IBC SOP:	Statement on IBC Roles and Responsibilities	
SOP#300.00	IBC Approval: 6/26/2024	IO Approval: 6/27/2024

3.0 Introduction

This section summarizes the roles and responsibilities of all stakeholders involved in IBC. Roles are appointed in accordance with the *NIH Guidelines* and other relevant regulatory standards.

3.1 Institutional (A&M-SA) Responsibilities:

Under the NIH Guidelines and A&M University System Regulation 15.99.06 Use of Biohazards in Research, Teaching and Testing, A&M-SA has an institutional responsibility to support the A&M-SA IBC and its activities. This includes, but is not limited to, the following:

- The IBC Rule 15.99.06.O1
- Establishing an IBC (NIH Guidelines Section IV-B-1-b; TAMUS Reg. 15.99.06 § 2.3)
- Ensuring that the IBC has adequate membership with necessary expertise (NIH Guidelines Section IV-B-2.
- Ensure appropriate training for the IBC Chair and members, Biological Safety Officer (BSO), Principal Investigators and laboratory staff regarding lab safety and implementation of NIH Guidelines Section IV-B-1-h.
- Filing an annual report with the NIH Office of Science Policy (OSP).
- Provide administrative support for IBC activities.
- Providing adequate lab space and facilities.

3.2 Institutional Official Responsibilities:

At A&M-SA, the Vice Provost for Research & Health Sciences serves as the Institutional Official (IO) for the IBC. The A&M-SA IBC is authorized by and reports to the Institutional Official (IO) as appointed by the A&M-SA President. Responsibilities of the IO include:

- Appoint the IBC Chair, Vice-Chair and committee members in accordance with the *NIH Guidelines* and other university requirements as applicable.
- Report any significant problems, or violations to U.S. Federal, State, or local agencies as applicable. If appropriate, agency reporting may be delegated to the Director of Research Compliance (DRC), (BSO) or IBC.
- Provides appropriate resources to support and sustain the core objectives and responsibilities of the committee and associated biosafety program.
- Grant the IBC, DRC and Biological Safety Officer (BSO) authority to oversee the safe and responsible use of biological hazards at A&M-SA.
- Impose or uphold disciplinary actions or sanctions on principal investigators (PIs) or laboratory supervisors who fail to comply with established regulations, standards, guidelines, or university policies.

3.3 Director of Research Compliance (DRC) Responsibilities:

At A&M-SA, the DRC serves as the advisor for the IBC. The Director is authorized by and reports to the Institutional Official (IO) as appointed by the A&M-SA President. Responsibilities of the DRC include:

- Files annual reports to NIH and OSP.
- Report committee composition annually to the NIH Office of Science Policy. See SOP 600.00.
- Monitor Federal and state regulations and draft revised policies and procedures to remain compliant.
- Complete Grant/Protocol comparison
- Review memberships and counsel IBC and chair
- Appointment of consultants

  To assist with the review, the IBC may request the services of a consultant, who will provide written

review and may attend the convened meeting but will not have voting privileges. The IBC office will follow the process outlined in Ad Hoc expert guidance document. Consultant(s) shall be included in the annual report to the NIH/OSP. DRC will complete administrative work related to this.
- Organize Meetings and Arrange for training PI's, staff and students as needed.
- Reporting unanticipated events and noncompliance to TAMU and NIH

3.4 Research Compliance Coordinator (Office of Research and Health Sciences)

The Research Compliance Coordinator (RCC) will provide overall administrative support and will coordinate IBC protocol reviews and meetings. Responsibilities of the RCC include, but are not limited to, the following:
- Provide the necessary liaison between the research personnel and the IBC.
- Provide all necessary documentation, forms, regulatory guidelines, and regulations to Principal Investigators.
- Draft IBC correspondences to the investigators.
- Maintain IBC registration forms and records.
- Communicate with the IRB or IACUC when protocols involve human subjects or animals.
- Provide administrative support for the IBC by scheduling meetings, arranging meeting space and taking meeting minutes.
- Distribute IBC documents to Chair and IBC for review.
- Maintain census of the primary reviewer assignments, meeting attendance, current CV and training records.

3.5 IBC Responsibilities and Objectives:

The primary objective of the IBC is to ensure the safe, responsible, and compliant management of biological molecules, biological hazards and toxins used in research, teaching, and diagnostic testing. To achieve that objective, the A&M-SA IBC will:
- Follow the system regulations and IBC rule. Establish, communicate, and monitor policies, practices, and procedures covering biological hazards which are in accordance with applicable regulatory standards and guidelines.
- Review biological hazard registrations to ensure compliance with regulations, guidelines, and adopted policies. Review will include an independent assessment of the risk(s), required safety practices, biological/physical containment and associated facilities, and training and expertise of affiliated personnel.
- Ensure that research involving GDMO's is reviewed by members with adequate expertise using ad hoc experts or consultants as necessary [ex: species specific containment, ecological or environmental risk assessment].
- Regularly assess safety practices and containment facilities to ensure they are appropriate for the proposed biological hazards removal and affiliated procedures. The IBC will use the biosafety levels published by the CDC as the usual standards of containment to be set or work with a given biological agent.
- Investigate and recommend corrective actions for accidents, exposures, illnesses, environmental releases or other adverse events involving biological hazards. The NIH Office of Science Policy (OSP), CDC, USDA, or other regulatory or funding agencies will be notified if required.
- Investigate and set corrective actions for violations of policies, safety practices, or procedures. The IBC, at its discretion, may deny, suspend, or terminate approval for use of biohazardous materials if such use poses a risk to personnel or public health and safety, or for issues of noncompliance.
- Periodically review the IBC policies and procedures and modify them as necessary to ensure appropriate biosafety measures and adherence with federal and state requirements.

- The IBC also assists RA-EH&S in the development and review of policy involving potentially biohazardous agents.
- To immediately report any confirmed BSL-2 research-related illnesses to the appropriate institutional officials and NIH's Office of Science Policy.
- To immediately report any accidents, or significant problems with or violations of the NIH Guidelines to the appropriate institutional officials and NIH's Office of Science Policy.

3.6 IBC Members Responsibilities:

The IBC members' responsibilities include:

- Complete biosafety regulatory awareness training (IBC training) before participating in topics as necessary. (see SOP 900.00).
- To maintain up-to-date knowledge about recombinant DNA technology, standards, biosafety, biosecurity, waste management, shipping requirements, institutional policies, and procedures.
- To assist RCC in answering Principal Investigators (PIs) if they have questions or require clarification regarding requested revisions to a protocol or amendment as necessary.
- To be familiar with the NIH Guidelines, Biosafety Manual, and BMBL recommendations.
- Attend meetings; notify the RCC if attendance is not possible.
- Review submitted protocols as assigned and provide feedback to the IBC as necessary.

3.7 IBC Chair:

The IBC Chair responsibilities include:

- Set meeting agendas and establish meeting dates.
- To convene the meeting, including calling the meeting to order, directing deliberations of the committee, requesting motions and seconds, taking votes, closing the meeting at the conclusion of business.
- Ensure IBC members are adequately trained to review protocols and present them to the committee (primary & secondary reviewers).
- To approve attendance of individuals other than IBC members or staff.
- Review protocols prior to official committee decisions made at the convened meeting.
- To assign IBC members to review protocols and present them to the committee (primary & secondary reviewers) and designate tasks for members as required.
- Lead or assign investigations of unanticipated events or non-compliance.
- Review and approve amendments and updates as necessary.

3.8 The Vice-Chair:

The IBC Vice-Chair responsibilities include:

- Participate in chair responsibilities as assigned.
- In addition to member responsibilities, the vice chair will assume the responsibilities of the Chair in the Chair's absence or in instances when the Chair is in conflict with a protocol review.

3.9 Biosafety Officer (BSO):

The Biosafety Officer (BSO) provides expert technical consultation and is responsible for developing, implementing, coordinating, and maintaining a comprehensive biosafety, biocontainment, and biosecurity management program for A&M-SA, to ensure compliance with appropriate regulatory requirements for research and teaching laboratories.

Responsibilities shall include but are not limited to:

- Develop, implement, and coordinate a comprehensive biological safety program for the university to enhance institutional biosafety-related objectives and to ensure compliance with all applicable regulations, guidelines, policies, and directives.

- Coordinates, quality controls, and monitors the delivery of biosafety education and training to all A&M-SA faculty, staff, and students who work with or have potential for exposure to biological pathogenic agents.
- Monitors A&M-SA teaching and research activities involving the use of biological materials and s/rNA molecules for compliance with appropriate regulations, policies, procedures, and best practices.
- Reviews, advises and conducts risk analysis for Gene Derived Modified Organisms [GDMO].
- Reviews research protocol applications, proposals, and activities involving biohazardous materials and s/rNA molecules and approves or recommends modifications to ensure safe practices; provides guidance to researchers and/or performs follow-up as appropriate.
- Informs and educates faculty, staff, students, and other constituencies regarding biosafety issues; develops comprehensive biosafety educational and outreach programs for teaching and research laboratories.
- Inspects research and teaching facilities for compliance with regulations and guidelines pertaining to the use, handling, and disposal of potential biohazards and s/rNA molecules; participates in the review and investigation of incidents and injuries involving biological materials occurring on university campus or off campus leased spaces and participates in the development of corrective action plans.
- Develops and implements emergency response procedures for incidents involving biohazardous agents and materials and maintains A&M-SA Spill Clean-up Plan for biohazards; develops medical surveillance criteria for activities involving biohazards and related materials; responds to biohazardous materials incidents as appropriate.
- Serves as principal source of expertise to the university regarding chemical safety, appropriate equipment, facilities, and work practices for protecting laboratories, staff, and the environment from contamination and infectious organisms.

Provides technical guidance to faculty and staff in the development of biosafety plans; advises facilities and physical plant staff regarding technical and programmatic issues involving laboratory biosafety design and maintenance.

3.10 Principal Investigator (PI)

The PI is defined as the faculty member or other university employee who is leading an activity (research, teaching, or other activity). The PI is accountable for all activities occurring in his/her lab and responsible for full compliance with applicable regulatory standards, guidelines and policies/procedures set forth by the University. The PI is primarily responsible for the prudent management of chemical biological hazards and the safety and health of laboratory staff, students, volunteers, and visitors. Although the PI may choose to delegate these aspects to other laboratory personnel or faculty, this does not absolve the PI of his/her ultimate responsibility.

- The PI is responsible for compliance with the NIH Guidelines in the conduct of recombinant or synthetic nucleic acid molecule research per system policy and TAMUSA rule:
  - The PI must determine whether experiments are covered by Section III-E, Experiments that Require Institutional Biosafety Committee Notice Simultaneous with Initiation and ensure that the appropriate procedures are followed.
  - Attend orientation and receive training. (see SOP 900.00)
- Select appropriate practices and laboratory techniques to be used for research.
- Determine the required levels of physical and biological containment in accordance with the NIH Guidelines. Investigate and report any significant problems pertaining to operation and implementation of containment practices and procedures in writing to appropriate authority.
- Submit an initial Application for IBC Permit and any subsequent changes to the IBC for review and approval or disapproval.
- Make available to all laboratory staff the protocols that describe potential biohazards and the precautions to be taken.

- Instruct, supervise and train laboratory staff in: (i) Practices and techniques required to ensure safety, (ii) Procedures for dealing with accidents, and submit copy of training to the IBC.
- Maintain updated list of active lab personnel.
- Inform laboratory staff of the reasons and provisions for any precautionary medical practices advised or requested.
- Create and maintain protocol Lab Specific Biosafety Safety Manual.
- Promptly attend to questions asked during review process.
- Remain in communication with the IBC throughout the conduct of the project.

3.11 Laboratory Personnel (staff, students, volunteers)

Individuals must complete the required training regarding biological safety practices and techniques. This includes working with potentially biohazardous agents using the appropriate containment and personal protective equipment as directed by the supervisor and PI. Laboratory personnel must complete:

- All required training programs offered by the university.
- Become familiar with lab-specific biological hazards of the protocol.
- Abide by all biosafety precautions that are relevant to the assigned duties.
- Use prescribed personal protective equipment directed by the supervisor and in accordance with proper biosafety precautions.
- Report any observed unsafe conditions and unsafe practices to the PI, DRC, IBC or RA-EH&S (BSO) to ibc@tamusa.edu.
- Understand the risks of working with biological materials/hazardous chemicals.
- Look out for the safety of others in the lab and lab facilities.
- Conscientiously follow lab-specific biosafety practices and procedures.
- Inform the PI of any health condition that may be a result of or complicated by their work in the lab.
- Report to the PI, BSO or IBC all problems, procedural discrepancies, spills, or accidental releases as soon as they occur.
- Report any significant violations in biosafety policy, practices, or procedures that are not resolved by the PI to the BSO, DRC or IBC.

History:

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