Plans and should be reviewed by researchers.

A. Bloodborne Pathogens Exposure Control Plan

B. Biological Safety Plan

C. Respiratory Protection Program

D. Select agents, controlled substances, recombinant DNA, and toxins

1.7. Recombinant DNA research is conducted with molecules constructed outside living cells where DNA segments are joined or replicated, where a DNA sequence may be modified, or where related research is conducted with this type of material. The purpose of this document is to summarize requirements, procedures, and expectations for conducting Recombinant DNA, Biohazardous, and/or Synthetic Nucleic Acids research at ASU. Certain general procedures are outlined to aid scientists in compliance. This also includes synthetic nucleic acids as defined in *NIH Guidelines*.

1.8. Any research conducted with recombinant DNA, regardless of the source of funding or source of recombinant material, must be conducted in accordance with institutional requirements and federal guidelines. ASU adheres to Texas Tech University System requirements as well as those outlined in the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines)* as issued. Research on recombinant DNA, biohazardous, and/or synthetic nucleic acids should also be conducted in accordance with CDC/NIH Biosafety Guidelines (Biosafety in Microbiological and Biomedical Laboratories), as appropriate. Experiments involving livestock or plants may require compliance with additional regulations and approval by the Office of Agricultural Biotechnology, U. S. Department of Agriculture.

1.9. It is essential that recombinant DNA research be conducted in accordance with biosafety intent (spirit), as well as specific requirements and guidelines. Because research is dynamic, it is not possible to anticipate every situation. The conscientious effort and good judgment of personnel are essential for protection of health and the environment during recombinant DNA research. Primary responsibility for compliance with institutional and governmental requirements and for safe and proper experimentation resides with the principal investigator (PI). The Institutional Biosafety Committee and Biological Safety Officer are appointed to review and monitor recombinant DNA research on behalf of ASU.

2. Registration, Review and Approval of Recombinant DNA Research, Biohazardous Research, Synthetic Nucleic Acids

2.1. Registration Requirements and Review Standards

A. All biohazardous material research including recombinant DNA, biohazardous, and/or synthetic nucleic acids conducted at Angelo State University must be registered with the IBC. All proposals for biohazardous material including recombinant DNA, biohazardous, and synthetic nucleic acids must be reviewed and approved by the IBC prior to initiating work. This includes, but is not limited to: recombinant products, DNA probes, vector systems, and related material received from outside sources. Review and approval by the IBC of cooperating institutions may be required. Coordinated reviews may be arranged by IBC chairpersons of cooperating institutions or agencies. PIs and department heads should seek clarification regarding institutional requirements for protocol or project approval and safety (independent of their own interpretations or uncertainties).

B. Review by the IBC includes evaluation for compliance and conformance with the *NIH Guidelines*; assessment of the containment levels required by the Guidelines; assessment of the facilities, procedures and practices; and consideration of the training and expertise of recombinant DNA personnel.

2.2. Research and Related Activities Requiring IBC Review and Approval

A. Projects: All research (regardless of the source of funding) conducted at ASU involving recombinant DNA, biohazardous, and/or synthetic nucleic acids must be registered, reviewed, and approved by the IBC.

NOTE: Certain types of research are specifically exempted (by *NIH Guidelines*) for review (see 2.3 below). However, ASU does require registration with the IBC (See 2.4 below).

B. Grant Proposals: All grant proposals for research involving biohazardous material including recombinant DNA should be identified as such by the PI, acknowledged by the department chair, and reviewed by the IBC before the grant award is accepted.

C. Project Modifications: Additional IBC review and approval is required if the nature, content, or risk level of research changes significantly or if recombinant DNA, either cloned or received from an outside source, is involved. For example, collaborative work may require evaluation of unanticipated recombinant products or in locations where prior recombinant DNA research was not anticipated. Proposal changes must be reviewed and approved before work proceeds.

D. Testing, Evaluation and/or Release: Research plans, protocols, and provisions for containment for recombinant DNA work under field conditions (outside a lab, growth chamber, containment, or cage) require additional information and IBC review. Environmental safety and risk must be considered for potentially self-replicating biological material. Investigators should anticipate potential testing, evaluation, or release of recombinant DNA products (at least one-year lead time) for preparation and review of approval documents.

2.3. Exempt Activities

Exempt experiments are those outlined in *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules*, Section III-F as follows:

A. Section III-F:

The following recombinant or synthetic nucleic acid molecules are exempt from the *NIH Guidelines* and registration with the Institutional Biosafety Committee is not required; however, other federal and state standards of biosafety may still apply to such research (for example, the Centers for Disease Control and Prevention (CDC)/NIH publication Biosafety in Microbiological and Biomedical Laboratories):

1) Section III-F-1

Those synthetic nucleic acids that: (1) can neither replicate nor generate nucleic acids that can replicate in any living cell (e.g., oligonucleotides or other synthetic nucleic acids that do not contain an origin of replication or contain elements known to interact with either DNA or RNA polymerase), and (2) are not designed to integrate into DNA, and (3) do not produce a toxin that is lethal for vertebrates at an LD50 of less than 100 nanograms per kilogram body weight. If a synthetic nucleic acid is deliberately transferred into one or more human research participants and meets the criteria of Section III-C, it is not exempt under this Section.

2) Section III-F-2

Those that are not in organisms, cells, or viruses and that have not been modified or manipulated (e.g., encapsulated into synthetic or natural vehicles) to render them capable of penetrating cellular membranes.

3) Section III-F-3

   Those that consist solely of the exact recombinant or synthetic nucleic acid sequence from a single source that exists contemporaneously in nature.

4) Section III-F-4

   Those that consist entirely of nucleic acids from a prokaryotic host, including its indigenous plasmids or viruses when propagated only in that host (or a closely related strain of the same species), or when transferred to another host by well-established physiological means.

5) Section III-F-5

   Those that consist entirely of nucleic acids from a eukaryotic host including its chloroplasts, mitochondria, or plasmids (but excluding viruses) when propagated only in that host (or a closely related strain of the same species).

6) Section III-F-6

   Those that consist entirely of DNA segments from different species that exchange DNA by known physiological processes, though one or more of the segments may be a synthetic equivalent. A list of such exchangers will be prepared and periodically revised by the NIH Director with advice of the RAC after appropriate notice and opportunity for public comment (see Section IV-C-1-b-(1)-(c), *Major Actions*). See Appendices A-I through A-VI, *Exemptions under Section III-F-6--Sublists of Natural Exchangers*, for a list of natural exchangers that are exempt from the *NIH Guidelines*.

7) Section III-F-7

   Those genomic DNA molecules that have acquired a transposable element, provided the transposable element does not contain any recombinant and/or synthetic DNA.

8) Section III-F-8

   Those that do not present a significant risk to health or the environment (see Section IV-C-1-b-(1)-(c), *Major Actions*), as determined by the NIH Director, with the advice of the RAC, and following appropriate notice and opportunity for public comment. See Appendix C, *Exemptions under Section III-F-8* for other classes of experiments which are exempt from the *NIH Guidelines*.

B. The PI will conduct the appropriate sections of the risk assessment included in the Biohazardous Use Protocol (***BUP) for an IBC Permit*** (Appendix B) and determine the appropriate risk level of the experiment. The ***BUP*** will be submitted through Environmental Health, Safety, and Risk Management for formal submittal to the IBC.

C. The IBC Academic (co-)Chair will notify the PI in writing of the results of the IBC's review and approval, including any approval conditions, protocol expiration date, and other pertinent information.

D. An updated ***BUP for an IBC Permit*** must be submitted annually when Biosafety Level 2 or above is required.

2.4. Registration of Recombinant DNA Research

All research projects involving recombinant DNA must be registered with the IBC. Completion of the Registration Document will fulfill this requirement. Submission of additional documentation is not required for research that is specifically exempted from IBC review.

2.5. Submitting Protocols for IBC Review

A. The **BUP** must accompany material submitted for review.

B. Documents for recombinant DNA review by the IBC should be submitted through established administrative channels. ASU departments and research groups should route proposals to Environmental Health, Safety, and Risk Management.

C. ***NOTE: Prior review by the IBC is required for all documents to be forwarded to the Recombinant DNA Advisory Committee of the National Institutes of Health (NIH/RAC).***

D. Documents submitted to the IBC for review must include complete and adequate information and protocols to allow appropriate peer review.

3. Responsibilities of Principal Investigators

3.1. The Principal Investigator, on behalf of the Institution, is responsible for fully complying with the *NIH Guidelines* in conducting any recombinant DNA research.

A. As part of that responsibility, the PI shall:

1) Be aware of recombinant DNA biosafety requirements and assure that requirements and procedures of ASU are followed.

2) Assure that all work involving recombinant DNA is registered with the IBC.

3) Assure that necessary safeguards and procedures are maintained in the work place.

4) Follow the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules*.

5) Assure that all review and approval requirements are fulfilled prior to initiating any new or modified research procedures.

6) Comply with shipping requirements for recombinant DNA molecules.

7) Submit the initial research protocol, if required by *NIH Guidelines* or institutional requirements.

8) Notify the Biological Safety Officer (BSO) when required safety inspections and certification of containment facilities and biological safety cabinets are needed.

9) Notify the IBC of any significant changes in experimental protocol or location of research.

10) Provide information to the IBC and BSO, as necessary.

11) Remain in communication with the IBC throughout the conduct of the project.

B. It is essential for PIs working with recombinant DNA to be thoroughly familiar with the *NIH Guidelines* and Biosafety in Microbiological and Biomedical Laboratories (BMBL).

1) Make the initial determination of the required levels of physical or biological containment in accordance with the *NIH Guidelines*.

2) Select appropriate microbiological practices, laboratory techniques, and minimum necessary personal protective equipment to be used in the research.

C. The Biological Safety Plan specifies physical containment requirements for standard laboratory experiments and defines Biosafety Level 1 (BSL1 or BL1) through Biosafety Level 4 (BSL4 or BL4).

D. See *NIH Guidelines* for information on containment requirements.

3.2. Responsibilities of the Principal Investigator prior to initiating research.

The PI shall:

A. Assure that labs and workplaces are identified with appropriate warning signs and that personnel are properly trained and are informed regarding biohazards.

B. Make available to the laboratory staff copies of the protocols that describe the potential biohazards and the precautions to be taken.

C. Assure that staff is trained in the safe work practices and techniques, proper use of personal protective equipment, and in the procedures for dealing with accidental spills and personnel exposure.

D. Inform staff of the reasons and provisions for any precautionary medical practices advised or requested, such as vaccinations or serum collection.

E. Prepare a written contingency plan for handling emergency conditions such as spills, personnel exposure, loss of containment, power failure, etc.

F. Report potential conflicts of interest as defined by the *NIH Guidelines* and related guidance and provide recommended measures to address conflict of interest.

3.3. Responsibilities of the Principal Investigator during the research.

The PI shall:

A. Supervise the staff to assure that the required safety practices and techniques are employed, minimum personal protection equipment is used, maintained, and stored appropriately, and that appropriate containment procedures are followed.

B. Investigate and provide written report to the BSO and the IBC regarding any significant problems pertaining to the operation and implementation of biohazard-containment practices and procedures, violations of the *NIH Guidelines*, and all significant research-related accidents and illnesses.

C. Correct work errors and conditions that may result in the release of recombinant DNA materials.

D. Ensure the integrity of physical containment (e.g., biological safety cabinets) and the biological containment (e.g., purity and genotypic and phenotypic characteristics).

E. Adhere to IBC-approved emergency plans for handling accidental spills and personnel contamination.

F. Assure proper handling and disposal of biohazardous waste.

4. The Institutional Biosafety Committee

4.1. Appointment of IBC Members and Chair

A. IBC members and chair are appointed in accordance with *NIH Guidelines*. The IBC is advisory to the Vice President of Academic Affairs (Provost) who reports to the President. The Vice President of Academic Affairs will report to the President on all matters relating to research and compliance.

B. The Provost/Vice President of Academic Affairs nominates and the President approves the faculty and outside members and the Dean of the College of Graduate Studies and Research selects the academic Chair. Members shall serve three-year terms and there are no limitations on the number of terms a person may serve. The Director of Risk and Emergency Management shall be a continuous member and may serve as co-Chair. Current members are listed in Appendix A.

C. Members shall be qualified, by expertise and experience, to review recombinant DNA research proposals and shall serve from approximately September 1 through August 31.

D. Membership and representation on the IBC shall be in accordance with *NIH Guidelines*.

1) The IBC shall be composed of no fewer than five members who collectively have experience and expertise in recombinant or synthetic nucleic acid molecule technology, the capability to assess the safety of research with recombinant or synthetic nucleic acid molecules, and the ability to identify any potential risk to public health or the environment.

2) At least two members not affiliated with the institution shall be appointed to represent the community.

3) The IBC must include at least one individual with expertise in plant, plant pathogen, or plant pest containment principles when experiments subject to Appendix P, *Physical and Biological Containment for Recombinant or Synthetic Nucleic Acid Molecule Research Involving Plants,* are conducted. When required, the individual serving as the plant expert should be indicated on Appendix A and the roster registered with NIH OSP.

4) The IBC must include at least one individual with expertise in animal containment principles when experiments subject to Appendix Q, *Physical and Biological Containment for Recombinant or Synthetic Nucleic Acid Molecule Research Involving Animals,* are conducted. Confer, coordinate, and communicate with IACUC as necessary. When required, the individual serving as the animal expert should be indicated on Appendix A and the roster registered with NIH OSP.

5) When conducting or sponsoring research with recombinant or synthetic nucleic acid molecules involving human subjects, the institution must ensure that there is an IBC member who has adequate experience and training in the field of human gene transfer. This individual must be indicated on Appendix A and the roster registered with NIH OSP.

E. An IBC member shall be disqualified from review or approval of a proposal or activity when a conflict of interest exists, except to provide information requested by the IBC.

1) Conflict of interest includes, but is not limited to, items where:

a) The IBC member is currently engaged or expects to be engaged in the research project under review, as defined in the *NIH Guidelines*.

b) The IBC member has a direct financial interest in the PI or the entity funding the research proposed by the PI, as defined in the *NIH Guidelines*.

c) The IBC member and the PI of the application under consideration have a familial relationship (1st or 2nd Degree affinity or consanguinity kinship).

d) The IBC member has other reasons to feel that he or she cannot render an independent assessment of an application.

2) The IBC member shall disclose the conflict of interest:

a) When the IBC member is contacted to participate in a review where a conflict exists.

b) Prior to the discussion at a convened meeting for a project for which a conflict exists.

4.2. Specific Responsibilities

A. Provide interface between the Institution, the BSO, and PIs concerning lab review, security, safety, emergency plans, and other activities, including new construction or remodel of facilities contemplating research.

B. The Office of Research and Sponsored Projects will maintain a registry of research projects and/or proposals involving the use of recombinant DNA, biohazardous, and/or synthetic nucleic acids at ASU.

C. Provide oversight, review, and assessment of:

1) Adherence to NIH requirements for recombinant DNA, biohazardous, and synthetic nucleic acids research, and shall:

a) Make an independent determination of the project biosafety level

b) Determine appropriate methods to address any potential conflict of interest.

2) Training and expertise of personnel consistent with Section 7.

3) Lab safety, security, and biological containment requirements and practices.

4) Emergency contingency plans including containment and cleanup of spills and exposure of personnel to biohazardous materials.

D. Investigate reports of problems of safety or non-compliance. Alert the Provost (or other administration officials as appropriate) and the PI to any noncompliance or other problems, and monitor corrective action. (NOTE: The IBC reviews and monitors research involving recombinant DNA, biohazardous, and/or synthetic nucleic acids and may assist PIs in voluntary compliance; however, the IBC assumes no responsibility for gaining compliance or for fulfilling research requirements.)

E. Coordinate and assist the BSO with safety and containment monitoring programs.

F. Meet as necessary and maintain a permanent record of IBC meetings and activities.

1) The IBC shall meet at least annually. The frequency of meetings should be commensurate with the volume of protocols needing review, the nature and risks of the research, and the need for continuing oversight. PIs are encouraged to attend.

2) Meetings may be attended in any manner that permits full interactive discussion and exchange. In person, video, and telephonic participation are all recognized methods of participation. Email may be used for transmission and communication and may normally only be used for voting where full interactive discussion and exchange is not required.

3) Meetings shall be open to the public when possible and consistent with protection of privacy and proprietary interests. Publicly available 'events' advertising meetings included on the ASU online calendar are an acceptable means of facilitating public awareness of meetings.

4) A quorum shall consist of a majority of members.

5) Meeting minutes shall provide a record of the IBC's proceedings and its fulfillment of performance expectations of the *NIH Guidelines*. At a minimum, the minutes shall document:

   a) Assessment of containment levels required by the *NIH Guidelines* when reviewing proposed research;

   b) Assessment of the facilities, procedures, practices, and training and expertise of personnel involved in recombinant or synthetic nucleic acid research; and

   c) Periodic review of recombinant or synthetic nucleic acid research to ensure compliance with *NIH Guidelines*.

6) Meeting minutes shall be made available to the public upon request and may be made publicly available on an ASU webpage. Meeting minutes shall be redacted as necessary for the protection of privacy and proprietary interests and consistent with state law.

G. Annual review of the status of current recombinant DNA, biohazardous, and/or synthetic nucleic acids research at ASU.

H. Provide guidance to PIs and review reports or proposals prepared for submission to the NIH Office for Recombinant DNA Activities (ORDA) and the NIH Recombinant DNA Advisory Committee (RAC).

I. Inform department chairs of recombinant DNA activities and proposals within their department.

J. Confer, coordinate, and communicate with the Institutional Review Board (IRB) and Institutional Animal Care and Use Committee (IACUC) and other review boards and committees as appropriate.

K. Other responsibilities as specified by the *NIH Guidelines*.

4.3. Reporting and Communications

A. The IBC Academic (co-)Chair shall help inform and involve department chairs in the review and compliance of recombinant DNA research activities in their department. Proposals, projects, or other documents shall reflect department chair awareness and concurrence prior to IBC review.

B. Provide an Annual Report (following the first meeting the fiscal year) on the status of recombinant DNA research, reviews, and compliance to the ASU Provost. The Annual Report should include a summary of proposals reviewed during the year; status of regulatory compliance, safety, and biological containment; emergency procedures; new issues; and other items, as appropriate.

C. Interim reports regarding significant deficiencies, noncompliance, or other emergency issues may be prepared and forwarded to the ASU Provost, and others, as necessary.

D. The Provost should be provided advance written notification of any proposed IBC communication with federal agencies or committees, other than proposal review assessments and approvals.

E. When required, submit annually to NIH OSP:

1) A roster of all IBC members clearly indicating the Chair, contact person, biological safety officer (if applicable), plant, animal, or human gene transfer experts (if applicable) and non-affiliated members

2) Biological sketches for all IBC members

F. When any funding source or agreement requires full compliance with *NIH Guidelines* and public comments are made on the IBC's actions, both the public comments and the IBC's response shall be forwarded to NIH OSP.

5. The Biological Safety Officer (BSO)

The Biological Safety Officer is the designated administrative officer who assists in assuring compliance and biosafety of recombinant DNA research conducted at ASU. Appointment of a BSO is required if research is conducted at Biosafety Level 3 or above or for Large Scale Research. If a Biological Safety Officer is not required or appointed due to the level and type of research, the Academic (co-)Chair shall ensure that the specific duties and responsibilities described below are accomplished.

5.1. Appointment

The BSO shall be designated by the Provost/Vice President of Academic Affairs to provide services and assistance as required by federal guidelines and regulations and Institutional requirements.

5.2. Specific Duties and Responsibilities

A. Serve as a member of the IBC to provide a focal point for compliance with recombinant DNA biological safety (lab, human and environmental aspects), biological containment, lab practices, and monitoring requirements in accordance with *NIH Guidelines*, *Biosafety in Microbiological and Biomedical Laboratories*, and institutional requirements. Confer, coordinate, and communicate with the IRB as necessary.

B. Conduct or supervise annual inspection and review of recombinant DNA laboratories or facilities and authorize qualified labs to conduct recombinant DNA research following CDC/NIH Biological Safety Guidelines, and institutional requirements.

C. Conduct or supervise safety inspection and testing of containment facilities. Maintain documents and results of certification.

D. Provide technical advice to investigators and the IBC on safety procedures and lab containment. Assist investigators in defining and interpreting safety and regulatory requirements. Identify procedures to be followed. Assist PIs, staff, and department heads in maintaining awareness of responsibilities and regulatory developments.

E. Identify safety problems, seek voluntary compliance, and report significant problems (such as containment, safety, lab techniques, and facilities) to the IBC, the PI, and others, as appropriate.

F. Assist investigators in developing emergency plans for containment and cleanup accidental spills or releases. Assist in emergencies. Investigate and review recombinant DNA lab accidents. Maintain documents and reports associated with the investigations and actions.

5.3. Reporting and Communications

A. The BSO shall inform department heads, PIs, and others of biosafety requirements and assist with maintaining compliance with institutional and governmental guidelines and regulations.

B. The BSO shall assist the IBC co-Chairs with preparation of an annual report summarizing activities and findings during the past year. Interim reports or notifications may be forwarded any time that significant deficiencies, noncompliance, or other emergency issues develop.

C. Inform the IBC co-Chairs and others, as appropriate, of instances of safety problems or noncompliance with Institutional and regulatory requirements.

6. Record Retention

6.1. No official state records may be destroyed without permission from the Texas State Library as outlined in Texas Government Code, Section 441.187 and 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.

6.2. ASU's Records Retention Schedule is certified by the Texas State Library and Archives Commission. Departments and EHSRM shall follow ASU's Records Retention Schedule as stated in the Operating Procedure OP 02.07 Records Retention. All official state records (paper, microform, electronic, or any other media) must be retained for the minimum period designated.

7. Training

7.1. IBC Committee, Biosafety Officer, and Principal Investigators

A. All IBC members shall review and successfully complete the examinations for CITI's online Institutional Biosafety Committee Member Training – Basic Course within 90 days of appointment. If a Biosafety Officer has not been appointed, at least two IBC members shall also complete the Biosafety Officer training.

B. All appointed biosafety officers shall review and successfully complete the examinations for CITI's online Initial Biosafety Training Course within 90 days of appointment.

C. All Principal Investigators shall review and successfully complete the examinations for CITI's Initial Biosafety Training – Basic Course before final approval by the IBC. If recombinant DNA research is involved, CITI's NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (ID: 13493) will be required.

7.2. Training for Laboratory Research Personnel

A. All laboratory research personnel shall have reviewed and successfully completed the examinations for ASU's Biological Safety and Chemical Safety trainings in BlackBoard once assigned.

B. The PI shall identify additional training requirements based upon reviews required in Section 3.1 and develop and deliver a training program as required in Section 3.2. The training shall be documented. In some cases, the IBC may require relevant sections of CITI's online training to be completed.

7.3. CITI Training Module Requirements noted below.

Angelo State University
Institutional Biosafety Committee

Biosafety Training Requirements for ASU BSS Course: Training Modules	IBC Co-Chairs Biosafety Officer Training - Basic/Initial	IBC Members Institutional Biosafety Committee Member Training	Researchers (Faculty and Students) Initial Biosafety Training
Introduction and Risk Assessment			
Biosafety and Biosecurity (BSS) Introduction (ID: 13987)	R	S	S
Biosafety Course Overview (ID: 13314)	R	R	R
Laboratory-Acquired Infections (ID: 13454)	R	R	R
Biohazard Risk Assessment (ID: 13455)	R	R	R
Medical Surveillance (ID: 13456)	R	R	R
Risk Management			
Risk Management: Work Practices (ID: 13898)	R	-	R
Risk Management: Personal Protective Equipment (ID: 13458)	R	-	R
Risk Management: Emergency and Spill Response (ID: 13459)	R	-	R
Risk Management: Engineering Controls (ID: 13929)	R	-	R
Risk Management: Laboratory Design (ID: 13484)	R	-	R
Work Safely with Sharp Instruments (ID: 13899)	R	-	R
Disinfection and Sterilization (ID: 13900)	R	-	R
Safe Sharps Devices (ID: 13946)	R	-	R
Centrifuge Precautions (ID: 13945)	R	-	R
Engineering Controls and Containment Devices (ID: 13497)	R	-	R
OSHA Bloodborne Pathogens			
Note: To fulfill the OSHA Bloodborne Pathogen Standard, a learner must complete all of the modules available within this "OSHA Bloodborne Pathogens" section. This requirement includes module ID: 13902, 13903, 13904, 13913, and 13914.			
OSHA Bloodborne Pathogens Standard (ID: 13902)	R	-	-
Hepatitis B Virus (HBV) Vaccination (ID: 13903)	R	-	-
Labels and Engineering Controls (ID: 13904)	R	-	-
Universal Precautions and Work Practices (ID: 13913)	R	-	-
Emergency Response Procedures (ID: 13914)	R	-	-
Recombinant DNA Research			
NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (ID: 13493)	R	R	-
Human Gene Transfer Research (ID: 13494)	R	R	-
Selects Agents, Biosecurity, and Bioterrorism			
Select Agents (ID: 13951)	R	-	-
Biosecurity (ID: 13857)	R	-	-
Bioterrorism (ID: 13524)	R	-	-
Shipping Regulated Biological Materials			
Shipping Regulated Biological Materials: Overview (ID: 13486)	R	-	-
Shipping Regulated Biological Materials: Classifications (ID: 13487)	R	-	-
Shipping Regulated Biological Materials: Packaging Requirements (ID: 13488)	R	-	-
Shipping Regulated Biological Materials: Shipping Papers (ID: 13655)	R	-	-
Shipping Regulated Biological Materials: Permits for Restricted Shipments and Transfers (ID: 13656)	R	-	-
Shipping Regulated Biological Materials: Security Awareness (ID: 13657)	R	-	-
Shipping Regulated Biological Materials: Emergency Response Information (ID: 13658)	R	-	-
Shipping Regulated Biological Materials: Refrigerants (ID: 13659)	R	-	-
Shipping Regulated Biological Materials: Appendix (ID: 13660)	R	-	-
Animal Biosafety			
Animal Biosafety (ID: 13654)	R	-	-
Nanotechnology			
Understanding Nanotechnology and Its Implications (ID: 14044)	R	-	-
Dual Use Research of Concern (DURC)			
Dual Use Research of Concern (DURC) (ID: 16263)	R	R	S
USDA Permits			
USDA Permits: Plant Pest (ID: 17256)	R	-	-
USDA Permits: Soils (ID: 17257)	R	-	-
USDA Permits: Veterinary Services (VS) (ID: 17258)	R	-	-
Passing Score for the course.	80%	80%	80%
Module Completion Key			
R = Required; required modules must be taken in order to obtain a completion report			
E = Elective; A set of elective modules are listed and a subset of them must be completed in order to earn a completion report.			
S = Supplemental; Optional modules to be completed by learners but not required to earn a completion report.			

8. Reference Material

The following references were used in drafting this Plan or provide additional information:

A. NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules Federal Register, 81 FR 22286, April 15, 2016, and updates.

B. Biosafety in Microbiological and Biomedical Laboratories, U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control and National Institutes of Health, 5th Edition, December 2009. HHS Publication No. (CDC) 21-1112.

C. USDA APHIS (Animal and Plant Health Inspection Service) Biotechnology Regulatory Services, Permit User's Guide, May 2012

Appendix A: Institutional Biosafety Officer, Committee Chair, and Committee Members

Biosafety Officer:	(Not Currently Required – Contact one of the co-Chairs for BSO issues)
IBC Co-Chairs:	Dr. Edith Osborne, PhD, Professor, Department of Chemistry and Biochemistry
	Mr. Samuel Spooner, Director, Office of Environmental Health, Safety, and Risk Management
University Members:	Dr. Loree Branham, PhD, Professor, Department of Agriculture
	Dr. Emerson Crabill, PhD, Assistant Professor, Department of Biology
	Dr. Denise Goddard, DNP, APRN, FNP-C, Assistant Professor, Department of Nursing
	Dr. Han-Hung Floyd Huang, PT, PhD, Associate Professor, Department of Physical Therapy
Outside Members:	Ms. Sandra Villarreal, Health Services Director, City of San Angelo
	Mr. Dale Weise, Texas Vet Lab
	Mr. Jim Bob Harris, Texas Vet Lab

Appendix B: Biohazardous Use Protocol (BUP) for IBC Permit

1. Research Requiring IBC Approval Prior to Initiation

1.1. Research involving any of the agents listed below must be approved by the Angelo State University Institutional Biosafety Committee (IBC) prior to initiation:

A. Pathogens and potential pathogens of humans, animals or plants;

B. Materials potentially containing human pathogens (including human blood, tissue, and cell lines; non-human primate blood, tissue, and cell lines);

C. Recombinant DNA (and RNA) including creation or use of transgenic plants and animals;

D. Select agents and toxins including strains and amounts exempted from the select agent regulations;

E. Any material requiring a CDC import license or a USDA permit; and/or

F. Any material that is considered extremely toxic or a hazardous substance.

2. Permit Process and Responsibility for Permit Completion, Submission, and Notifications

2.1. The Principal Investigator (PI) is responsible for completing all appropriate parts of this registration document and for notifying the IBC when information submitted in this document changes, such as personnel, laboratory location, procedures, funding, etc. If such changes occur, the PI will be required to fill out an Amendment Form (located online).

2.2. Protocols are currently approved for the duration of three (3) year with annual renewals and laboratory inspections.

2.3. Only typed forms will be accepted. For your convenience, each required form is available electronically (Word format). Only the most current forms will be accepted and reviewed; therefore we ask that you access our website for all submissions. The application must be completed, signed by all appropriate personnel, and submitted to the IBC at the Office of Environmental Health, Safety, and Risk Management prior to initiation of research. At the time of submission, you are also asked to submit all grant proposals pertaining to your research. Failure to provide all information requested, including signatures, will lead to a delay in processing your request. If further instructions are necessary, please contact the IBC at ehsrm@angelo.edu or call (325) 942-2180.

2.4. The IBC Academic (co-)Chair will notify the PI in writing of the results of the IBC's review and approval, including any approval conditions, protocol expiration date, and other pertinent information.

Routing # _____
AUP # _____
IRB # _____

For Internal Use Only
IBC # _____

Biohazardous Use Protocol (BUP) for IBC Permit

Checklist and Table of Contents for Institutional Biosafety Protocols

The following is a table of contents of the items included in the BUP for the IBC permit. In order for research to be approved, you must provide all applicable sections to the IBC and a copy of the grant proposal. Please check and attach all items that apply to your research.

Part I, II, and IV are required. Parts III and V should be completed and submitted as applicable. Only typed applications will be processed for review. You need not submit blank pages or pages that are not applicable to the IBC.

Please send completed BUP for IBC Permits to Environmental Health, Safety, and Risk Management.

Your protocol will be delayed if it is missing any required information. Please allow sufficient time for processing of your application. It may take 30-60 days to obtain IBC approval.

List of Included Parts (check included parts)

☐ Part I: BUP for IBC Permit (required for all applications)

☐ Part II: Agent Information (required for all applications)

☐ Part III: Viral Vectors

☐ Part IV: Personnel Information (required of BSL-1 and above laboratories, personnel working with animals and human materials)

☐ Part V: Select Agent Plan Review Form

☐ Grant Proposal or Draft Grant Proposal (required for all applications supported by grants)

☐ Biosafety Manual (required for all BSL-2 or higher research)

Part I: ASU Biohazardous Use Protocol for IBC Permit

1. Title & Principal Investigator/PI Supervisor Information

A. Project Title: _____

B. Principal Investigator:

Last Name: _____ First Name: _____

Department: _____ College: _____

Office Building: _____ Office Room Number: _____

Mailing Address: _____

Phone: _____ _____ _____ _____
Office Laboratory Emergency/After Hours Fax

ASU Email: _____

C. Principal Investigator Supervisor:

Last Name: _____ First Name: _____

Department: _____ College: _____

Office Building: _____ Office Room Number: _____

Mailing Address: _____

Phone: _____ _____ _____ _____
Office Laboratory Emergency/After Hours Fax

ASU Email: _____

2. Investigator Assurance

- I attest that the information contained in this registration is accurate and complete.
- I agree to comply with all Angelo State University IBC requirements regarding research involving biohazardous and/or recombinant materials.
- I agree not to initiate any research subject to IBC approval unless I have received such approval.
- I agree to notify the IBC via the BSO immediately of incidents involving biohazardous and / or recombinant agents.
- I am thoroughly familiar with the *NIH Guidelines* and BMBL as they relate to this research project. 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 according to the BSL of the laboratory.
- 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. All personnel are provided training in sterile technique, the use of automatic pipetters and the proper disposal of biohazardous materials. All personnel are advised that if they are in an immunocompromised or 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. 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.*

		Click here to enter text.
Principal Investigator Signature	Date	Typed/Printed Name
		Click here to enter text.
Principal Student Investigator Signature	Date	Typed/Printed Name
		Click here to enter text.
Department Chair Signature	Date	Typed/Printed Name

3. Protocol Information

A. Funding Source (Please check all that apply)

☐ NIH ☐ NSF ☐ USDA ☐ N/A ☐ Other: _____

B. Routing Agency

☐ ASU ☐ TEES ☐ Texas AgriLife ☐ Other: _____

C. Grant Proposal (☐ Not Applicable)

Please include a copy of all grants associated with this IBC Permit. The submission should include all sections of the grant that contain information pertaining to the research. (Budget information is not required.)

Grant PI if different from this protocol PI: _____

Grant Title(s): _____

D. Lay description of the project

In terms understandable to a non-scientist please provide, in the space below, a brief summary of this project describing its goal(s), methodology, and use of biohazardous or recombinant material.

_____

E. Technical description of the project

Please provide a technical description in the space below. Provide information detailed enough so that IBC members can perform a risk assessment of your protocol. Include the following information:

- Procedures, practices, and manipulations involving biohazardous or recombinant agents (e.g. cloning of genes in *E. coli* for sequencing; creation of transgenic mice by means of lentiviral vectors; isolation of bacteria from sewage – may include human pathogens).
- Identify all manipulations that may increase risk to personnel or the environment; describe how these risks will be mitigated (e.g. all manipulations involving agents listed in this protocol will be conducted in a biosafety cabinet; transgenic plants will be grown in locked growth chambers and will not be allowed to flower)
- Briefly describe your experience with the manipulations described in this section (e.g. I have use identical methodology to generate transgenic mice over 100 times in the last 10 years; I have never used this method to isolate proteins from pathogenic bacterial before; however, Dr. Smith, who developed this method 7 years ago, has agreed to assist me for the first 3 runs.)
- Decontamination and waste disposal methods

_____

_____

F. Agent use and storage locations.

Enter building name, room number, room use, current biosafety level and shared lab status. If laboratory is shared, please indicate all of the Principal Investigators.

Location ID	Building	Room Number	Room Use (Storage, Laboratory, Animal Housing)	Current Biosafety Level (Identify Level 1-4)	Shared Lab?
1					
2					
3					
4					
5					
6					
7					
8					
9					
10					

G. Protocol Subjects

Does this protocol involve:

Yes No

☐ ☐ Humans Subjects? If Yes, enter the Institutional Review Board (IRB) approval date _____ and ID: _____

☐ ☐ Live vertebrate animals? If Yes, enter the Institutional Animal Care and Use Committee (IACUC) approval date _____ and ID: _____

☐ ☐ Live invertebrate animals? (i.e. Drosophila)

☐ ☐ Plants?

H. Agent Characteristics

Does this protocol involve:

Yes No

☐ ☐ Agents potentially affecting humans?

☐ ☐ Agents potentially affecting animals?

☐ ☐ Agents potentially affecting plants?

☐ ☐ Materials potentially containing human pathogens (including human cell lines, human blood, unfixed human tissue)?

☐ ☐ Biological Toxins?

☐	☐	Select Agents and Toxins (including exempt strains and exempt quantities of toxins)? *F. tularensis* and *C. burnetii* are exempt strains
☐	☐	Any material requiring a CDC or USDA permit?

If you answered "Yes" to any of the above questions, enter the agent name(s) and information into Table A of Part II.

I. Recombinant DNA

Does this protocol involve:

Yes	No	
☐	☐	The use of recombinant agents created elsewhere?
☐	☐	Creation of recombinant bacteria or yeast non-pathogenic to humans, plants, or animals?
☐	☐	Creation of recombinant bacteria or yeast potentially pathogenic to humans, plants, or animals?
☐	☐	Use of viral vectors?
☐	☐	The creation of transgenic animals?
☐	☐	The creation of transgenic plants?
☐	☐	The use of transgenic animals or plants (excluding the use of commercially obtained transgenic rodents kept at BL-1)?

If you answered "No" to all of the above questions, skip to question M below.

If you answered "Yes" to any of the above questions you must enter the following information into Tables A and B of Part II, then continue with question J:

- Enter host (target) name (e.g. *Mus musculus*) and information into Table A of Part II;
- Enter vector, if used, name (e.g. adeno-associated virus (AAV)) and information into Table A of Part II;
- Enter information regarding the cloned DNA insert (e.g. insulin) into Table B of Part II.

J. Viral Vectors Characteristics

If viral vectors are use, complete a separate Part III for each.

K. Insert Characteristics

Please answer the following questions regarding the inserts listed in Part II.

Yes	No	
☐	☐	From a Risk Group 2 Agent?
☐	☐	From a Risk Group 3 or 4 Agent?
☐	☐	From an animal or plant pathogen not effecting humans?
☐	☐	From a Select Agent or coding for a Select Toxin?
☐	☐	Encodes for a known or suspected oncogene gene?

☐ ☐ Encodes for a toxin molecule (whole or partial)? If yes please describe the LD50 of the toxin and whether the insert will code for an active toxin.

_____

☐ ☐ Will antibiotic resistance be transferred to microorganisms? If yes:

Describe what antibiotic resistance genes will be transferred to which agents (microorganism?).

_____

Explain why this action would not fall under Section III-A-1-a of the *NIH Guidelines*. Include relevant references.

_____

L. Which Sections of the *NIH Guidelines* does research described in this protocol fall (pick all that apply for each agent):

Table A ID	Agent Genus, species	Strain	BL/ABSL/BL-P (pick)	Sections of the *NIH Guidelines* that cover experiments (pick all that apply)
A-1				
A-2				
A-3				
A-4				
A-5				
A-6				
A-7				
A-8				
A-9				
A-10				

Rules pertaining to Sections III-A, III-B, III-C, III-D, III-E, and III-F may be found in the *NIH Guidelines*.

For assistance, contact Environmental Health, Safety, and Risk Management.

M. Risk Assessment

Yes No

☐ ☐ Will any experimental procedures result in acquisition of new characteristics such as enhanced virulence, infectivity, or change in host range?

☐ ☐ Will any procedures with the agent be conducted outside of a biological safety cabinet?

☐ ☐ Will any of the agents be transported outside of the laboratory?

☐ ☐ Will more than 1 liter of agent be generated at any one time?

☐ ☐ Will any of the agents be administrated to animals? If yes please describe the experiment in detail below (e.g. animal species, how is the agent given, how long will the animal be followed.)

☐ ☐ Does this project involve the environmental release of genetically engineered material?

☐ ☐ Does this project involve the environmental release of pathogenic or potentially pathogenic material (other than recombinant agents)?

☐ ☐ Will human tissue or cells be transplanted into animals?

☐ ☐ Will animal tissue or cells be transplanted into a different species of animal?

☐ ☐ Do any of the agents you intend to work with require pre-project serum samples, immunization, medical monitoring, and/or health surveillance?

☐ ☐ Will the deliberate aerosolization of any agent occur?

☐ ☐ Will an attempt be made to obtain expression of a foreign gene, and if so, indicate the protein that will be produced?

☐ ☐ Will specialty signage and specialized access control be necessary to prohibit unauthorized access to the area without approval, escort, or PPE?

If you answered "Yes" to any of the above questions, please provide an explanation:

N. Medical Risks

Describe health risks associated with the use of all pathogens used in your laboratory and list the symptoms/disease that may occur.

Agent ID	Health Risks, Symptoms, Disease, Target Organ(s)
A-1	
A-2	
A-3	
A-4	
A-5	
A-6	
A-7	
A-8	
A-9	
A-10	

O. Medical Treatment

What are the treatment options/plans available in case of a potential exposure to pathogens?

P. Exposure Control

Indicate the personal protective equipment you will use. Please check the applicable boxes.

☐ Face Mask ☐ Gloves ☐ Shoe Covers ☐ Head Covers

☐ Boots/Crocs ☐ N95 (HEPA)* ☐ Eye Protection ☐ Double Gloves

☐ Lab Coats ☐ Face Shield ☐ Disposable Outers ☐ P100 (HEPA)*

☐ PAPR (HEPA)*

☐ Other (Specify): _____

_____

*Please contact Environmental Health, Safety, and Risk Management to schedule respirator medical clearance, training, and fit testing.

Q. Biological Safety Cabinet

Indicate the type of Biological Safety Cabinet(s) (BSC) you intend to use. Please check the applicable boxes and enter the locations:

☐ Class II A (recirculating) Location: _____

☐ Class II B1 (70% exhausted – ducted outside) Location: _____

☐ Class II B2 (100% exhausted – ducted outside Location: _____

☐ None

☐ Other (Specify:) _____

Is the biological safety cabinet(s) certified annually?

☐ No

☐ Yes Provide date(s) of most recent certification. _____

4. Disposal/Decontamination of Laboratory Facilities

The following materials must be sterilized, decontaminated or inactivated before disposal:

- All materials containing infectious agents (including materials potentially exposed to infectious agents, for example gloves)
- As per *NIH Guidelines*: All materials containing recombinant DNA (or items potentially exposed to recombinant DNA, such as pipette tips, tubes, gloves). This includes any recombinant DNA containing cell cultures, microorganisms, plants, animals (vertebrate, invertebrate, protists)
- All biological toxins (or materials potentially exposed to biological toxins), human blood or other potentially infected body fluids

Decontamination or inactivation procedures must also be in place for working surfaces (benchtops) and equipment that may become contaminated with infectious agents, recombinant DNA or biological toxins.

A. Materials Sterilization/Decontamination/Disposal Methods

Indicate the methods and laboratory procedures that are in place for decontamination and disposal of contaminated waste.

- See section C below for suggested autoclave temperature and exposure times.
- If using chemical disinfection, indicate final concentration of disinfectant and contact time required to achieve decontamination. Please refer to BMBL (5th edition), Appendix B.

- If using incineration please indicate the facility to be used.

Type of Waste	Potential Hazard	Decontamination, Sterilization, Disposal Procedure
Liquids		
Solids		
Glassware		
Animals		

B. Surface/equipment decontamination

Indicate the methods/laboratory procedures that are in place for decontamination of work surfaces and equipment. Please refer to BMBL (5th edition), Appendix B.

C. Disposal, Autoclave Testing, Autoclave Efficacy and Recordkeeping

Suggested temperatures and exposure times for autoclaving from NIH Biohazards Guidelines are:

Liquids *121°C (250°F) 1 hour, (each gallon)*
Laundry *121°C (250°F) 30 minutes*
Trash *121°C (250°F) 1 hour*
Glassware *121°C (250°F) or 160°C (320°F) 1 hour to 4 hours (dry heat)*

1. Please provide assurance that you will use the guidelines listed above or provide scientific rationale for using an alternate method.

   ☐ I give assurance that the method indicated above will be used.

   ☐ Other (*Please attach explanation and include scientific rationale for the use of alternate conditions, i.e.: time, temperature, etc.*) _____

2. Autoclaves should be tested before being placed into service and then periodically for effectiveness.

   a. ☐ The autoclave is departmentally operated

      Contact Name: _____ Phone No: _____

      Building and Room Number: _____

      Indicate testing frequency:

      ☐ Minimum - 1 time per week (BL3)
      ☐ Minimum - 1 time every other week (BL2)
      ☐ Minimum - 1 time per month (BL1)

   b. ☐ The autoclave is individually operated (supervised by Principal Investigator)

      Building and Room Number: _____

      Indicate testing frequency:

      ☐ Minimum - 1 time per week (BL3)
      ☐ Minimum - 1 time every other week (BL2)
      ☐ Minimum - 1 time per month (BL1)

3. A test indicator kit will be used to test autoclave efficiency for BL2 or above.

   For the research project, ….

   ☐ I give assurance that the method indicated above will be used.

4. The IBC requires that the treatment of each load of Biohazardous waste be documented on an autoclave waste treatment record. The record should contain the date of treatment, the amount of waste treated, the method/conditions of treatment, and the printed name and initials of the person performing the treatment. If provided, charts or printout strips should be kept with the record as documentation. Additionally, documentation of the date and results of all verification tests using biological indicators is required.

   ☐ I give assurance that the method indicated above will be used.

Contact Environmental Health, Safety, and Risk Management for more information on disposal of hazardous materials or instructions regarding Select Agent disposal.

Part II: Agent Information

A. Table A: Agent/Vector/Host Characteristics

In the table below, list each agent that will be used. Note the ID of the agent for later use in your application. If the agent is recombinant, indicate "Yes" in the appropriate cell and enter insert information into Table B. If a vector is used to generate a recombinant host, both the vector and host need to be entered into Table A. If the agent is to be used with animals or plants give the species, otherwise enter "No."

ID	Genus, Species	Strain	RG-Risk Group (pick)	BSL (pick)	ABSL Animal Biosafety Level (pick)	Recombinant? (pick)	List all location IDs where agent will be used or stored	Use in Animals/Plants? (give specifics)
	Example – E. coli	K-12	RG-1	BSL-1	N/A	Yes	1, 2, 3	No
A-1								
A-2								
A-3								
A-4								
A-5								
A-6								
A-7								
A-8								
A-9								
A-10								

Table B: Insert characteristics

In the table below, enter information about each vector or host DNA inserts. Enter the appropriate Host ID from Table A to indicate which host will contain the insert.

ID	Host ID (Table A)	Strain	Insert Source Risk Group (pick)	Insert Name (e.g. insulin)	Insert Characteristic or Function (e.g. hormone)
	Example	Human	RG-2	Insulin	hormone
I-1	A-				
I-2	A-				
I-3	A-				
I-4	A-				
I-5	A-				
I-6	A-				
I-7	A-				
I-8	A-				
I-9	A-				
I-10	A-				

Part III: Viral Vector Information

(One Agent per Page – Reproduce as Needed)

A. Agent ID from Table A: _____

B. Is the virus replication competent?

_____

C. Are assay systems used to measure the titer of replication competent viruses that may be present? If yes, please describe: _____

D. What is the host range of the viral vector?

_____

E. What percent of the original viral genome remains in the vector?

_____

F. Describe the genome organization of the viral vector. Include information about what genes or genome regions have been removed.

_____

G. The possibility of homologous recombination with endogenous viruses exists. Indicate the reversion rate and the recombination event of such a possibility. Describe methods you will use to ensure that replication competent viruses are excluded.

_____

Part IV: Personnel Information

Personnel List

To be completed by the lab director (or PI) when working in laboratories that are BSL2 and above containment.

Action A=Add D=Del M=Mod	First Name	Last Name	CID	Associated with an Animal Use Protocol (AUP)? Y/N	List all organisms (Pathogens, Toxins, rDNA) employees will have access	Laboratory Building/Room	Position Title	Employee Email Address

Part IV: Personnel Acknowledgement

Signature Page

(Reproduce this page as needed)

Each employee working in BSL2 and above laboratories must complete this page.

Employees working in laboratories containing Select Agents may
submit copies of training certificates instead of signature pages.

By my signature below, I certify that I have read and understand the laboratory security and emergency policies and procedures for working with (list of agents) in laboratory building (building name) and room(s) (room numbers) under the direction of (principle investigator).

I further certify that I understand the hazards of working with (list of agents); the indications of infection or intoxication by this biological material; the reporting system for potential exposure and accidents; how to seek evaluation and therapy; the standard microbiological practices for this laboratory; the special Biosafety practices required for Biosafety Level work, in accordance with the Biosafety in Microbiological and Biomedical Laboratories (BMBL) Guidebook and the standard operating procedures for this laboratory.

Finally, I certify that any transfer of this biological material will be done in accordance with Angelo State University policies and regulations and under the supervision of the Angelo State University Office of Environmental Health, Safety, and Risk Management. In addition, I ensure that the detailed records of information necessary to account for all activities related to this agent will be maintained.

Signature	Date	Laboratory Director/Supervisor Signature
Typed Name	Position/Title	Laboratory Director/Supervisor Typed Name

Have you completed lab-specific training for this research?

☐ Yes ☐ No Date of lab-specific training: _____

Appendix C: IBC Short Form

Angelo State University
Institutional Biosafety Committee

APPENDIX C-Short Form
(BSL1 Only)

Part I: ASU Biohazardous Use Protocol for IBC Permit

1. Principal Investigator Information

1. Principal Investigator (PI):	Click here to enter text.			
2. PI's Department:	Click here to enter text.			
3. PI's College	Click here to enter text.			
4. Office Building and Rm #:	Click here to enter text.			
5. Mailing Address:	Click here to enter text.			
6. Phone:	Office: Click here to enter text.	Laboratory: Click here to enter text.	Emergency/After Hours: Click here to enter text.	Fax: Click here to enter text.
7. ASU Email:	Click here to enter text.			
8. Title of Project:	Click here to enter text.			
9. Abbreviated Project Title:	Click here to enter text.			

2. Investigator Assurance

- I attest that the information contained in this registration is accurate and complete.
- I agree to comply with all Angelo State University IBC requirements regarding research involving biohazardous and/or recombinant materials.
- I agree not to initiate any research subject to IBC approval unless I have received such approval.
- I agree to notify the IBC via the BSO immediately of incidents involving biohazardous and / or recombinant agents.
- I am thoroughly familiar with the *NIH Guidelines* and BMBL as they relate to this research project. 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 according to the BSL of the laboratory.
- 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. All personnel are provided training in sterile technique, the use of automatic pipetters and the proper disposal of biohazardous materials. All personnel are advised that if they are in an immunocompromised or 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. 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.*

Click here to enter text.

Principal Investigator Signature	Date	Typed/Printed Name Click here to enter text.
Principal Student Investigator Signature	Date	Typed/Printed Name Click here to enter text.
Department Chair Signature	Date	Typed/Printed Name

3. Project Information

Is this project being submitted for funding?	Yes ☐ No ☐
If yes, list agency	Click here to enter text.
Is this project being submitted for IACUC?	Yes ☐ No ☐
Is this project being submitted for IRB approval?	Yes ☐ No ☐

4. Brief Description of Agents Used:

Click here to enter text.

5. Location(s) of project and reagents:

Click here to enter text.

6. Brief protocol description (include pertinent media, methods, organisms, and strains; may attach protocol to this form):

Click here to enter text.

7. Brief Discussion of Risks:

Click here to enter text.

8. Training, Controls, Safety Methods:

Click here to enter text.

9. Certifications:

I certify that all proposed materials, methods, and activities may be safely performed at BSL-1: Yes ☐ No ☐

I certify that all personnel have at minimum completed the Blackboard Biosafety training: Yes ☐ No ☐

10. Include up to a 500 word abstract of the project in the space below.

Click here to enter text.

		Click here to enter text.
Principal Investigator Signature	Date	Typed/Printed Name
		Click here to enter text.
Principal Student Investigator Signature	Date	Typed/Printed Name
		Click here to enter text.
Department Chair Signature	Date	Typed/Printed Name

Appendix D: Self-Assessment Tool

Question Number	*NIH Guidelines* Citation	Question	NIH Comments	Institution Comments/Notes
IBC MEMBERSHIP				
1	IV-B-2-a-(1)	How many members are currently on the institution's IBC?	The institution's IBC must be composed of no fewer than five members who collectively have experience and expertise in recombinant or synthetic nucleic acid molecule technology, the capability to assess the safety of research with recombinant or synthetic nucleic acid molecules, and the ability to identify any potential risk to public health or the environment. At least two of these individuals must not be affiliated with the institution except for their membership on the IBC.	4.1(D)(1) Appendix A
2	IV-B-2-a-(3)	Has the institution an IBC Chair?	The institution must file an annual report with NIH OSP which includes a roster of all members of the IBC and clearly indicates who is serving as the IBC Chair.	4.1(B) Appendix A
3	IV-B-2-a-(1)	Has the institution a BSO on the IBC (if necessary)?	A BSO must be appointed to the IBC if the institution conducts research at BL3, BL4, or conducts Large Scale research (defined as research in which a single containment vessel has greater than 10 liters of volume). When required, the individual serving as the BSO should be indicated on the roster registered with NIH OSP.	N/A (See Section 5)
4	IV-B-2-a-(1)	Has the institution designated a plant, plant pathogen, or plant pest containment expert on the IBC (if necessary)?	The IBC must include at least one individual with expertise in plant, plant pathogen, or plant pest containment principles when experiments subject to Appendix P, *Physical and Biological Containment for Recombinant or Synthetic Nucleic Acid Molecule Research Involving Plants,* are conducted at the institution. When required, the individual serving as the plant expert should be indicated on the roster registered with NIH OSP.	4.1(D)(3)

Question Number	*NIH Guidelines* Citation	Question	NIH Comments	Institution Comments/Notes
5	IV-B-2-a-(1)	Has the institution designated an animal containment expert on the IBC (if necessary)?	The IBC must include at least one individual with expertise in animal containment principles when experiments subject to Appendix Q, *Physical and Biological Containment for Recombinant or Synthetic Nucleic Acid Molecule Research Involving Animals* are conducted at the institution. When required, the individual serving as the animal expert should be indicated on the roster registered with NIH OSP.	4.1(D)(4)
6	IV-B-2-a-(1)	How many IBC members are not affiliated with the institution but represent the interests of the surrounding community with respect to health and protection of the environment?	The IBC shall have at least two members who are not affiliated with the institution (apart from their membership on the IBC) and who represent the interests of the surrounding community with respect to health and protection of the environment. These two individuals must be indicated on the roster registered with NIH OSP.	4.1(D)(2)
7	IV-B-2-a-(3)	Has the institution designated an IBC contact person on the IBC?	NIH OSP requires institutions to designate a contact person on the IBC roster whom NIH OSP can contact with questions and important information regarding the institution's IBC.	4.3(E)(2)
8	IV-B-2-a-(3)	Does the institution file a committee membership report annually with NIH OSP?	The institution must submit to NIH OSP at least annually: I. a roster of all IBC members clearly indicating the Chair, contact person, biological safety officer (BSO - if applicable), plant, animal or human gene transfer experts (if applicable) and non-affiliated members; and II. biographical sketches for all IBC members. IBC registrations and annual updates can be submitted using the IBC Registration Management System (IBC-RMS).	4.3(E)(2)

Question Number	*NIH Guidelines* Citation	Question	NIH Comments	Institution Comments/Notes
9	IV-B-6	Has the institution designated a human gene transfer expert on the IBC (if necessary)?	When conducting or sponsoring research with recombinant or synthetic nucleic acid molecules involving human subjects, the institution must ensure that there is an IBC member who has adequate experience and training in the field of human gene transfer. This individual must be indicated on the roster registered with NIH OSP.	4.1(D)(5)
10	Recommended Practice	Does the institution formally appoint IBC members?	A written policy should be in place that addresses the appointment of IBC members. Appointments of IBC members should be made by a senior institutional official.	4.1(A) - (D)
11	Recommended Practice	Are IBC members appointed for a fixed term?	NIH OSP recommends that members of the IBC be appointed for a fixed term of appointment, thus allowing for fresh perspectives to rotate periodically onto the IBC.	4.1(B)
12	Recommended Practice	How many staff members support the IBC and what are the lines of reporting for those staff?	Institutions should periodically conduct a thorough assessment of the resources necessary for the IBC to fulfill all of its responsibilities as articulated in Section IV- B of the *NIH Guidelines*, taking into account not only the protocol submission and review process, but also training and surveillance responsibilities as required under Sections IV-B-1-h and IV-B-2-b-(5) of the *NIH Guidelines* respectively.	None
13	Recommended Practice	What does the institution do to recognize or promote service on the IBC?	The ability to retain and recruit qualified IBC members is critically important for an IBC program to succeed. Recognition of service on the IBC is valuable not only for encouraging faculty to join the committee when invited to serve, but also for acknowledging institution-wide the value that the institution places on the IBC's role. At many institutions, IBC service counts toward service requirements that are a consideration for promotion and tenure.	Expectation and recognition of service: OP 04.01 ASU Councils and Committees OP 06.23 Tenure and Promotion Standards and Procedures

Question Number	*NIH Guidelines* Citation	Question	NIH Comments	Institution Comments/Notes
MEETINGS AND MINUTES				
14	IV-B-2-a-(4)	How does the IBC identify and handle potential conflicts of interest between IBC members and the review or approval of a research project in which they have a personal or financial interest? Is there a written policy for conflicts of interest?	Section IV-B-2-a-(4) of the *NIH Guidelines* states that no member of an IBC may be involved in the review or approval of a project in which he or she has been or expects to be engaged or has a direct financial interest. NIH encourages institutions to develop formal conflict of interest policies since this promotes attention to this matter and consistent approaches to dealing with it.	4.1(E)
15	IV-B-2-a-(6)	Are members of the public (other than non-institutional IBC members) permitted to attend IBC meetings?	When possible and consistent with the protection of privacy and proprietary interests, the institution is encouraged to open its IBC meetings to the public.	4.2(F)(3)
16	IV-B-2-a-(6)	How would an interested member of the general public learn about future IBC meetings dates, times and location?	When possible and consistent with the protection of privacy and proprietary interests, the institution is encouraged to make information regarding meeting times and locations available. Such Information could be posted on the institution's website or be otherwise publically accessible.	4.2(F)(3)
17	IV-B-2-a-(6) and IV-B-2-a-(7)	Is the conduct of official IBC business (e.g., protocol review and approval) done at a convened meeting (e.g., interactive / real-time / in-person)?	The *NIH Guidelines* do not prescribe how IBCs should be convened, but they do speak to the preparation of meeting minutes, and they encourage institutions to accommodate public attendance at meetings. Thus, IBCs should be convened in a manner that allows for fulfillment of these two expectations. Email exchanges cannot fulfill these expectations and thus are not an acceptable manner for the IBC to conduct official business. For further information regarding the conduct of IBC meetings, please visit our FAQs on the conduct of IBC meetings.	4.2(F)(2)

Question Number	*NIH Guidelines* Citation	Question	NIH Comments	Institution Comments/Notes
18	IV-B-2-a-(7)	Has the IBC ever received comments or questions from the general public about its activities? Are there policies or procedures for how such comments or questions would be handled? Has the institution forwarded any such comments to NIH OSP?	When public comments are made on the IBC's actions, the institution must forward both the public comments and the IBC's response to NIH OSP.	4.3(F)
19	IV-B-2-a-(7)	Does the IBC record minutes for every meeting?	Minutes must be kept for every IBC meeting. For information regarding NIH OSP's expectations on content of meeting minutes please refer to our FAQs.	4.2(F)(5)
20	IV-B-2-a-(7)	Are IBC meeting minutes available to the public upon request? If so, how are they provided?	Upon request, the institution shall make IBC meeting minutes available to the public. NIH OSP recommends the institution develop a formal written policy for how requested minutes will be provided.	4.2(F)(6) Upon request
21	IV-B-2-a-(7)	Is any information pertaining to the IBC meeting routinely not captured in the meeting minutes (e.g., Select Agent information, PI names, research agent descriptors, location of agents)? If so, please describe.	For information regarding NIH OSP's expectations on the content of meeting minutes please refer to our FAQs.	Regular meeting minutes created and preserved 4.2(F)(6) (Redaction Process)
22	Recommended Practice	With what frequency is the IBC convened?	While the *NIH Guidelines* do not speak to the frequency that the IBC should meet, NIH OSP encourages institutions assess the volume of their research and determine an appropriate frequency for the IBC to convene in order to ensure timely review of research.	4.2(F)(1)

Question Number	*NIH Guidelines* Citation	Question	NIH Comments	Institution Comments/Notes
23	Recommended Practice	Are PIs encouraged to attend IBC meetings where their research is discussed?	PI participation in the IBC meeting can not only enrich the discussion of the research at hand, but also raises the profile of the IBC within the investigator community. PI attendance can be particularly useful if the project is novel or especially complex and the IBC would benefit from a full description of the activities.	4.2(F)(1)
24	Recommended Practice	Does the institution have written policies for the redaction of IBC meeting minutes before they are released to the public?	In keeping with Section IV-B-2-a-(6) of the *NIH Guidelines*, institutions may redact certain information from IBC minutes if there are privacy or proprietary concerns. For information regarding NIH OSP's expectations on content of meeting minutes please refer to our FAQs.	4.2(F)(6)
PROTOCOL REVIEW AND RISK ASSESSMENT				
25	III-D	Does the institution have a form for registering protocols involving research with recombinant or synthetic nucleic acid molecules with the IBC?	The *NIH Guidelines* require that PIs submit a registration document to the IBC with pertinent information regarding their protocols. This information includes, but is not limited to, the source of the nucleic acid, the nature of the inserted nucleic acid sequence, the host and vector to be used, and containment conditions.	Appendix B
26	IV-B-2-b-(1)	Does the IBC use delegated or expedited reviews whereby any individual or subcommittee approves research on behalf of the IBC?	The IBC is responsible for reviewing all research with recombinant or synthetic nucleic acid molecules conducted at or sponsored by the institution that is subject to the *NIH Guidelines*. Expedited reviews or approvals by a subgroup of the IBC on behalf of the entire IBC for research subject to the *NIH Guidelines* is not in keeping with the requirements of the *NIH Guidelines*. Such formal business should only be conducted when a quorum of the IBC is present at a convened meeting.	N/A

Question Number	*NIH Guidelines* Citation	Question	NIH Comments	Institution Comments/Notes
27	IV-B-2-b-(1) and IV-B-7-c-(3)	Do PIs determine whether their research is exempt from the *NIH Guidelines?* See FAQ. Is the determination verified by the BSO or IBC? Are PIs required to register exempt work with the IBC?	Recombinant or synthetic nucleic acid molecule research that is exempt from the *NIH Guidelines* under section III-F need not be registered with the IBC, however the institution is responsible for ensuring PIs are correctly determining under which section of the *NIH Guidelines* their research falls. Many institutions register all recombinant DNA research and have the BSO or IBC Chair verify that the PI's initial determination is correct.	2.4 All rDNA research must be registered using Appendix B
28	IV-B-7-c-(3)	Do PIs register all research subject to Section III-A though III-E of the *NIH Guidelines*?	PIs must submit the initial research protocol and any subsequent changes if covered under Section III-A, III-B, III- C, III-D, or III-E to the IBC for review and approval or disapproval.	1.1 2.0 2.5
29	IV-B-7-c-(3) and IV-B-7-a-(2)	Does the registration document require PIs to identify what section of the *NIH Guidelines* their research is subject to?	PIs must submit the initial research protocol and any subsequent changes if covered under Section III-A, III-B, III-C, III-D, or III-E to the IBC for review. Thus it is incumbent upon PIs to be able to identify the appropriate section of the *NIH Guidelines* their research falls under.	Appendix B
30	Recommend Practice	How does the institution assess the IBC's performance and compliance with the *NIH Guidelines*?	NIH OSP recommends that institutions have mechanisms in place that allow senior administration to assess the performance of the IBC. For example, annual reports to the Institution's Responsible Official.	4.3(B)
31	Recommend Practice	How do PIs submit registrations detailing their research with recombinant or synthetic nucleic acid molecules to the IBC for review? How are PIs informed of the procedures for submitting new research to the IBC?	NIH OSP recommends institutions have a formalized written policy that communicates how PIs should submit their registrations to the IBC for review and approval. Furthermore, the institution should develop training for PIs in order to communicate these requirements.	2.1

Question Number	*NIH Guidelines* Citation	Question	NIH Comments	Institution Comments/Notes
32	Recommend Practice	What systems does the institution have in place to ensure that all research with recombinant or synthetic nucleic acid molecules that is subject to the *NIH Guidelines* and requires IBC review is being captured?	Various approaches can be used to ensure that all research requiring IBC review and approval is being captured. These include coordination and sharing of information between the IBC, IACUC, and the IRB, coordination with the grants and contracts office, and surveying relevant academic departments.	4.2(J)
33	Recommend Practice	Is the IBC empowered with the authority to enforce the *NIH Guidelines* and ensure that IBC approved conditions are adhered to?	The IBC should be granted the appropriate authority to fully investigate potential violations or compliance problems. The IBC's authority should be articulated in an IBC charter or similar document.	4.2(D)
34	Recommend Practice	Does the IBC ever grant approvals dependent upon certain conditions being met?	If the IBC grants approvals based on specific conditions being met then there should be a formal mechanism for verifying the conditions are indeed fulfilled.	N/A
35	IV-B-2-b-(2)	How are PIs informed of the outcome of the IBC's review of their submitted research protocols involving recombinant or synthetic nucleic acid molecules?	Section IV-B-2-b-(2) requires the IBC to notify PIs of the results of the IBC's review and approval. For example, sending a formal letter stating the approval conditions, protocol expiration date and other pertinent information.	2.3(C) Appendix B Instructions 2.4 Written notice of IBC determination to PI
36	Recommend Practice	Do registrations have an expiration date? How long is approval granted for? Does the IBC require periodic (annual) updates? How are PIs made aware of these requirements?	Because research is typically dynamic, NIH OSP recommends that protocol registrations have an expiration date, after which time a new registration document must be submitted. Many institutions also have a periodic (annual) update form or an amendment form for registering any changes to the protocol.	2.3(D) IBC determines permit length BSL2 and above requires annual update Written notice of IBC determination

Question Number	*NIH Guidelines* Citation	Question	NIH Comments	Institution Comments/Notes
37	Recommend Practice	Does the institution encourage communication and coordination between the IBC and other institutional oversight committees (such as the IRB and IACUC)?	Communication between the IBC, the IRB, and the IACUC can be one of an array of mechanisms for institutions to ensure that they are capturing all research with recombinant or synthetic nucleic acids subject to the *NIH Guidelines*.	4.2(J)
POLICIES AND PROCEDURES				
38	IV-B-1-A	What policies are in place to ensure that the institution is in compliance with the *NIH Guidelines?*	The *NIH Guidelines* require that institutions establish and implement policies that provide for the safe conduct of research with recombinant or synthetic nucleic acid molecules and ensure compliance with the *NIH Guidelines*.	Biosafety Plan Institutional Biosafety Committee
39	Recommend Practice	Has the institution developed a charter or other document defining IBC member roles and responsibilities, and policies and procedures for the general implementation of the *NIH Guidelines*?	NIH OSP recommends that institutions develop an IBC charter or similar document that clearly articulates the responsibilities the IBC. The IBC charter is also an ideal mechanism for documenting IBC policies and procedures, such as managing conflict of interest, minute taking, etc.	IBC Charter and Process Document
40	Recommend Practice	What review activities, if any, beyond those described in the *NIH Guidelines* have been delegated to the IBC by the institution?	Although not required by the *NIH Guidelines*, many IBCs review research that is not subject to the *NIH Guidelines* but nonetheless may pose a biohazard.	1.1 2.1
TRAINING AND EDUCATION				
41	IV-B-7-d-(2)	Does the institution provide resources to investigators to assist them in conducting training for laboratory staff regarding laboratory safety and the implementation of the *NIH Guidelines?*	The *NIH Guidelines* require that institutions ensure appropriate training for laboratory staff regarding laboratory safety and implementation of the *NIH Guidelines*. Many institutions offer a standard general biosafety course (including material addressing requirements under the *NIH Guidelines*) to assist investigators with the training requirements.	<u>General Training</u>: Chemical Hygiene Plan and Training Biosafety Plan and Training <u>IBC Permitted or Registered Activities</u>: CITI Training Program – See Section 7.3: Training in document

Question Number	*NIH Guidelines* Citation	Question	NIH Comments	Institution Comments/Notes
42	IV-B-7-d-(2)	How do PIs instruct and train laboratory staff in the procedures for dealing with research-related accidents / illnesses in the laboratory?	PIs are required to train their laboratory staff in the practices and techniques required to ensure safety and the procedures for dealing with accidents. IBC-approved written policies for dealing with accidents involving recombinant or synthetic nucleic acid molecules in the laboratory should be available to all applicable personnel.	3.2(C)
43	IV-B-1-h	Does the institution conduct training with respect to the *NIH Guidelines* (e.g. content, format, timing, requirements) for PIs and laboratory staff?	The *NIH Guidelines* require that the institution ensure appropriate training for PIs and laboratory staff regarding laboratory safety and implementation of the *NIH Guidelines*. Furthermore, institutions should provide training to PIs regarding the responsibilities and expectations of PIs under the *NIH Guidelines.* NIH OSP has an informational brochure available that institutions can use to instruct their investigators in the requirements of the *NIH Guidelines*.	CITI Training Program – See section 7.3: Training in document
44	IV-B-1-h	How are animal handlers informed of the risks associated with research involving recombinant or synthetic nucleic acid molecules used with animals? Are there postings in the rooms / cages etc?	It is the responsibility of the PI to ensure that laboratory staff and others involved in the conduct of research with recombinant or synthetic nucleic acid molecules are sufficiently trained regarding laboratory safety and the *NIH Guidelines*. Training programs should be in place that fulfill these expectations.	N/A
45	Recommended Practice	Does the institution keep records documenting the training individual personnel have undergone relative to the *NIH Guidelines*?	NIH OSP recommends keeping records of training that individual personnel have undergone relative to the *NIH Guidelines*. This includes laboratory specific training given by the PI.	General Training: Blackboard Biosafety IBC Training: CITI Program – See section 7.3: Training in document

Question Number	*NIH Guidelines* Citation	Question	NIH Comments	Institution Comments/Notes
SURVEILLANCE, EMERGENCY PLANNING, AND RESPONSE				
46	IV-B-1-i	Does the institution have a health surveillance program for laboratory workers conducting research with recombinant or synthetic nucleic acid molecules?	The institution shall determine the necessity for health surveillance of personnel conducting research with recombinant or synthetic nucleic acid molecules; and if appropriate, establish a health surveillance program for such projects. The institution must establish and maintain a health surveillance program for personnel engaged in large-scale research or activities involving viable organisms containing recombinant or synthetic nucleic acid molecules which require BL3 or higher containment.	1.2(F) Appendix B, Section M (Risk Assessment)
47	IV-B-1-i	Does the institution have a health surveillance program for animal care workers involved in high containment research with recombinant or synthetic nucleic acid molecule research?	The institution must establish and maintain a health surveillance program for personnel engaged in animal research involving viable recombinant or synthetic nucleic acid molecules that require BL3 or higher laboratory containment.	N/A
48	IV-B-1-j	Does the institution report significant incidents, violations and research- related accidents and illnesses to NIH OSP? Are such incidents reported to NIH OSP in the appropriate time frame?	The *NIH Guidelines* require that significant incidents, violations and research-related accidents and illnesses be reported to NIH OSP within thirty days or immediately depending on the nature of the incident. For information regarding incident reporting requirements please refer our FAQs.	1.3 Reported immediately to IBC Within 30 days to NIH OSP
49	IV-B-2-b-(5)	Does the IBC keep track of all protocols falling under the *NIH Guidelines* currently registered with the IBC?	Section IV-B-2-b-(5) of the *NIH Guidelines* requires IBCs to periodically review research with recombinant or synthetic nucleic acid molecules conducted at the institution. By having mechanisms for tracking currently registered protocols, the institution can ensure compliance with this requirement.	4.2(B)

Question Number	*NIH Guidelines* Citation	Question	NIH Comments	Institution Comments/Notes
50	IV-B-2-b-(6) and B-7-a-(6)	Does the institution have plans or policies for the following if recombinant or synthetic nucleic acid molecules are involved: A) Personnel contamination, B) Research-related illness, C) Accidental spills, D) Loss of containment, E) Violations?	On behalf of the institution, the IBC must adopt emergency plans covering accidental spills and personnel contamination resulting from research with recombinant or synthetic nucleic acid molecules subject to the *NIH Guidelines*.	3.2(C) & (E) 3.3(E) 4.2(C)(4) 5.2(F)
51	IV-B-2-b-(7	What procedures are followed to ensure reporting of any significant violations of the *NIH Guidelines,* or significant research-related accidents / illnesses to the appropriate institutional official and to NIH OSP? How has this policy been conveyed to the lab personnel?	Significant problems with, or violations of, the *NIH Guidelines* and any significant research related accidents or illnesses must be reported to NIH OSP within 30 days (or immediately depending on the nature of the incident). The most effective way to ensure this provision is met is to have a formalized institutional policy describing how these incidents will be reported to NIH OSP and by whom. This policy should be widely disseminated to PIs and laboratory staff and discussed during training.	3.3(B) 4.3(C) 5.2(E) 5.3(B) Biosafety Plan (BSP) PI communicates to lab staff All employees with exposure trained in BSP
52	IV-B-3-c-(1)	Are periodic inspections conducted to ensure that laboratory standards and containment conditions required by the IBC are rigorously followed? If so, how often and by whom? Are problems communicated to the IBC?	The Biological Safety Officer is charged with performing periodic inspections to ensure that laboratory standards are rigorously followed. Any significant problems that are encountered as a result of these inspections should be promptly reported to the IBC.	5.2(B) BSO inspects, Chair ensures if no BSO Frequency based upon risk Reported directly to IBC
53	Recommended Practice	Does the institution have a laboratory inspection checklist?	Section IV-B-3-c-(1) requires periodic inspections to ensure that laboratory standards are rigorously followed. Having an inspection checklist can help ensure standardized inspection practices.	Not at this time

Question Number	*NIH Guidelines* Citation	Question	NIH Comments	Institution Comments/Notes
PHYSICAL CONTAINMENT – LABORATORY ENVIRONMENT				
54	IV-B-7-e-(1) and Appendix G	Who determines the minimum required Personal Protective Equipment (PPE) for laboratory staff working with recombinant or synthetic nucleic acid molecules? Who trains personnel in the proper use of PPE? How is compliance monitored?	Determining the minimum PPE required for laboratory staff is a responsibility of the PI. Training for the proper use of PPE should also be conducted by the PI. The PI is also responsible for supervising the safety performance of the laboratory staff. This would include monitoring PPE compliance.	3.1(B)(2) 3.2(C) 3.3(A) PI trains in use and enforces BSO monitors and reviews
55	IV-B-7-e-(4)	Does the institution ensure that laboratory equipment (cabinets, HEPA filters) are properly maintained and functioning properly?	The PI is responsible for ensuring the integrity of the physical containment (e.g. biosafety cabinets) and the biological containment (e.g. purity and genotypic and phenotypic characteristics). The institution should consider a policy of periodic certification and maintenance of laboratory equipment.	3.3(D) Biosafety Plan
56	IV-B-2-b-(1)	Does the IBC review and approve plans for the renovation or construction of laboratories and other facilities where research with recombinant or synthetic nucleic acid molecules is conducted?	IBCs are responsible for assessments of facilities contemplating research. The IBC's review of construction plans can help ensure that new facilities comport with the conditions and containment measures described in the *NIH Guidelines*.	Biosafety Plan
57	Appendix G	How does the institution dispose of liquid and solid waste containing recombinant or synthetic nucleic acid molecules? Are there written Standard Operating Procedures (SOP) for waste disposal?	As part of standard microbiological practice, all liquid and solid laboratory waste containing recombinant or synthetic nucleic acid molecules must be decontaminated before disposal.	Appendix B Biosafety Plan

Question Number	*NIH Guidelines* Citation	Question	NIH Comments	Institution Comments/Notes
58	Appendix G-II-C	Does the institution engage in research with recombinant or synthetic nucleic acid molecules at BL3 or higher? If so, has a BSO been appointed?	Appendix G-II-C discusses the standard microbiological practices, the special practices, containment equipment and laboratory facilities requirements for research being conducted at BL3. A BSO must be appointed when conducting research at BL3 or higher.	N/A No (See Section 5)
59	Appendix G-II-D	Does the institution engage in recombinant or synthetic nucleic acid molecule research at BL4? If so, has a BSO been appointed?	Appendix G-II-D discusses the standard microbiological practices, the special practices, containment equipment and laboratory facilities requirements for research being conducted at BL4. A BSO must be appointed when conducting research at BL3 or higher.	N/A No (See Section 5)
60	Appendix G	Does the institution have policies and procedures regarding the disposal of recombinant or synthetic nucleic acid molecule containing animal waste?	Appendix G-II-B-2-i and Appendix G-II- C-2-n require that all recombinant or synthetic nucleic acid molecule containing wastes (including transgenic animal carcasses) from laboratories and animal rooms are appropriately decontaminated before disposal. NIH OSP strongly recommends the institution have formalized written policies for how animal waste containing recombinant or synthetic DNA is disposed.	Appendix B Biosafety Plan
61	Recommended Practice	Does the institution have any autoclave verification program?	Autoclave verification programs should be employed in order to ensure that autoclaves are working properly and effectively. The institution should consider having a written SOP detailing the methodology and frequency of testing.	Appendix B Biosafety Plan

Question Number	*NIH Guidelines* Citation	Question	NIH Comments	Institution Comments/Notes
PHYSICAL CONTAINMENT – LARGE SCALE RESEARCH				
62	Appendix K	Does the institution engage in large-scale research or production activities involving organisms containing recombinant or synthetic nucleic acid molecules? What is the largest volume? What BL is used? If the institution does conduct Large Scale Research has a BSO been appointed?	Appendix K specifies physical containment guidelines for large scale (greater than 10 liters of culture) research or production involving viable organisms containing recombinant or synthetic nucleic acid molecules. Appendix K applies to large scale research or production activities as specified in Section III-D-6 of the *NIH Guidelines*. If the institution is performing large scale research, a BSO must be appointed.	N/A BSL 1
EXPERIMENTS REQUIRING IBC, RAC REVIEW, AND NIH DIRECTOR APPROVAL				
63	III-A-1-a	Does the institution conduct any experiments that involve the deliberate transfer of a drug resistance trait to microorganisms not known to acquire that trait naturally?	Experiments involving the deliberate transfer of a drug resistance trait to microorganisms not known to acquire that trait naturally that could compromise the ability to control disease agents in humans, veterinary medicine, or agriculture, must be reviewed by the RAC and approved by the NIH Director before initiation. Additional information on Major Actions can be found in the following FAQs	N/A
EXPERIMENTS REQUIRING NIH AND IBC APPROVAL				
64	III-B-1	Does the institution conduct research involving the deliberate formation of recombinant or synthetic acid molecules containing genes for the biosynthesis of toxin molecules lethal to vertebrates at an LD50 of less than 100 ng/kg of bodyweight?	Experiments involving the deliberate formation of recombinant or synthetic acid molecules containing genes for the biosynthesis of toxin molecules lethal to vertebrates at an LD50 of less than 100 ng/kg of bodyweight must be reviewed and approved by both NIH OSP and the IBC before initiation. A list of specific experiments already approved under Section III-B-1 may be obtained by contacting NIH OSP at: NIHGuidelines@od.nih.gov.	N/A

Question Number	*NIH Guidelines* Citation	Question	NIH Comments	Institution Comments/Notes
65	III-B-2	Does the institution wish to conduct an experiment previously approved as a Major Action under Section III-A-1-a of the *NIH Guidelines?*	NIH OSP may determine that a proposed experiment is equivalent to an experiment that has previously been approved by the NIH Director. An experiment will only be considered equivalent if, as determined by NIH OSP, there are no substantive differences and pertinent information has not emerged since submission of the initial III-A-1-a experiment that would change the biosafety and public health considerations for the proposed experiments. If such a determination is made by NIH OSP, these experiments will not require review and approval under Section III-A, but will instead be subject to Section III-B.	N/A
EXPERIMENTS INVOLVING HIGHLY PATHOGENIC INFLUENZA				
66	III-D-7	Does the institution conduct research involving Highly Pathogenic Influenza?	Research involving influenza viruses containing the H2 HA segment must be conducted at BL3 enhanced containment, while experiments with H2 HA gene in cold- adapted, live attenuated vaccine strains may be conducted at BL2 (III-D-7-a). Experiments involving influenza viruses containing a majority of genes and/or segments from HPAI H5N1 must be conducted at BL3 enhanced containment. Experiments with a minority of genes and/or segments from HPAI H5N1 influenza virus must be performed at BL3 enhanced unless a risk assessment determines that the can be safely conducted at BL2 (III-D- 7-b). Experiments involving influenza viruses containing any gene or segment from 1918 H1N1 must be performed at BL3 enhanced containment (III-D-7-c).	N/A
EXPERIMENTS INVOLVING HUMAN GENE TRANSFER				
67	Appendix M	Does the institution participate in or sponsor research with recombinant or synthetic nucleic acid molecules involving human subjects?	The requirements of Appendix M apply to human gene transfer research conducted at or sponsored by an institution that receives any support for research with recombinant or synthetic nucleic acid molecules from NIH.	N/A

Question Number	*NIH Guidelines* Citation	Question	NIH Comments	Institution Comments/Notes
68	Appendix M	Has a PI at the institution ever submitted a human gene transfer protocol to the NIH OSP? Did the protocol undergo in-depth public review at one of the RAC meetings?	Research proposals involving the deliberate transfer of recombinant or synthetic nucleic acid molecules, or DNA or RNA derived from recombinant or synthetic nucleic acid molecules, into one or more human subjects must be registered with NIH OSP and may undergo review by the RAC if specific criteria are met. The IBC may not give final approval of a protocol until the registration process is complete. For protocols that undergo RAC review, the registration process is not complete until RAC review has occurred. This is to ensure that the PI and the IBC take the RACs recommendations into consideration before the protocol is approved.	N/A
69	Appendix M	Does the institution have written policies for reporting serious adverse events on human gene transfer trials to the IBC?	Appendix M-I-C-4-a and Appendix M-I- C-4-b describe the content and format and time frame for reporting, respectively. NIH OSP recommends written policies and procedures be in place for reporting serious adverse events to the IBC.	3.3(B) 4.2(D)
70	Appendix M	Does the institution have written policies for reporting serious adverse events that are associated with the use of human gene transfer products to NIH OSP? What is the required time frame for reporting serious adverse events as well as the threshold for determining what is a reportable event to NIH OSP?	Appendix M-I-C-4-a and Appendix M-I-C-4-b describe the content and format, and time frame for reporting, respectively. NIH recommends institutions have written policies and procedures in place for reporting serious adverse events to NIH OSP and other required entities.	3.3 4.2(D) Biosafety Plan Immediately reported to BSO and IBC 30 days to NIH OSP
71	Appendix M	Does the IBC review informed consent documents to ensure that human subjects are adequately informed of the possible risks, discomforts, and side effects that are associated with the use of gene transfer agents?	Section III-C of the *NIH Guidelines* requires that the IBC approve human gene transfer protocols prior to subject enrollment. As part of this approval process IBCs should review the informed consent documentation from the perspective of risks associated with the use of recombinant or synthetic nucleic acid molecules.	N/A

Question Number	*NIH Guidelines* Citation	Question	NIH Comments	Institution Comments/Notes
72	Recommended Practice	Does the institution encourage the use of the GeMCRIS database for the submission of annual reports and the reporting of adverse events on human gene transfer trials to NIH OSP?	For additional information, visit the GeMCRIS page on the NIH OSP Web site.	N/A
PHYSICAL AND BIOLOGICAL CONTAINMENT FOR RESEARCH INVOLVING PLANTS				
73	Appendix P	Does the institution engage in research with recombinant or synthetic nucleic acid molecules involving plants subject to Appendix P of the *NIH Guidelines*?	Appendix P of the *NIH Guidelines* specifies the physical and biological containment conditions and practices suitable to the greenhouse conduct of plant experiments involving recombinant or synthetic nucleic acid molecules.	N/A
74	Appendix P	Does the institution have policies and procedures regarding the proper disposal of transgenic plants?	Transgenic plants and associated organisms must be decontaminated in accordance with the requirements of Appendix P of the *NIH Guidelines.* NIH OSP recommends having formalized written policies describing procedures to be followed when disposing of transgenic plants. These plans should be approved by the IBC.	Biosafety Plan
75	Appendix P	Has the institution ever allowed the field release of a transgenic plant? If so, was authorization obtained from the proper agency?	The *NIH Guidelines* address contained research only. Experimental field releases require proper authorization from a responsible federal agency.	N/A

Question Number	*NIH Guidelines* Citation	Question	NIH Comments	Institution Comments/Notes
PHYSICAL AND BIOLOGICAL CONTAINMENT FOR RESEARCH INVOLVING ANIMALS				
76	Appendix Q	Does the institution engage in research with recombinant or synthetic nucleic acid molecules involving large animals subject to Appendix Q of the *NIH Guidelines*? (Large animals subject to Appendix Q include transgenic animals and animals into which viable modified recombinant or synthetic nucleic acid molecules have been introduced).	If the institution engages in recombinant or synthetic nucleic acid molecule experiments involving large animals then the institution is required to follow the procedures of Appendix Q of the *NIH Guidelines.* Appendix Q pertains to research involving animals of a size or having growth requirements that preclude the use of containment for laboratory animals.	N/A
77	Appendix Q-1-B-2	Does the institution inventory and track large animals subject to Appendix Q to ensure proper disposal?	The *NIH Guidelines* require that institutions keep a permanent record of the experimental use and disposal of animals covered under Appendix Q.	N/A
78	Appendix Q	Does the institution have policies and procedures regarding the proper disposal of transgenic animals covered under Appendix Q?	Large animals must be disposed of in accordance with the procedures of Appendix Q of the *NIH Guidelines.* NIH OSP recommends that the institution have formalized, IBC approved polices describing how large animals are to be disposed.	N/A
79	Appendix Q	Does the institution have policies and procedures regarding the disposal of infectious animal waste covered under Appendix Q?	Infectious animal wastes must be disposed of in accordance with Appendix Q of the *NIH Guidelines.* NIH OSP recommends that the institution have formalized, IBC approved polices describing how infectious animal wastes containing recombinant or synthetic nucleic acid molecules will be disposed.	Biosafety Plan
80	Appendix Q	Has the institution conducted the field release of a transgenic animal covered under Appendix Q? From what agency was authorization obtained?	The *NIH Guidelines* address contained research only. Experimental field releases require proper authorization from a responsible federal agency.	N/A

Question Number	*NIH Guidelines* Citation	Question	NIH Comments	Institution Comments/Notes
RESOURCES				
81	Recommended Practice	Has the institution developed tools for communicating requirements for the conduct of research subject to the *NIH Guidelines*?	NIH OSP recommends that the institution develop a method for disseminating information regarding the *NIH Guidelines* to those faculty and staff in need of such information. Effective methods include newsletters, email blasts and FAQ's.	Website
82	Recommended Practice	Does the institution encourage attendance at professional or scientific conferences related to biosafety or the *NIH Guidelines*?	NIH OSP encourages support of professional development particularly for IBC members and staff.	CITI Training Program

NIH OSP hopes you find this resource helpful. Comments are always welcomed and may be sent to NIH OSP at: SciencePolicy@od.nih.gov

For general questions related to the NIH Guidelines and the submission of incident reports, please email: NIHGuidelines@od.nih.gov

For questions related to human gene transfer protocols and all human gene transfer protocol related submissions, please email: HGTprotocols@mail.nih.gov