

# **The University of Texas at San Antonio Institutional Biosafety Committee Policy**

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## **1. INTRODUCTION**

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### **1.1. PURPOSE**

The University of Texas at San Antonio (UTSA) promotes the ethical and responsible use of all potentially biohazardous material in research and educational activities. It is the charge of the Institutional Biosafety Committee (IBC) to review, approve and oversee the use of recombinant and / or synthetic nucleic molecules, potentially biohazardous materials, agents and toxins in research and educational activities conducted at UTSA. The Institutional Biosafety Committee Policy should be used in conjunction with other UTSA policies, manuals and committees overseeing work with other hazardous materials such as chemical and radiological items and the Institutional Animal Care and Use Committee.

### **1.2. SCOPE**

The IBC is established to ensure that UTSA promotes the safety of the personnel engaged in research and education activities and the environment by complying with the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines)* and the *Biosafety in Microbiological and Biomedical Laboratories (BMBL) 5<sup>th</sup> edition*. The IBC will review all submitted protocols to assure that activities with recombinant and / or synthetic nucleic molecules, potentially biohazardous materials, agents and toxins comply with the required legal and safety requirements. The IBC will work with other entities at UTSA to minimize risks to personnel and the environment by ensuring all individuals have completed the institutionally required safety training and follow safe laboratory practices

IBC policies apply to all personnel engaged in activities involving recombinant and / or synthetic nucleic molecules, potentially biohazardous materials, agents and toxins that are: sponsored by UTSA, conducted by UTSA personnel, conducted using UTSA property, and facilities.

### **1.3. AUTHORITY**

The Vice President for Research is responsible for appointing the members to the IBC and has charged the committee with review, approval and oversight of research involving recombinant and / or synthetic nucleic molecules, potentially biohazardous materials, agents and toxins. The IBC has the authority to approve, require modifications to secure approval, disapprove, and recommend suspension or termination of research activities as required to assure compliance with the appropriate regulations and guidelines.

In determining the approval of an individual protocol the IBC shall evaluate a number of items including:

- Facilities – including adequate containment.
- Institutional and federal procedures and practices
- Training and expertise of personnel
- Potential for dual use research of concern (DURC)
- Compliance with select agent regulations where applicable
- Compliance with other institutional committees overseeing human and animal research subjects

UTSA receives funding from NIH and is therefore required to ensure that all work with recombinant and / or synthetic nucleic acids (regardless of project funding source) follows the *NIH Guidelines*. Failure to adhere to the guidelines can result in suspension or termination of NIH funding. The IBC will establish and implement policies that will ensure adherence to the *NIH Guidelines*. The IBC, via the Institutional Biosafety Officer (BSO), will report to OBA and institutional officials within 30 days any substantial problems or violations of the *NIH Guidelines* and significant research related accidents or illnesses.

#### **1.4. COMMITTEE COMPOSITION**

Members of the committee will consist of members of the UTSA research community and at least two members of the local community. The term of service is one year and is renewable upon mutual agreement.

In accordance with the *NIH Guidelines* the IBC must be comprised of no fewer than five members so selected that they collectively have experience and expertise in recombinant or synthetic nucleic acid molecule technology and the capability to assess the safety of recombinant or synthetic nucleic acid molecule research and to identify any potential risk to public health or the environment.

- 2 members not affiliated with the institution (apart from their membership on the Institutional Biosafety Committee) and who represent the interest of the surrounding community with respect to health and protection of the environment.
- At least one individual with expertise in plant, plant pathogen, or plant pest containment principles.
- At least one individual with expertise in animal research and animal containment principles.
- The BSO must be a permanent member of the IBC.
- At least one individual with experience in Select Agent Research / BSL-3 facilities.

The IBC reserves the right to invite non-voting consultants to meetings for their expert advice when necessary. The IBC will also appoint appropriately qualified scientific alternates who can assist in reviews if required.

#### **1.5. REGISTRATIONS**

The IBC must be registered with the Office of Biotechnology Activities (OBA). UTSA must file an annual report comprising an updated committee roster indicating the role of each committee member, contact information for committee members and a biosketch for each new member on

the committee. The annual report will be submitted by the Laboratory Compliance Manager through the Office of Research Integrity.

Laboratory registrations, with the CDC or USDA, for research involving non-exempt strains and quantities of Select Agents and / or Select Agent Toxins will be maintained by the Responsible Official (RO).

## **1.6. DEFINITIONS**

### **Biohazardous materials, agents and toxins**

Infectious biological or synthetic agents

Biological material or toxins that may be hazardous to human, animal or plant health or present a risk of damaging the environment.

Potentially hazardous materials can include:

- Bacteria, parasites, fungi, viruses, prions and toxins
- All human and non-human primate blood, blood products, tissues and body fluids.
- Cultured cells with or without known infectious agents
- Animals and animal tissues

### **Recombinant or Synthetic Nucleic Acid**

The *NIH Guidelines* define recombinant and synthetic nucleic acids are defined as:

- molecules that a) are constructed by joining nucleic acid molecules and b) that can replicate in a living cell, i.e., recombinant nucleic acids;
- nucleic acid molecules that are chemically or by other means synthesized or amplified, including those that are chemically or otherwise modified but can base pair with naturally occurring nucleic acid molecules, i.e., synthetic nucleic acids, or
- molecules that result from the replication of those described in above.

### **Other**

NIH – National Institutes of Health

OBA – Office of Biotechnology Activities

DURC – Dual Use Research of Concern

CDC – Centers for Disease Control

USDA – U.S. Department of Agriculture

BSL – Biosafety Level

BMBL - Biosafety in Microbiological and Biomedical Laboratories

BSO – Biosafety Officer

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P.I. – Principal Investigator

RAC – National Institutes of Health Recombinant DNA Advisory Committee

RO – Responsible Official for the UTSA Select Agent Program

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## 2. RESPONSIBILITIES

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The *NIH Guidelines* provide detailed descriptions of the responsibilities of each component of the IBC these are summarized here with specific reference to UTSA policies.

### 2.1. UTSA RESPONSIBILITIES

Responsibility for the IBC is held by the Vice President for Research who will appoint members to the IBC. In addition, UTSA will:

- Assist and ensure compliance with the *NIH Guidelines* by Principal Investigators conducting research.
- Establish and implement policies that provide for the safe conduct of recombinant or synthetic nucleic acid molecule research and that ensure compliance with the *NIH Guidelines*.
- Establish an Institutional Biosafety Committee
- Appoint a Biological Safety Officer as a permanent member of the IBC.
- Appoint at least one IBC member with expertise in plant, plant pathogen, or plant pest containment principles and at least one IBC member with expertise in animal containment principles.
- Ensure that if the institution participates in or sponsors recombinant or synthetic nucleic acid molecule research involving human subjects: (i) the IBC has adequate expertise and training (using *ad hoc* consultants as deemed necessary), (ii) all aspects of [Appendix M](#) have been appropriately addressed by the Principal Investigator; and (iii) no research participant shall be enrolled in a human gene transfer experiment until the RAC review process has been completed, IBC approval has been obtained, Institutional Review Board (IRB) approval has been obtained, and all applicable regulatory authorizations have been obtained. IBC approval must be obtained from each institution at which recombinant or synthetic nucleic acids will be administered to human subjects (as opposed to each institution involved in the production of vectors for human application and each institution at which there is *ex vivo* transduction of recombinant or synthetic nucleic acid molecule material into target cells for human application).
- Ensure appropriate training for the Institutional Biosafety Committee Chair and members, Biological Safety Officer and other containment experts (when applicable), Principal Investigators, and laboratory staff regarding laboratory safety and implementation of the *NIH Guidelines*, where necessary.
- Review the need for health surveillance of personnel involved in connection with individual recombinant or synthetic nucleic acid molecule projects; and if appropriate recommend that a health surveillance program is conducted for such projects. The institution shall establish and maintain a health surveillance program for personnel engaged in large-scale research or production activities involving viable organisms containing recombinant or synthetic nucleic acid molecules which require BSL3 containment at the laboratory scale. The institution shall establish and maintain a health surveillance program for personnel engaged in animal research involving viable recombinant or synthetic nucleic acid molecule-containing microorganisms that require BSL-3 or greater containment in the laboratory

- Report any significant problems, violations of the *NIH Guidelines*, or any significant research-related accidents and illnesses to NIH/OBA within thirty days (reports will be made by the BSO).

## **2.2. IBC RESPONSIBILITIES**

- Review and approve work involving recombinant and / or synthetic nucleic molecules, potentially biohazardous materials, agents and toxins conducted at UTSA for adherence with the *NIH Guidelines*, the BMBL and Select Agent and Toxins regulations.
- Notify the principal investigator of the results of the IBC review
- Set containment levels and modify containment levels for ongoing experiments as warranted, implement contingency plans for handling accidents involving recombinant and / or synthetic nucleic acids.
- Review individual protocols for any DURC and establish an appropriate risk assessment for any work approved under the DURC regulations.
- Conduct an annual check of protocols using agents listed in the DURC regulations to ensure ongoing compliance with the regulations.
- Review research protocol renewals involving recombinant and / or synthetic nucleic molecules, potentially biohazardous materials, agents and toxins on a three-year basis.
- Review any amendments, changes to research scope and changes to research personnel for individual protocols.
- Complete an annual IBC registration with NIH/OBA.
- Recommend the suspension or termination of protocol approval for recombinant and / or synthetic nucleic molecules, potentially biohazardous materials, agents and toxins when notified of non-compliance or that the study, procedures or practices pose an undue risk to personnel, the environment or the community. The IBC will recommend to the Assistant Vice President for Research Integrity (AVPRI) that a protocol meets the criteria for suspension or termination and the AVPRI will inform the P.I.

## **2.3. IBC CHAIR**

- Acts as a liaison between the IBC, IBC administrative personnel and research personnel.
- Signs the approved minutes for the convened meetings of the IBC.
- Calls the meeting, directs meeting deliberations, requests motions and seconds and closes the meeting.

## **2.4. PRINCIPAL INVESTIGATORS**

On behalf of UTSA the Principal Investigator (P.I.) is responsible to be familiar with and follow the *NIH Guidelines*, the BMBL, IBC Policies and Select Agent and Toxin Regulations (if applicable). P.I. responsibilities include, but are not limited to, the following:

- Be adequately trained and ensure their staff are adequately trained to perform the research detailed in the approved protocol and respond to any emergencies or accidents.

- Conduct a risk assessment of the work in the protocol and mitigate identified risks as necessary.
- Adhere to institutional biosafety plans.
- Notify the BSO immediately of any accidents or incidents involving recombinant and / or synthetic nucleic molecules, potentially biohazardous materials, agents and toxins. The BSO will then generate a report to NIH.
- Obtain IBC approval prior to initiating or modifying any research involving recombinant and / or synthetic nucleic molecules, potentially biohazardous materials, agents and toxins.
- Maintain up to date IBC approval for use of recombinant and / or synthetic nucleic molecules, potentially biohazardous materials, agents and toxins by the timely submission of three-year protocol renewals. Changes to protocols, including personnel changes and experimental changes must be submitted to the IBC as amendments to the original protocol.
- Ensure all research personnel involved in the use of or potentially exposed to biohazard materials are registered with the Occupational Health Program (OHP) if appropriate to the study requirements.
- Ensure that work is conducted at the containment levels specified within the approved IBC protocol.

## **2.5. OFFICE OF RESEARCH INTEGRITY AND LABORATORY COMPLIANCE MANAGER**

Staff based in the Office of Research Integrity, will provide administrative support and coordinate IBC reviews and meetings. Responsibilities include, but are not limited to, the following:

- Provide a point of contact between research personnel, the IBC, federal and regulatory agencies.
- Provide documentation and forms to the P.I.
- Maintain the IBC registration with NIH OBA and file the annual reports.
- Assist the BSO, IBC Chair and other UTSA offices in initial reviews of non-compliance with the *NIH Guidelines*.
- Maintain the IBC Policies, SOPs and protocol forms in accordance with the *NIH Guidelines*.
- Support the IBC meeting activities and review process.
- Initiate suspension or termination of protocols, through the AVPRI, when required.

## **2.6. CHAIRS, DEANS, VICE PRESIDENT FOR RESEARCH AND THE PROVOST**

The Department Chairs, Deans, Vice President for Research and the Provost are responsible for enforcing UTSA wide compliance with this policy.

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### **3. PROTOCOL SUBMISSION, AMENDMENT, RENEWALS AND REVIEW**

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#### **3.1. SUBMISSION**

The IBC is responsible for local review and oversight of research involving recombinant and / or synthetic nucleic molecules, potentially biohazardous materials, agents and toxins to ensure that institutional and federal regulations and guidelines are implemented.

All IBC protocol submissions, whether new, amendments or renewals, must be submitted to the IBC office ([ibc@utsa.edu](mailto:ibc@utsa.edu)) by the P.I. for review and IBC approval.

Research involving recombinant and / or synthetic nucleic molecules, potentially biohazardous materials, agents and toxins cannot be initiated until the P.I. has received approval from the IBC.

The P.I. must submit an application for all projects using recombinant and / or synthetic nucleic molecules, potentially biohazardous materials, agents and toxins. In some cases the IBC may determine that the work is exempt according to the federal regulations.

Modifications to approved protocols shall not be implemented until approved by the IBC.

#### **3.2. NEW SUBMISSIONS**

The application for IBC review and approval is available on the Office of Research Integrity website. The forms must be completed fully and accurately for review. The IBC office will assign a unique IBC identifying number to each protocol which should be used in all communications with the IBC office.

- When submitting a new protocol, it is recommended that the P.I. contacts the BSO to verify that the facilities are appropriate for the work being conducted.
- The P.I. must ensure that all the personnel listed on the protocol have completed all the training requirements for the project. IBC approval will be complete only when all training requirements are fulfilled by all personnel in the protocol.
- The P.I. may be asked to submit additional information prior to review by the IBC.
- New submissions should be submitted at least 1 week before the monthly IBC meeting.
- Protocols will be assigned a score of 1-3, with 1 being approval without changes, 2 being changes required by the P.I. followed by re-review by the IBC Chair and 3 being changes required by the P.I. followed by re-review by the full IBC committee. The IBC may also disapprove protocols as written.
- The P.I. will be notified of the committee's decision.

#### **3.3. AMENDMENTS**

Any changes or modifications to approved protocols, including, but not limited to, addition or removal of personnel, room changes, new procedures or agents, must be reviewed and approved by the IBC prior to initiation. Personnel changes may be approved administratively by the IBC

chair or ORI Staff without full committee review only when all training requirements are fulfilled. Administrative approvals of personnel changes must be listed in the next IBC meeting agenda and made available to all committee members. Any other changes to a protocol must be submitted to the IBC for full committee review.

### **3.4. CONTINUING REVIEW AND RENEWALS**

The P.I. is required to resubmit their protocol(s) for *de novo* re-review by the committee every three years. Notification of protocol expiration will be sent from the IBC office at 90, 60 and 30 days prior to the IBC meeting of the month of the project expiration, however it is the PI's responsibility to renew his/her protocol in a timely manner if continuation of the project is needed. Renewals are reviewed in the same manner as new submissions. Research may not continue if the protocol has expired.

Protocols involving agents with DURC potential or NIH approved DURC experiments must submit an annual statement to the IBC confirming that the scope of work has not changed from the approved protocol. These annual submissions will be reviewed by the Laboratory Compliance Manager, IBC Chair and BSO and may be sent to the full committee if required. Work on protocols with DURC must cease immediately if the scope of work changes from the originally approved protocol and be submitted for re-review and NIH approval.

### **3.5. FAILURE TO SUBMIT RENEWALS / RESPOND TO IBC REQUIREMENTS**

Failure to renew an approved protocol by the expiration date, without P.I. termination of the protocol, will result in a notification letter being sent to the P.I. from the AVPRI and copied to the Chair/Dean of the appropriate department. All research activities pertaining to the research described in the approved protocol must cease. If a renewal is not submitted by the next IBC meeting the committee will be notified and a determination made whether to recommend suspension of the IBC protocol. Project suspension letters will be initiated by the AVPRI. Suspension of an IBC protocol may lead to notifications to related committees such as IRB and / or IACUC and to the departmental Research Service Center (RSC) and Office of Sponsored Program Administration (OSPA). P.I.s are encouraged to contact the IBC office to discuss any delays to protocol renewal in advance of the protocol expiration date.

### **3.6. PROJECT SUSPENSIONS**

The P.I. should notify the IBC office when a protocol involving recombinant and / or synthetic nucleic molecules, potentially biohazardous materials, agents and toxins is no longer active. These projects will be considered terminated and no further work in this area should continue unless a new protocol is initiated.

As stated in Section 3.5 failure to renew an approved protocol may result in suspension of the protocol. Non-compliance with institutional and federal regulations, guidelines, policies or requirements of the IBC that are serious and ongoing will be evaluated and the IBC may determine that incidents require protocol suspension or additional project oversight.

### **3.7. IACUC AND IRB**

IBC protocols involving the use of live animals will require an IACUC protocol approval prior to study initiation.

IBC protocols involving the administration of recombinant and / or synthetic nucleic molecules, potentially biohazardous materials, agents and toxins to humans, or involving the collection of tissues or fluids from humans, requires IRB review and approval (if appropriate) prior to study initiation.

## **4. IBC MEETING PROCESS**

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### **4.1. QUORUM**

Quorum must be established before official IBC business occurs at convened meetings. Quorum is defined as 50% + 1 of voting members as a minimum. A protocol is approved only if quorum is present, and if more than 50% of the quorum votes in favor of approval. For reasons other than conflict of interest, abstentions from voting do not alter the quorum or change the number of votes required. Members are required to notify, when possible, the IBC office in advance if they cannot attend a convened meeting.

### **4.2. REVIEW**

Protocols should be submitted by the submission deadlines posted on the IBC website (1 week prior to the scheduled meeting) to allow for adequate review time by the committee. The IBC may hold over protocols to the next convened meeting if the protocol is not submitted by the deadline. Additional information or documentation may be requested from the P.I. prior to the convened meeting. The P.I. can attend the IBC meeting in order to answer any questions related to the protocol.

### **4.3. PROCEDURES**

Upon meeting quorum, the IBC Chair will call the meeting to order and follow a previously prepared agenda. Typical meeting format will be:

- Call to order
- Approval of the minutes from the previous meeting
- Review of new or renewal protocols
- Review of protocol amendments
- Notification to the committee of any administrative approvals
- Notification to the committee of expired protocols
- New business – to include a general report from the BSO
- Meeting adjournment

Review of all protocols will address the following in accordance with the *NIH Guidelines*:

- Assessment of the containment levels required
- Assessment of the facilities, procedures, practices, training and expertise of personnel involved in research involved with recombinant and / or synthetic nucleic molecules, potentially biohazardous materials, agents and toxins.
- Compliance with the *NIH Guidelines*, BMBL and Select Agent and Toxin Regulations (where applicable).
- Agent characteristics.
- Manipulations planned.
- Source of nucleic acid molecules sequences (e.g. species)

- Nature or function of the gene encoded by recombinant or synthetic nucleic acid molecule sequences.
- Hosts and vectors.
- Expression of foreign genes and the protein produced.
- Change in biosafety risk for an organism formed through the combination of sequences from multiple sources or synergistic effect of combining transgenes resulting in new phenotypes.
- Containment conditions.
- Applicable sections of the *NIH Guidelines*.

#### **4.4. REVIEW OUTCOMES**

All protocols will be assigned a score as follows:

- Score 1 – Approval - The IBC has determined that all review criteria have been adequately addressed by the P.I., the protocol is approved and the study may proceed.
- Score 2 – Approval Pending Changes by the P.I. – The protocol requires the addition of further information, required training has not been completed, and / or there are remaining issues or questions regarding the safety of the study. The Committee may decide that the protocol can be re-reviewed and approved by the Chair, once all the required changes have been made.
- Score 3 – Approval withheld – The protocol requires the addition of further information, required training has not been completed, and there are remaining issues or questions regarding the safety of the study resulting in substantial amendments needed or other issues of concern remain. Protocols will be returned to the P.I. and must be resubmitted for full committee review.

#### **4.5. CONFLICT OF INTEREST**

*NIH Guidelines* state that no IBC member may participate in the IBC review or approval who has a conflict of interest in the project (e.g. the member is listed in the protocol).

If a conflict of interest with a specific protocol is determined, the member:

- May not vote.
- May not participate in the discussion, except to answer protocol specific questions or provide clarification to the IBC.
- May be asked to leave the room for portions of the discussion and for the vote.
- Is not counted towards quorum.

#### **4.6. MINUTES**

*NIH Guidelines* require that the IBC keep minutes of each meeting that contain sufficient detail about the rationale for decisions regarding research and serve as a record of major discussion points. The IBC has some latitude in defining the structure and content of the minutes.

Minutes will contain:

- Date, time and place of meeting.
- Members in attendance.
- Protocol number and title. A brief description of the project proposed will be included, the applicable biosafety and risk group designations and the applicable sections of the *NIH Guidelines* applied to the project.
- Major motions, major points of order, and whether the motions were approved.
- A list of any comments and requirements of the committee for each individual protocol.
- Time of meeting adjournment.

#### **4.7. MEETING FREQUENCY**

IBC meetings will occur monthly unless cancelled in consultation with the IBC chair. The Chair may schedule an emergency meeting as necessary to address unexpected events, issues or non-compliance involving recombinant and / or synthetic nucleic molecules, potentially biohazardous materials.

## **5. INCIDENT REPORTING**

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### **5.1. REPORTABLE INCIDENTS**

All incidents involving recombinant and / or synthetic nucleic molecules, potentially biohazardous materials must be reported immediately to the BSO.

The P.I. and any staff are required to notify the BSO of any significant incidents, accidents occurring during the course of research and illnesses potentially resulting from research activities.

If the incident involves materials included in the scope of the *NIH Guidelines* the BSO will make a report to NIH/OBA within 30 days of the incident being reported or discovered. Incidents occurring at BSL-3 resulting in overt or potential exposure will be reported immediately to NIH/OBA and any other relevant federal, state or local organization. Additional reporting requirements for Select Agents will be undertaken by the RO for the Select Agent Program.

## **6. EXTERNAL REQUESTS FOR INFORMATION**

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### **6.1. REQUESTS UNDER THE FREEDOM OF INFORMATION ACT**

Minutes from IBC meetings will be made available, upon request. Requests will be addressed using the same process as the Texas Public Information Act. Records requests are coordinated by UTSA's Public Information Officer in the Office of Legal Affairs. UTSA reserves the right to redact information that could compromise the safety and security of the facility, personnel or research or where proprietary information is included. Redaction will be applied with consistency to minutes.

### **6.2. ATTENDANCE AT IBC MEETINGS BY OUTSIDE ENTITIES**

IBC meetings are open to the public as required by the *NIH Guidelines*. However, requests to attend meetings should be made to the Laboratory Compliance Officer, in writing, 2 weeks prior to the meeting date to allow for any necessary room changes needed to accommodate additional attendees. Visitors to the meeting may not disrupt the normal business or voting of the meeting and are allowed to comment during the discussion period, comments will be restricted to five minutes to facilitate timely progression of the meeting.