# TEXAS A&M UNIVERSITY – CORPUS CHRISTI
## INSTITUTIONAL BIOSAFETY COMMITTEE (IBC)
### POLICIES AND PROCEDURES MANUAL

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Section 1: Introduction

1.0 Purpose
It is the responsibility of the Texas A&M University – Corpus Christi Institutional Biosafety Committee (IBC) to review, approve and oversee the use of recombinant DNA (rDNA), biohazardous agents, materials and toxins in all research or teaching activities conducted by Texas A&M – Corpus Christi facilities or research personnel.

The Institutional Biosafety Committee Policies and Procedures Manual (IBC Policies) provides a review of the relevant regulatory and local requirements. Since laboratory work can involve exposure not only to rDNA, biohazardous agents, materials and toxins, but also to chemical and radiological hazards, the IBC Policies should be used in conjunction with any other pertinent A&M – Corpus Christi policies and procedures.

1.1 Mission Statement
Ensure A&M – Corpus Christi safeguards human health and the environment by maintaining an adherence with the NIH Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines) and the Biosafety in Microbiological and Biomedical Laboratories (BMBL) 5th ed. Through a balance of outreach and support for research personnel, the IBC will:
- Assure activities meet the ethical and legal requirements for the responsible use of rDNA, biohazardous agents, materials and toxins.
- Establish policies and make recommendations regarding such activities.
- Minimize risks to the research personnel, community and the environment by educating the A&M – Corpus Christi community regarding the regulatory requirements for the use of rDNA, biohazardous agents, materials and toxins.

1.2 Charge and Authority of the IBC
The committee is charged with review, approval and oversight of research involving rDNA and biohazardous materials, agents and toxins in research and teaching activities. Responsibilities of the IBC include assessment of facilities, procedures, practices and training of research personnel to assure compliance with NIH/OBA and other pertinent guidelines and regulations.

To successfully carry out these responsibilities, the IBC is appointed to achieve sufficient knowledge and expertise in biomedical research and biosafety. The IBC has the authority to approve, require modifications to secure approval, disapprove, suspend or terminate research activities as required to assure adherence to the appropriate regulations and guidelines.

The IBC has been charged in the planning and implementation of the campus Biosafety program with a purpose to ensure the health and safety of all personnel working with rDNA and biohazardous materials, agents and toxins. The IBC is responsible for establishing and implementing policies that provide for the safe conduct of research involving rDNA and biohazardous materials, agents and toxins to ensure adherence with NIH Guidelines, BMBL, and the USDA regulations. The IBC reviews individual research proposals using rDNA and biohazardous materials, agents and toxins. IBC responsibilities with regards to activities involving rDNA and biohazardous materials, agents and toxins are specified in the NIH Guidelines.
The committee is also given authority to oversee all research involving rDNA and biohazardous materials, agents and toxins including suspension or termination of research not in compliance with IBC Policies.

1.3 Committee Composition
The Vice President for Research, Commercialization and Outreach appoints IBC members and alternates as needed. Members represent faculty, research personnel, and the community. The Chair is elected for a three-year term and shall be a scientific researcher with experience in rDNA and biohazardous materials, agents and toxins. The Chair is eligible for re-election. The term of membership is five years and is renewable upon mutual agreement.

Members will collectively have appropriate expertise and experience in the use of rDNA and biohazardous materials, agents or toxins. Members must have knowledge in assessment of risk to the environment and public health along with knowledge of institutional commitments and policies, applicable laws and professional standards. The IBC will have no fewer than five members.

Consultants may be invited to meeting to provide expert advice when necessary but will not be allowed to vote on any protocol.

1.4 Scope
The IBC policies apply to all research personnel engaged in activities and/or research involving rDNA, biohazardous agents, materials and toxins that are:
- Sponsored by A&M – Corpus Christi.
- Conducted by A&M – Corpus Christi research personnel.
- Conducted using A&M – Corpus Christi property, and facilities.
- Received, stored, used, transferred or disposed of at any A&M – Corpus Christi facilities.
- Research at other institutions conducted on behalf of A&M – Corpus Christi.

1.5 Federal Registrations
The purpose of registration and annual membership updates are:
- Provide assurance of local review of Biosafety risks to the Office of Biotechnology Activities (OBA).
- Indicates A&M – Corpus Christi point of contact.
- Provides census of the field: where rDNA research is being conducted.

The IBC is registered with OBA for purposes of rDNA research. For more information visit http://www4.od.nih.gov/oba/ or http://oba.od.nih.gov/oba/index.html.

An annual report is filed with OBA, which includes an updated list of IBC members indicating the role of each member and NIH or NSF biosketches for each member. The OBA is notified of any changes in IBC membership when changes occur. Such notice shall include a revised list of members, contact information and a biosketch for each new member. The Office of Research Compliance (ORC) notifies OBA of changes in IBC membership and submits an annual report on behalf of A&M – Corpus Christi.
A&M – Corpus Christi currently does not work with any select agents as defined by HHS and USDA guidelines. Before embarking on any research involving such agents, A&M – Corpus Christi will have a certificate of registration for Select Agents and Select Agent Toxin with the Centers for Disease Control (CDC) for the possession, use, receipt, or transfer of listed select agents or select agent toxins. For more information visit http://www.cdc.gov/od/sap/

The CDC registration is maintained by the Responsible Official (RO) in the Office of Environmental Health and Safety (EHS).

1.6 Regulations and Guidelines
The IBC Policies are based upon the following regulations and guidelines:

**NIH Guidelines** This document specifies practices and provides guidelines for constructing and handling rDNA molecules and organisms containing rDNA molecules. Institutions conducting or sponsoring rDNA research covered by NIH Guidelines are responsible, through established policies and its IBC, for ensuring that such research is conducted in compliance with the NIH Guidelines are available online at http://oba.od.nih.gov/oba/rac/guidelines_02/NIH_Gdlines_2002prn.pdf

**BMBL** is published by Centers for Disease Control and Prevention (CDC) and the NIH – BMBL contains guidelines for microbiological practices, safety equipment, and facilities that constitute the four established biosafety levels. The BMBL is considered the standard for biosafety. The BMBL is available online at http://www.cdc.gov/OD/ohs/biosfty/bmbl5/bmbl5toc.htm

**Select Agents and Select Agent Toxins** – The Department of Health and Human Services (HHS), Center for Disease Control and Prevention (CDC) regulations, 42 CFR Part 73, and the United States Department of Agriculture (USDA) regulations, 9 CFR Part 121, establish requirements regarding the possession, use, receipt, and transfer of listed select agents and select agent toxins. The regulations set forth the requirements for registration of listed select agents and select agent toxins, security risk assessments, safety plans, security plans, emergency response plans, training, transfers, record keeping, inspections, and notifications. For more information visit http://www.selectagents.gov/

*A&M – Corpus Christi does not currently conduct research involving select agents or select toxins.

**Guidelines for Working Safely with Human Cell Lines**
http://www.utexas.edu/research/rsc/ibc/human_cell_lines.html

*A&M – Corpus Christi does not currently conduct research involving human cell lines.

**Guidelines for Research Involving Human Specimen Collection**
http://www.utexas.edu/research/rsc/ibc/human_spec_coll.html

*A&M – Corpus Christi does not currently conduct research involving human specimen collection.

**For Research Involving Animals and Plants** -The Animal and Plant Health Inspection Service (APHIS) regulates genetically engineered (GE) organisms and certain GE organisms that may pose a risk to plant or animal health. APHIS uses the term biotechnology to mean the use of recombinant DNA technology, or genetic engineering to modify living organisms. Permits are
required for the importation, transit, domestic movement and environmental release of organisms that impact plants. For more information visit:


### 1.7 Definitions

**Biohazardous Materials, Agents and Toxins:** Infectious biological or synthetic agents, biologically derived materials and toxins that present a risk or potential risk to the health of humans, animals, or plants either directly through exposure or infection or indirectly through damage to the environment. Categories of potentially infectious biological materials include the following:

- Human, animal, and plant pathogens (bacteria, parasites, fungi, viruses, prions).
- All human and non-human primate blood, blood products, tissues, and certain body fluids (use of human blood and body fluid for clinical diagnostic and treatment purposes is excluded).
- Cultured cells and potentially infectious agents these cells may contain.
- Infected animals and animal tissues.

**Recombinant DNA (rDNA):** *NIH Guidelines* context defines recombinant and synthetic nucleic acids as (1) recombinant nucleic acid molecules that are constructed by joining nucleic acid molecules and that can replicate in living cells, (2) synthetic nucleic acid molecules that are chemically, or by other means, synthesized or amplified nucleic acid molecules that may wholly or partially contain functional equivalents of nucleotides, or (3) molecules that result from the replication of those described in (1) or (2) above. Synthetic DNA segments that are likely to yield a potentially harmful polynucleotide or polypeptide (e.g., a toxin or a pharmacologically active agent) are considered as equivalent to their natural DNA counterpart.
Section 2: Responsibilities

The *NIH Guidelines* will never be complete or final since all conceivable experiments involving rDNA cannot be foreseen. Therefore, it is the responsibility of A&M – Corpus Christi and those associated with it to adhere to the intent of the *NIH Guidelines* as well as the specifics. Good judgment is a key along with the assistance of ORS and OBA.

Potential consequences of noncompliance with the *NIH Guidelines* consist of:
- Suspension, limitation or termination of NIH funds for rDNA research at A&M – Corpus Christi.
- A requirement for prior NIH approval of any or all rDNA projects at the A&M – Corpus Christi.

2.0 Institutional Official (IO) and A&M – Corpus Christi Responsibilities

The responsibility for the Biosafety Program at A&M – Corpus Christi rests with the Vice President of Research, Commercialization and Outreach. The IO:
- Appoints members to the IBC.
- Annually evaluates allocation of resources to research compliance and the IBC and adjusts as necessary.

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

2.1 IBC Responsibilities

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

Review, approve and oversee research utilizing rDNA and biohazardous materials, agents and toxins research, conducted at or sponsored by A&M – Corpus Christi, for adherence with the *NIH Guidelines* and the BMBL. This pertains to the initial and continuing reviews and modifications to the currently approved research.
- Notify the Research Compliance Officer (RCO) of the results of the IBC’s review, approval, or disapproval. The RCO will notify the Principal Investigator of the results of the IBC’s review, approval, or disapproval.
- Make final determination of physical and biological containment for rDNA and biohazardous materials, agents and toxins research and modify containment levels as necessary.
- Assess the facilities, procedures, practices, training and expertise of personnel involved in research utilizing rDNA and/or biohazardous materials, agents and toxins.
- Review any significant problems, violations of the *NIH Guidelines* and any significant research-related accidents or illnesses. Report such instances to the RCO and IO who will report to the NIH/OBA per the *NIH Guidelines*. 
- Direct development of appropriate procedures as required by NIH/OBA, CDC, and USDA regulations to oversee the possession and/or use of rDNA and biohazardous materials, agents and toxins.
- Suspend or terminate protocol approval for the possession or use of rDNA and biohazardous materials, agents and toxins, where the IBC finds noncompliance or that such use or possession poses undue risk to research personnel or a threat to the health and safety of the community.
- Periodically review the IBC policies and procedures and modify them as necessary to ensure appropriate biosafety measures and adherence with federal and state requirements.
- Review research protocols that include the possession and/or use of rDNA and biohazardous materials, agents and toxins for compliance with NIH Guidelines, the BMBL, and Select Agents and Toxins regulations. As part of the review process, the IBC will do the following:
  - Conduct an independent assessment of the containment levels (BSL-1 to BSL-3), as required by the NIH Guidelines or the BMBL.
  - Conduct an assessment of the facilities, procedures, practices, training, and expertise of personnel conducting research involving rDNA and biohazardous materials, agents and toxins.
  - Ensure adherence with all surveillance, data reporting, and adverse event reporting requirements set forth in the NIH Guidelines for rDNA research and the select agents and toxins regulations.
- Submit membership information to the RCO for registration of the IBC.
- Notify the RCO of required review, registration and/or approval from NIH/OBA for research that fall under Sections III-A, III-B, III-C and Appendix M.

2.2 IBC Review Subcommittees Responsibilities
Exempt protocol submissions will be reviewed by the IBC Chair.
The IBC Chair will be responsible for:
- Reviewing research submittal for completeness.
- Determining overall risk assessment.
- Setting appropriate containment levels.
- Determining exempt status.
- Requesting clarifications or changes.
- Recommending additional conditions.

Non-exempt submissions will be reviewed by a designated IBC Subcommittee (subcommittee). Subcommittees will consist of the IBC Chair or designee and one additional university member. The subcommittees will review submitted research protocols prior to a convened IBC meeting. The subcommittee will be responsible for:
- Reviewing research submittal for completeness.
- Determining overall risk assessment.
- Setting appropriate containment levels.
- Determining exempt status, if applicable.
- Requesting clarifications or changes.
- Recommending additional conditions.
- Presenting an overview of the protocol at the convened IBC meeting.
2.3 IBC Chair Responsibilities
The IBC Chair responsibilities include:
- Serve as one of the contacts for all regulatory agencies.
- Act as liaison between the research personnel and IBC.
- Review exempt protocols.
- Review protocols as a member of the review subcommittee prior to official committee decisions made at the convened meeting.
- Approve the agenda for the convened meeting of the IBC.
- Calls the meeting and directs the meeting deliberations, requests motions and seconds, and closes the meeting once it has concluded business.

2.4 Environmental Health & Safety Responsibilities
A representative from Environmental Health & Safety (EHS) shall be a member of the IBC. EHS responsibilities include:
- Performing periodic inspections of laboratories conducting research using rDNA and biohazardous materials, agents and toxins to ensure that laboratory standards are rigorously followed.
- Report to the IBC and RCO any problems, violations, research-related accidents or illnesses.
- Performing and reviewing the required risk assessment to determine appropriate Biosafety level for handling an organism.
- Developing emergency plans for handling accidental spills and personnel contamination and investigating laboratory accidents involving rDNA and biohazardous materials, agents and toxins.
- Providing advice on laboratory security to the IBC research personnel.
- Providing technical advice to research personnel and the IBC on research safety procedures.

The principal function of the BSO should be to advise the research personnel, the IBC and laboratory workers concerning the most appropriate safety practices that will assure the safe conduct of research with rDNA and biohazardous materials, agents and toxins.

The EHS representative will receive a courtesy copy of all protocols during the subcommittee review period for comment.

2.5 Principal Investigator Responsibilities
The Principal Investigator is responsible for following the NIH Guidelines, the BMBL and IBC Policies when using rDNA and biohazardous materials, agents and toxins.

The Principal Investigator will also have the following responsibilities:
- Make the initial risk assessment and determination of required levels of physical and biological containment in accordance with the NIH Guidelines and the BMBL. The list is available online at http://www.cdc.gov/OD/ohs/biosfty/bmbl5/BMBL_5th_Edition.pdf.
- Be adequately trained in safe microbiological techniques.
- Provide laboratory research personnel with protocols describing potential biohazards and necessary precautions.
- Instruct, train and supervise research personnel in (1) the practices and techniques required to ensure safety, and (2) the procedures for dealing with spills or potential exposures to the agents described in the research.
- Ensure the integrity of the physical containment (e.g., biological safety cabinets) and the biological containment (e.g., purity and genotypic and phenotypic characteristics) and correct procedures or conditions that might result in release of or exposure to rDNA and/or biohazardous materials, agents or toxins.
- Develop and obtain IBC approval of and adhere to biosafety plans (available from EHS) for handling accidental spills and personnel contamination.
- Inform EHS personnel of any precautionary medical practices advised or requested, e.g., vaccinations.
- Ensure all research personnel, including students, have the required training in the accepted procedures for laboratory practices and safety.
- Obtain IBC approval prior to initiating or modifying any research involving use of rDNA and/or biohazardous materials, agents and toxins.
- Maintain IBC approval for use of rDNA and biohazardous materials, agents and toxins through timely submission of annual updates.
- Immediately report any significant problems or any research-related accidents and/or illnesses to EHS and any other A&M – Corpus Christi committees (Institutional Review Board (IRB), Institutional Animal Care and Use Committee (IACUC)) which have reviewed and approved the research activity.
- Comply with permit and shipping requirements for biohazardous materials.
- Although federal regulations allow exemptions for some types of rDNA use, the Principal Investigator must submit an application for all projects using rDNA and biohazardous materials, agents and toxins so the IBC can verify that they are exempt.

2.6 Office of Biotechnology Activities Responsibilities
OBA serves as the focal point for information on recombinant DNA activities and provides advice to all within and outside NIH/OBA. OBA’s responsibilities include, but are not limited to, the following:
- Serving as the focal point for all aspects of gene transfer experiments.
- Reviewing and approving experiments in conjunction with ad hoc experts involving the cloning of genes for toxin molecules that are lethal for vertebrates at an LD50 of less than or equal to 100 ng/kg body weight in organisms other than Escherichia coli K-12.
- Publishing proposed changes to rules or guidelines in the Federal Register.
- Reviewing and approving the membership of an Institution’s Biosafety Committee, and where it finds the IBC composition to meet the requirements set forth in the NIH Guidelines, giving approval for the IBC membership.

2.7 Office of Research Compliance (ORC) Responsibilities
The Office of Research Compliance (ORC) will provide overall administrative support, and will coordinate IBC reviews and meetings.

Responsibilities of the ORC include, but are not limited to, the following:
- Provide the necessary liaison between the research personnel, the IBC, federal and regulatory agencies.
- Serve as the office of record for documentation involving IBC.
- Provide all necessary documentation, forms, regulatory guidelines and regulations, to Principal Investigators.
- Maintain IBC registration forms and records.
- File annual updates and other reports to the NIH/OBA.
- Communicate with the IRB or IACUC when protocols involve human subjects or animals.
- Draft revised policies and procedures to remain in compliance with those regulations by monitoring Federal and state regulations.
- Provide administrative support for the IBC by scheduling meetings, arranging for meeting space and taking meeting minutes.
Section 3: Protocol/Modification

Submission and Review

3.0 Submissions
The IBC is responsible for overseeing and evaluating all aspects of research involving rDNA and biohazardous materials, agents and toxins, and is charged with reviewing proposals that involve rDNA and biohazardous materials, agents and toxins to ensure the criteria established in the IBC Policy and the federal regulations and guidelines are implemented. The primary goal of the IBC is to review proposals in a manner to facilitate research personnel compliance with applicable laws, regulations, guidelines and policies consistent with the performance of appropriate and productive scientific endeavors.

IBC protocol submissions, whether IBC protocol submissions, modifications or renewals, must be submitted to the Office of Research Compliance (ORC) by the Principal Investigator for review and IBC approval. No research involving rDNA and biohazardous materials, agents and toxins can be initiated until the Principal Investigator has received the approval of the IBC. Principal Investigators must submit potentially exempt applications for all projects using rDNA and biohazardous materials, agents and toxins so the IBC is aware of the activities and can verify the studies are exempt. Visit http://oba.od.nih.gov/oba/ibc/FAQs/FAQs_about_Experiments_that_are_Exempt_from_the_NIH_Guidelines.pdf for more information on exemptions.

No one shall obtain or use rDNA and biohazardous materials, agents and toxins until the protocol has been approved by the IBC. Modifications to approved protocols shall not be implemented until approved by the IBC.

3.0.1 Who can be a Principal Investigator?
Principal Investigators (PI) can submit applications to the IBC to work with rDNA and/or biohazardous materials, agents, and toxins. A PI is generally a tenured, tenure track, or research faculty with assigned research space. The PI must submit the below statement from the person who is responsible for the research space should a PI not have assigned space to conduct the research. Exceptions to the policy will be considered by the IBC on a case-by-case basis.

Acknowledgement Statement
I, [insert name of person with assigned research space] am aware of the attached research of [insert name of PI without assigned space] that will be conducted in [insert space location] assigned to me. I acknowledge my responsibility for ensuring the research will be conducted in a safe manner and in accordance with institutional and federal regulations.

3.1 Experiments Requiring IBC Review
Experiments requiring IBC review include, but are not limited to:
- Recombinant studies potentially exempt from the NIH Guidelines.
- The deliberate transfer of a drug resistance trait to micro-organisms that are not known to acquire the trait naturally.
- The deliberate transfer of rDNA or DNA or RNA derived from rDNA into human research participants (human gene transfer).
- The deliberate formation of rDNA containing genes for the biosynthesis of toxin molecules.
- The use of RG-2 or RG-3 agents as host-vector systems.
- The use of human etiologic and animal viral etiologic agents.
- The cloning of DNA from RG-2 or greater agents into non-pathogenic prokaryotes or lower eukaryotic host-vector systems.
- The use of infectious or defective RG-2 or greater agents.
- Whole animals in which the animal’s genome has been altered by stable introduction of rDNA or DNA derived into the germ-line (transgenic animal).
- Viable rDNA-modified micro-organisms or cell lines tested on whole animals.
- Genetically engineered plants by rDNA methods.
- More than 10 liters of rDNA culture in a single vessel.
- The formation of rDNA molecules containing one-half or more of the genome of a eukaryotic virus or from the same virus family.
- Experiments using BSL-2 or BSL-3 containment.
- Non-recombinant research using biohazardous materials, agents or toxins.
- All research using biological toxins or bioactive derivatives or subunits of toxins.
- Research collecting or analyzing human or non-human primate cell lines, tissues, fluids or other potentially infectious material.

3.2 New Submissions
IBC protocols must be accurately completed and submitted for review and IBC approval.

IBC Exempt Protocol Applications:
- The protocol will be reviewed by the IBC Chair. It may be necessary for the Principal Investigator to submit additional information if requested to ensure a complete application.
- Approval/Non-approval will be determined by the IBC Chair.
- The IBC protocol application is available online at: http://research.tamucc.edu/biosafety.html

IBC Non-Exempt Protocol Applications:
- All BSL-2 and BSL-3 laboratories are required to be inspected and develop a Lab Biosafety Manual. Environmental, Health & Safety (EHS) can assist the Principal Investigator in completing this step of the application process. The EHS website is: http://safety.tamucc.edu/
- The protocol will be reviewed by the IBC Chair and one additional IBC member. It may be necessary for the Principal Investigator to submit additional information if requested to ensure a complete application.
- Approval/Non-approval will be determined by the IBC.
- The IBC protocol application is available online at: http://research.tamucc.edu/biosafety.html
Once applications have been saved, a protocol number will be assigned and can be used to reference the study with ORC. The Principal Investigator will be notified of the IBC decision.

### 3.3 Continuing Review / Renewal

**Exempt Protocols**
The Principal Investigator is not required to submit annual renewal applications. Approval of non-exempt protocols does not expire.

**Non-Exempt Protocols**
The Principal Investigator is required to submit a renewal application annually for each non-exempt protocol. Renewal applications should be submitted at least 30 days prior to the expiration of the IBC protocol to ensure the IBC has time to review the application. Research cannot be continued if protocol renewal is not approved prior to the expiration date from the previous approval.

### 3.4 Failure to Submit Renewal/Respond to IBC Requirements

A letter will be sent to the Principal Investigator and copied to the PI’s Dean/Director if the Principal Investigator fails to provide a renewal form to the IBC by the anniversary date. All research activities pertaining to the research described in the expired protocol must cease. If the Principal Investigator does not provide a renewal by the next IBC meeting, this issue is added to the agenda and the IBC determines whether or not to terminate the IBC protocol. Termination of the IBC protocol may require termination of any related IACUC or IRB protocols and notification to any external funding agencies.

### 3.5 Modification Process

Changes or modifications to exempt and non-exempt approved protocols (i.e; change in or additional of research personnel, room changes, new procedures or agents) must be reviewed and approved by the IBC prior to initiation. A new protocol may be requested if the changes are extensive or change the scope of the review.

### 3.6 Protocol Termination

The Principal Investigator will notify the Office of Research Compliance (ORC) when the research covered by exempt and non-exempt approved protocols is completed or no longer active. The IBC shall contact the Principal Investigator if there are any questions or concerns regarding Termination of Approval.

Failure to renew a previously approved IBC protocol, described in Section 4.3, may result in termination of the protocol(s). Issues of non-compliance with institutional and federal regulations, policies and guidelines or requirements of the IBC may also initiate protocol termination. Instances of non-compliance will be evaluated and the IBC may determine protocol termination is appropriate.

### 3.7 Relationships to IACUC and IRB

IBC protocols submission involving the use of live animals will require IACUC review and approval prior to initiation.
IBC protocol submissions involving the administration of biohazardous agents or rDNA to humans, or involves the collection of tissues or fluids from humans, requires IRB review and approval prior to initiation.

Current IACUC and IRB protocol numbers must be included on the IBC submission.
Section 4: Meeting Process

4.0 Requirements for Quorum
The conduct of official IBC business occurs at convened meetings with a quorum of members present for the meeting to be held. The IBC defines a “quorum” as more than half the regular voting members. A protocol is approved only if a quorum is present and more than 50% of the quorum votes in favor or protocol approval. Abstentions from voting do not alter the quorum or change the number of votes required unless for reasons other than conflict of interest.

Members are expected to attend the convened meetings unless the Research Compliance Officer (RCO) has been notified ahead of time that they are unable to do so. Members failing to attend meetings on a regular basis may be removed from the committee.

4.1 Protocol Review
The protocol submission deadline is listed on the Office of Research Compliance (ORC) IBC website http://research.tamucc.edu/biosafety.html. Submissions deadlines are not flexible to allow ample time for committee members to review the protocol prior to the convened meeting. Protocols must be submitted by the submission deadline or the protocol will be held until the next convened meeting.

Each member of the IBC will receive a copy of the proposed research protocols a week prior to the convened meeting. Exceptions to this requirement can be approved by the IBC Chair.

4.2 Procedures
IBC meetings are routinely held once per month unless no protocols are submitted for review. Rescheduling may occur due to inability to achieve a quorum of members and non-scheduled meetings may be called by the IBC Chair to discuss matters which may arise and require immediate resolution. The RCO is responsible for assuring that a meeting room is located and scheduled and that all other arrangements for the meeting are made.

The IBC Chair will call the meeting to order and follow an agenda prepared prior to the meeting at the scheduled meeting time and upon reaching a quorum.

Activities the IBC carries out on behalf of A&M – Corpus Christi when reviewing IBC protocols, amendments and renewals include:
- Conducting an assessment of the containment levels required by the NIH Guidelines.
- Assessing the facilities, procedures, practices, and training and expertise of personnel involved in research with rDNA and/or biohazardous materials, agents or toxins.
- Ensuring compliance with the NIH Guidelines and the BMBL.

The IBC should consider the following NIH Guidelines, Sections II and III, when reviewing proposed rDNA research:
- Agent characteristics (e.g. virulence, pathogenicity, environmental stability).
- Types of manipulations planned.
- Source(s) of the inserted DNA sequences (e.g., species).
- Nature of the inserted DNA sequences (e.g., structural gene, oncogene).
- Host(s) and vector(s) to be used.
- Whether an attempt will be made to obtain expression of a foreign gene, and if so, the protein that will be produced.
- Containment conditions to be implemented.
- Applicable section of the NIH Guidelines (e.g., Section II-D-1. Section III-E-1, etc.).

4.3 Possible Review Outcomes
All non-exempt protocols are presented and discussed individually and the IBC votes on the disposition of the protocol. Possible outcomes include:

- **Approval:** When the IBC has determined that all review criteria, based on the IBC Policies and federal-mandated regulations have been adequately addressed by the Principal Investigator, the IBC may approve the research, thus providing the Principal Investigator permission to perform the research.

- **Approval with conditions:** This status is used for protocols for which all required information has not been received, required training has not been completed and/or remaining issues or questions exist regarding the safety of the protocol.

- **Tabled:** The IBC may defer or table a review if the protocol requires clarification in order for the IBC to make judgment, certain committee members with certain expertise is not present, the IBC wishes to seek external consultation, or any of a number of other reasons preventing the IBC from conducting its review.

- **Withhold Approval:** When the IBC determines that a protocol has not adequately addressed all of the requirements of the IBC Policies and regulations as applicable, the IBC may withhold approval.

4.4 Conflict of Interest
Both the NIH Guidelines and the IBC Policies state that no IBC member* may participate in the IBC review or approval who have a conflict of interest in the project (e.g., acting as Principal Investigator, have financial interest in the project). All Principal Investigators and/or IBC members are required to disclose any conflicts of interest. Should an IBC member declare involvement in any way in a research protocol under review by the IBC, or state a conflict of interest with a research protocol, then the member(s):

- Are excluded from discussion and voting except to provide information requested by the IBC.
- May be asked to leave the meeting room for discussion and voting.
- Are not counted towards quorum.

* A&M – Corpus Christi considers “Member” to include the research personnel’s spouse and dependent children.

4.5 Minutes
Review of protocols by the IBC invokes a deliberative process, and section IV-B-2-b of the NIH Guidelines require that the IBC meeting minutes should offer sufficient detail about the discussion of the matters discussed in order to document the IBC rationale for particular decisions. The IBC has some latitude in the degree of detail in these minutes.

Recorded minutes of IBC meetings are intended to reflect the substantive discussion of protocols. Minutes are intended to contain sufficient information that a reasonable person could understand the nature of the discussion. The minutes should offer sufficient detail to serve as a record of major points of discussion and the Committee’s rationale for particular
decisions, documenting that the IBC has fulfilled its review and oversight responsibilities as outlined under Section IV-B-2-b of the NIH Guidelines.

Meeting minutes are not intended to provide a verbatim transcript of discussion nor to reiterate shared knowledge of the Committee such as recent discussions about a protocol in previous minutes. Historical evidence of compliance or non-compliance would be recorded in the minutes if it were germane to the discussion. Minutes may include reference to historical discussion by the IBC from members who have served on the Committee and observed the procedures being proposed, served as reviewers for protocols involving similar procedures (where questions were answered), or participated in past IBC discussions about the procedures.

Guidance and clarification concerning the preparation of, and the public access to, minutes of the IBC meetings has been issued by NIH/OBA:
http://oba.od.nih.gov/oba/IBC/IBC_Minute_Q_A.

Minutes of each IBC meeting are recorded in writing and contain:
- Date and place of meeting,
- Individuals in attendance,
- Whether and why the meeting was open or closed,
- All major motions, major points of order, and whether motions were approved,
- Protocols reviewed (identified by protocol number and protocol title), and
- The time of meeting adjournment.

The meeting minutes should also document the IBC’s consideration of several matters described in Section II and Section III of the NIH Guidelines (see Section 4.2) to document the adequate fulfillment of the Committee’s review and oversight responsibilities described in Section IV-B-2-b of the NIH Guidelines. The inclusion of the material in the meeting minutes will document the biosafety aspects of each protocol.

4.6 Principal Investigator Notification
The Principal Investigator will receive written notification of the review decisions (approved/not approved) and whether any special conditions for approval of work is required after the completion of the review process (Section 3). Included in the notification will be the IBC decision on the biocontainment/biosafety level to be used for the proposed research, any special safety considerations, applicable sections of the NIH Guidelines, along with the approval period (begin/end dates).

4.7 Reports to the IO
Copies of minutes and reports of laboratory incidents, accidents, spills, potential or actual exposure to infectious or biohazardous materials, and incidents of non-compliance, protocol suspensions or terminations will be available for review by the IO. The IO will be consulted on any reports required and filed with the Office of Biotechnology Activities or other agencies (See Section 5).

4.8 Meeting Frequency
Convened meetings of the IBC occur monthly unless cancelled by the IBC Chair. Meeting schedules are typically set six months in advance and posted on the IBC website (http://research.tamucc.edu/biosafety.html). The Chair may call an emergency meeting of the IBC as necessary to address such issues as noncompliance or serious and/or unexpected events involving rDNA and biohazardous materials, agents and toxins.

4.9 Attendance of Non-Members
IBC meetings are considered open and members of the A&M – Corpus Christi community and the public at large may request to attend an IBC meeting. Individuals who wish to attend an IBC meeting must notify the Research Compliance Officer (RCO) in advance at (361) 825-24971 or erin.sherman@tamucc.edu regarding the desire to attend. The RCO must be made aware of additional attendees in order to schedule a room of appropriate size. Last minute requests may not be honored if the meeting room cannot accommodate additional attendees.
Section 5: Reporting Requirements

5.0 Reportable Incidents and Violations
Incidents/problems involving rDNA and biohazardous materials, agents and toxins must be immediately reported to the Research Compliance Officer (RCO) and Environmental, Health and Safety (EHS). Examples of reportable significant incident include but are not limited to any overt exposure, such as a needle stick, splash, and contamination due to equipment failure, and any potential exposure in a BSL-3 facility. A significant event may also occur from a containment breach, which may be subsequently determined to pose either an overt or potential exposure to individuals. It should be noted that waste from rDNA research is also considered biohazardous and incidents involving improper disposal of rDNA must also be reported. Questions regarding reportable incidents should be directed to the RCO and EHS.

Failure by research personnel to follow federal and institutional regulations, guidelines, policies and/or procedures may also require reporting to the appropriate institutional, local, state and/or federal agencies. Violations may include and are not limited to conduct of new or ongoing research without appropriate federal or institutional registration, review, approval or oversight.

5.1 Principal Investigator Reporting
The Principal Investigator and other research personnel must report any significant incident, violation of the NIH Guidelines, or any significant, research-related accidents and illnesses immediately by contacting the RCO and EHS. Examples of incidents and violations include:

- Overt exposures are defined as exposures that result in direct personnel exposure to biohazardous materials such as injection, spills, splashes or aerosol inhalation.
- Potential exposures are defined as exposures that have a high risk of exposing personnel to biohazardous materials such as spills, containment failure while working with the agent or equipment failure that may produce aerosols.
- Any exposure (overt or potential) in a BSL-3 lab.
- Overt exposure in BSL-1 or BSL-2 labs
- Any illness that may be caused by the agents used in the laboratory incidents involving the improper disposal of rDNA.

Principal Investigators must also report other information to the IBC as soon as they become aware of the information (must also be reported to RCO):

- Information to support a new host-vector system.
- Petitions for proposed exemptions to the NIH Guidelines.
- Petitions for approval to conduct experiments specified in Sections III-A-1 and III-B.
- Petition for determination of containment for experiments not covered by the NIH Guidelines.
5.2 Office of Research Compliance (ORC) Reporting

The ORC is required, by the *NIH Guidelines*, to report to the IBC:
- All violations of the *NIH Guidelines* and significant incidents.
- Any significant research-related accidents or illnesses.

5.3 IBC Reporting

The IBC, through the RCO, will file an annual report with OBA that includes:
- A roster of all IBC members clearly indicating the Chair, contact person, BSO, plant expert, and animal expert.
- Biographical sketches of all IBC members.

The IBC is required by the *NIH Guidelines* to report to the appropriate A&M – Corpus Christi official and to the NIH/OBA within 30 days any significant incidents, violations of the *NIH Guidelines*, or any significant research-related accidents and illnesses. The IBC will be responsible to determine what actions, if any, are necessary. The IBC may choose to change the frequency of lab inspections, or change the Biosafety Level of the protocol, based on results of the incident. The IBC is required to complete a final copy of the Biological Incident Reporting Form which it will be signed and dated by the IO, IBC Chair and the RCO.

Other IBC reporting requirements (to OBA and other agencies) include but are not limited to:
- Research involving rDNA and biohazardous materials, agents and toxins without prior IBC approval.
- Lax security, unsafe procedures used in a laboratory setting, improper disposal of recombinant waste.
- Significant changes to proposed research risk without prior notification and approval by IBC.

Certain types of incidents must be reported to OBA on an expedited basis. Spills or accidents in BL2 laboratories (involving rDNA) resulting in an overt exposure must be immediately reported to OBA. Spills or accidents involving rDNA occurring in high containment (BL3 or higher) laboratories resulting in an overt or potential exposure must also be immediately reported to OBA. The IBC will report to the appropriate institutional official who will report to OBA any of the above-described incidents.

Institutional violations that will be reported to the appropriate College or department head may include but are not limited to:
- Lapses in protocol approval.
- Failure to comply with institutional and federal regulations, guidelines, and policies.

The IBC, through the IO, will forward any public comments made on IBC actions and the IBC’s response to the Office of Biotechnology Activities as required by Section IV-B-2-a-(7) of the *NIH Guidelines*.

5.4 IO Reporting
The IO will report the following upon notice from the IBC:

- Any problems with or violations (non-compliance) of the NIH Guidelines any significant incident, accidents, or illnesses related to rDNA to the NIH/OBA within 30 days or immediately for overt exposure to a BSL-2 agent or potential/overt exposure to a BSL-3 agent. Reports will be made in writing.
- Incidents involving Select Agents and/or Select Toxins will be reported to the CDC/USDA
- Any significant research-related illness or accident that may be hazardous to the public health and cooperate with state and local public health departments.

5.5 Response to External Requests for Information
The institution will make all IBC meeting minutes and any documents submitted to or received from funding agencies publicly available upon request, in accordance with the NIH Guidelines. Redaction of proprietary and private information is allowed but “must be done so judiciously and consistently for all requested documents.” The IBC will also adhere to requirements for providing copies of minutes and files as specified in the Texas Public Information Act.
Section 6: Non-Compliance

6.0 Allegations
Any allegations of non-compliance or unsafe working conditions shall be made to the IBC Chair, to any member of the IBC, the Office of Research Compliance (ORC) or to the IO. Allegations shall be immediately forwarded to the IBC Chair in all instances. The IBC Chair, in cooperation with the RCO, is responsible for investigation and resolution of all allegations of non-compliance. The allegations and resulting investigations will remain confidential to the extent possible.

6.1 Investigation and Review Process
The IBC Chair will appoint a subcommittee to investigate the allegation. The subcommittee will inform all persons involved in the investigation of the purpose and the manner in which it will be conducted. The subcommittee will examine all documents and procedures relating to the allegation and will interview individuals named in the allegation and others who may have knowledge of the circumstances surrounding the allegation and determine if there is a basis in fact to support the allegation. The subcommittee will report its findings to the full IBC for the final determinations (see Section 6.2).

6.2 IBC Determination
The IBC will discuss the subcommittee report at a convened meeting and determine if a consensus concerning whether the allegation of non-compliance is substantiated and, if so, the seriousness of the incident. All persons involved in the allegation of non-compliance will be given the opportunity to appear to respond to the allegation and/or findings. The report and recommendations will be further discussed and voted upon once persons involved have responded and exited the meeting. The IBC will inform all parties involved, including the submitter of the allegations, of the committee’s findings.

6.3 Possible Outcomes
The IBC has the authority to address non-compliance with the NIH Guidelines, the BMBL, A&M – Corpus Christi policies and procedures and other legal requirements. Findings of non-compliance may result in one or more of the following actions:
- Suspension of use of rDNA and/or biohazardous materials agents or toxins.
- Termination of approval for use of rDNA and/or biohazardous materials agents or toxins.
- Confiscation of the rDNA and/or biohazardous materials agents or toxins.
- Destruction of the rDNA and/or biohazardous materials agents or toxins.
- Any other action necessary to protect the public and/or A&M – Corpus Christi, including restricting access to the laboratory in order to suspend activities.
Section 7: Training

Training is required for all research personnel working with rDNA and biohazardous materials, agents and toxins. Completion of the courses is a requirement for the approval of new and continuing biosafety and rDNA protocols. All existing training materials and course content required by the IBC will be reviewed every two years by a subcommittee of IBC members, and any new training material or course content will be reviewed by a subcommittee of IBC members prior to release.

7.0 IBC Member Training
All IBC members will complete initial training regarding the IBC Policies. A handbook and other essential training can be found on the IBC webpage [http://research.tamucc.edu/biosafety.html](http://research.tamucc.edu/biosafety.html).

The training program for all members consists of information provided at each IBC meeting. The objective of providing ongoing training for IBC members is to increase the committee’s knowledge base, provide awareness of current laws and regulations, update new directives, and strengthen best practice guidelines and institutional policies. A regular forum is also provided for the IBC to discuss concerns or questions brought forth by the faculty and research personnel. Information provided for these sessions will include questions and concerns brought to the attention of the IBC, official directives, relevant publications, conference announcements, seminar proceedings, and compliance issues. It will be the responsibility of the Research Compliance Officer (RCO) to document all training.

7.1 Principal Investigator and Research Personnel Training
General biosafety training is mandatory for all Principal Investigators and research personnel. The CITI Biosafety training is mandatory for Principal Investigators and research personnel performing rDNA research. It is the Principal Investigator’s responsibility to complete and ensure all research personnel has received the required training prior to protocol review by IBC. Documentation of successful completion of training is required in order to receive IBC approval. Links to the CITI training course can be found on the IBC website: [http://research.tamucc.edu/biosafety.html](http://research.tamucc.edu/biosafety.html)
Section 8: Record Retention and Recordkeeping

8.0 IBC
The Office of Research Compliance (ORC) will retain the following records for at least three (3) years after the project’s expiration:

- IBC minutes, including members and vote counts.
- Related IBC Principal Investigator’s protocols and any attachments (3 years begins after termination) of protocol.
- List of IBC Members.

The IBC Policies will be maintained on the IBC website until superseded by any updated or revised document.

8.1 Principal Investigator
Principal Investigators are required to comply with 45 CFR 46.115(b) and:

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