UNIVERSITY OF TEXAS AT ARLINGTON

INSTITUTIONAL BIOSAFETY COMMITTEE

ROLES AND RESPONSIBILITIES SOP

I. The Institutional Biosafety Committee

A. In accordance with the *NIH Guidelines*, the University of Texas at Arlington (UTA) has established an Institutional Biosafety Committee (IBC) responsible for the review of all research involving recombinant or synthetic nucleic acid molecules, hereafter referred to as r/sNA. The IBC is a University-wide standing committee advisory to the Vice President for Research (VPR). The VPR appoints all IBC members and alternate members. The length of the appointment is at the discretion of the VPR. Members who do not adequately fulfill their responsibilities as judged by the IBC Chair and VPR may be asked to step down from their role as IBC member.

B. IBC membership shall adhere to the requirements of the *NIH Guidelines* Section IV-B-2-a. The IBC must be comprised of no fewer than five members so selected that they collectively have experience and expertise in r/sNA 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. At least two members shall not be affiliated with the institution (apart from their membership on the IBC) and who represent the interest of the surrounding community with respect to health and protection of the environment. The IBC shall include at least one individual with expertise in plant, plant pathogen, or plant pest containment principles when experiments utilizing Appendix L, *Physical and Biological Containment for Recombinant or Synthetic Nucleic Acid Molecule Research Involving Plants*, require prior approval by the IBC. The IBC shall include at least one scientist with expertise in animal containment principles when experiments utilizing Appendix M, *Physical and Biological Containment for Recombinant or Synthetic Nucleic Acid Molecule Research Involving Animals*, require IBC prior approval. When the institution conducts r/sNA research at BL3, BL4, or Large Scale (greater than 10 liters), a Biological Safety Officer is mandatory and shall be a member of the IBC (see Section IV-B-3, *Biological Safety Officer*). When the institution participates in or sponsors r/sNA research involving human research participants, the institution must ensure that the IBC has adequate expertise and training (using ad hoc consultants as deemed necessary). All IBC committee meetings will retain an appropriate quorum when conducted. A quorum is defined to be a simple majority (>50%) of voting members and does not require the unaffiliated member to be present.

C. On behalf of the Institution, and in accordance with the *NIH Guidelines*, the IBC is responsible for appropriate review, approval, and oversight of r/sNA research including:

1. Reviewing r/sNA research for compliance with the *NIH Guidelines* as specified in Section III, *Experiments Covered by the NIH Guidelines*, and approving those research projects that are found to conform with the *NIH Guidelines*. This review shall include: (a) independent assessment of the containment levels required by the *NIH Guidelines* for the proposed research; (b) assessment of the facilities, procedures, practices, and training and expertise of personnel involved in recombinant or nucleic acid molecule research; (c) ensuring that all aspects of Section III-C-1 (transfer of r/sNA into human research participants) have been met before final IBC approval is granted and before enrollment of any human research participant in a human gene transfer experiment.

2. Notifying the PI of the results of IBC review and approval.

3. Lowering containment levels for certain experiments as specified in Section III-D-2, *Experiments in which DNA from Risk Group 2, Risk Group 3, Risk Group 4, or Restricted Agents is Cloned into Nonpathogenic Prokaryotic or Lower Eukaryotic Host-Vector Systems*, and setting containment levels as specified in Sections III-D-4, *Experiments Involving Whole Animals*, and III-D-5, *Experiments Involving Whole Plants*.

4. Periodically reviewing r/sNA research conducted at the institution to ensure compliance with the *NIH Guidelines*.

5. Adopting emergency plans covering accidental spills and personnel contamination resulting from r/sNA research as described in the *NIH Guidelines*. The IBC works with EH&S to develop such plans according to the UTA Biosafety Manual which covers biohazardous spills as well as decontamination.

6. Ensuring appropriate training for PIs regarding laboratory safety and implementation of the *NIH Guidelines*.

7. Determining the necessity for health surveillance of personnel involved in connection with individual r/sNA projects; and if appropriate, conduct a health surveillance program for such projects.

D. The IBC may not authorize initiation of experiments which are not explicitly covered by the *NIH Guidelines* until NIH establishes the containment requirement.

E. The IBC will provide consultation to the Institution's research community including faculty, staff, and students, concerning issues of biohazards, biosafety procedures, and appropriate biological techniques (best practices) involving r/sNA to minimize risk and hazard. Serving in this consultancy capacity, the IBC may provide written recommendations, as requested by UT Arlington Administration or EH&S, pertaining to

risk assessment, establishment of appropriate containment, and laboratory safety procedures.

F. The IBC shall operate in close association with the Office of Regulatory Services with regard to registration, document preparation, educational efforts, materials, and compliance with biosafety regulations and guidelines.

G. The IBC shall maintain strong liaisons with UT Arlington's Institutional Review Board for the Protection of Human Subjects (IRB), the Institutional Animal Care & Use Committee (IACUC), and the Radiation Safety Committee (RSC).

H. No member of the IBC may be involved (except to provide information requested by the IBC) in the review or approval of a project in which he/she has been or expects to be engaged or has a direct financial interest.

II. The IBC Chairperson

A. The Chairperson shall be appointed by the VPR according to the following criteria:

1. Commitment to the goals of ensuring the safety of research involving r/sNA, preventing threats to the safety of UT Arlington personnel from biological hazards, and assisting/advising UT Arlington Investigators to become knowledgeable and comply with appropriate regulations and guidelines.

2. Willingness to devote energies necessary to maintain and oversee effective continual integrity of the IBC structure and function.

3. Possess the expertise necessary to review specific research activities involving r/sNA and determine applicable exemptions in accordance with the *NIH Guidelines*.

4. Flexibility to participate in seminars, workshops, etc. at the state and national level serving as a spokesperson from the University as an intermediary transmitting information to the IBC and the University.

B. The specific responsibilities of the IBC Chair include, but are not limited to, the following:

1. Call and preside over IBC meetings.

2. Act as a liaison between the Committee and University administrators, federal and state officers involved in the practices of institutional biosafety committees, and spokespersons representing committees from other institutions.

3. Ensure IBC members are appropriately trained to review r/sNA research in accordance with the *NIH Guidelines*.

4. Review r/sNA research proposals to determine applicable exemptions as described in the *NIH Guidelines* Section III-F.

5. Review, with full committee membership, research proposals involving non-exempt r/sNA research.

6. Oversee continuing review of protocols involving non-exempt r/sNA research.

7. Prepare and distribute written notices when research activities have been approved and forward a copy to the IBC Office of Record, the Office of Regulatory Services.

8. Remain abreast of any literature or information issued by federal, state, or local sources concerned with the nature and procedures of biosafety. The Chairperson must keep Committee members informed of pertinent information.

9. Submit written statements of evaluation concerning the Committee structure and function to the University administrative sources as requested.

III. Principal Investigators

A. In accordance with the *NIH Guidelines* Section IV-B-7, on behalf of the institution, the PI is responsible for full compliance with the *NIH Guidelines* in the conduct of recombinant or synthetic nucleic acid molecule research. As part of this general responsibility, the PI shall:

1. Initiate or modify no r/sNA research which requires IBC approval prior to initiation, until that research or the proposed modification thereof has been approved by the IBC and has met all other requirements of the *NIH Guidelines*.

2. Determine whether experiments are covered by *NIH Guidelines* Section III-E, *Experiments that Require Institutional Biosafety Committee Notice Simultaneous with Initiation*, and ensure that the appropriate procedures are followed.

3. Promptly report (within 5 business days) any significant problems, violations of the *NIH Guidelines*, or any significant research-related accidents and illnesses to the IBC and Office of Regulatory Services. Accidents and injuries must be reported immediately (within 24 hours) to EH&S.

4. Report discovery of new information regarding r/sNA and its associated hazards that would necessitate revision to the *NIH Guidelines* to the IBC and NIH.

5. Be adequately trained in good microbiological techniques and ensure that research staff and students are appropriately trained regarding laboratory safety and implementation of the *NIH Guidelines*.

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

7. Comply with shipping requirements for r/sNA (see *NIH Guidelines* Appendix H, *Shipment*, for shipping requirements and the *Laboratory Safety Monograph* for technical recommendations).

8. Ensure that all aspects of *NIH Guidelines* Section III-C-1 have been appropriately addressed in regard to human gene transfer experiments.

B. For submissions to the IBC the PI shall:

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

2. Select appropriate microbiological practices and laboratory techniques to be used for the research.

3. Submit the initial research protocol and any subsequent changes (e.g., changes in the source of DNA or host-vector system) to the IBC for review and approval or disapproval.

4. Remain in communication with the IBC throughout the conduct of the project and submit appropriate information in a timely manner for continuing or periodic reviews of approved research.

C. Responsibilities of the PI prior to initiating research include:

1. Make available to all laboratory staff the protocols that describe the potential biohazards and the precautions to be taken.

2. Provide site-specific training to laboratory staff as described in IBC Review Procedures and Training SOP (Section H).

3. Inform the laboratory staff of the reasons and provisions for any precautionary medical practices advised or requested (e.g., vaccinations or serum collection).

D. Responsibilities of the PI during the conduct of research include:

1. Follow the IBC-approved protocol procedures. Any modification to the protocol

procedures must be reviewed and approved by the IBC before implementation.

2. Supervise the safety performance of the laboratory staff to ensure that the required safety practices and techniques are employed.

3. Investigate and promptly report to the IBC, in writing, any significant problems pertaining to the operation and implementation of containment practices and procedures.

4. Correct work errors and conditions that may result in the release of r/sNA materials.

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

6. Comply with reporting requirements for human gene transfer experiments conducted in accordance with approved IBC protocol and federal regulations.

IV. The Office of Regulatory Services

A. The Institutional Official (IO) for Biosafety related to r/sNA research shall be the VPR. Regulatory Services shall report to the VPR in matters related to r/sNA research and the IBC.

B. The responsibilities of Regulatory Services shall include:

1. Assist and ensure compliance with the *NIH Guidelines* by PIs conducting research at the institution as specified in Section IV-B-7.

2. Serve as the Office of Record for the IBC, maintaining all documentation as required by the *NIH Guidelines*. Maintain confidential and secure database records and files of all registration documents, research protocols, correspondence, membership, meeting minutes, and decisions related to IBC issues.

3. Receive research protocols involving recombinant or synthetic nucleic acid molecules, assist PIs with proper completion of protocols, and facilitate review by the IBC.

4. Initiate continuing reviews on active research protocols as required by the IBC.

5. Receive periodic review reports and amendments, assist PIs with proper completion, and facilitate review by the IBC.

6. Gather and distribute information relevant to the IBC's functions.

7. Report any significant problems, violations of the *NIH Guidelines*, or any significant research-related accidents and illnesses to NIH/OBA within thirty days or as required, unless the institution determines that a report has already been filed by the PI or IBC.

8. File an annual report with NIH Office of Science Policy which includes: (a) a roster of all IBC members clearly indicating the Chair, contact person, Biological Safety Officer (if applicable), plant expert (if applicable), animal expert (if applicable), human gene therapy expertise or *ad hoc* consultant (if applicable); and (b) biographical sketches of all IBC members (including community members).

9. When possible and consistent with protection of privacy and proprietary interests, open the IBC meetings to the public. Upon request, the institution shall make available to the public all IBC meeting minutes and any documents submitted to or received from funding agencies which the latter are required to make available to the public. If public comments are made on IBC actions, the institution shall forward both the public comments and the IBC's response to NIH/OBA.

10. Facilitate and document online training in r/sNA and transgenic animals for PIs and protocol personnel.

V. Environmental Health & Safety (EH&S)

A. EH&S is the operational arm of the biological research program. As related to r/sNA research, the responsibilities of EH&S include:

1. Advising and instruction of PIs, staff, and students in matters of appropriate safety practices and techniques, containment equipment, hazardous waste disposal, and construction design.

2. Providing and documenting, as applicable, appropriate education and training on research safety techniques/practices such as shipping of hazardous materials, blood borne pathogens, chemical safety, waste disposal, radiation safety, laser safety, and occupational health & safety.

3. Conducting routine laboratory inspections of work areas and performing or recommending preventive/corrective actions when necessary.

4. Reporting violations of the *NIH Guidelines* to the IBC.

5. Investigation of laboratory accidents or injuries.

6. Responding to emergencies (spills, personnel contamination, etc.).

7. Keeping record of, and obtaining when necessary, Pathogen Safety Data Sheets (PSDS) / Safety Data Sheets (SDS) on infectious agents / hazardous materials related to approved recombinant or synthetic nucleic acid molecule research.