UNIVERSITY OF TEXAS AT ARLINGTON

INSTITUTIONAL BIOSAFETY COMMITTEE

REVIEW PROCEDURES AND TRAINING SOP

A. For all experiments involving recombinant and synthetic nucleic acid molecules, hereafter referred to as r/sNA, including those which are considered exempt by *NIH Guidelines*, Principal Investigators (PIs) must submit an IBC Protocol Application for (i) exemption determination and documentation **or** (ii) IBC review and approval of non-exempt experiments. IBC Protocol Applications should be submitted to the Office of Regulatory Services at regulatoryservices@uta.edu.

B. The IBC Protocol Application Form is divided into 2 parts. Experiments qualifying for exemption under the *NIH Guidelines* Section III-F require completion of Part I of the Protocol Application. Experiments that do not qualify for exemption under the *NIH Guidelines* Section III-F (non-exempt) require completion of both Part I and Part II of the Protocol Application.

C. The Protocol Application will be initially reviewed by the Office of Regulatory Services and the IBC Chairperson to determine if it falls under the eight categories of exemption as described in the *NIH Guidelines* Section III-F.

D. Experiments determined as exempt by the IBC Chairperson will receive an acknowledgement letter from the IBC documenting the exemption and determination. No further action is required by the PI unless there is a change in procedures or the use of r/sNA that would affect the IBC's initial determination as exempt (allowable exemptions are outlined in *NIH Guidelines* Section III-F). If there is a change that would affect the exempt determination, the PI should notify the Office of Regulatory Services at regulatoryservices@uta.edu before implementing the change. The Office of Regulatory Services will advise the PI whether a new protocol application is required or an amendment to the original protocol is sufficient.

E. New protocol applications for experiments that do not meet criteria for exemption as outlined in *NIH Guidelines* Section III-F will be scheduled for review by the fully convened IBC at the next scheduled meeting. It is strongly recommended that the PI attend the meeting to answer any questions or address concerns of the IBC during review in order to avoid tabling of the protocol.

F. The IBC will consider the Protocol Application in conjunction the *NIH Guidelines'* review requirements including:

   i. The source(s) of DNA.

ii. The nature of the inserted DNA sequences.

iii. The host(s) and vector(s) to be used.

iv. If an attempt will be made to obtain expression of a foreign gene, and if so, the protein that will be produced.

v. The containment conditions that will be implemented as specified in the *NIH Guidelines*.

G. If the IBC requests additional information or modifications to secure approval following review of a Protocol Application, the Office of Regulatory Services will summarize these requests and notify the PI.

H. Training requirements as determined by the PI and the IBC must be completed by the PI and their research staff. In accordance with the *NIH Guidelines* Appendix G, the PI is responsible for ensuring that everyone in their laboratory has received adequate instruction in aseptic technique, the biology of the organisms used in the experiments, potential hazards, and the specific project emergency plan. This site-specific training must be documented by the PI (dates, attendees, topics) and made available to the IBC and Environmental Health & Safety (EH&S) as requested. Laboratory Site-Specific Training Sign-in Sheet Template can be found on the EH&S website.

In addition to site-specific training performed by the PI, there may be additional training requirements depending upon the type of research activity. For example RCOI training is required for personnel on protocols that have pending or awarded PHS funding, in accordance with UTA's RCOI Policy. Training may occur simultaneously with the protocol review process, but final approval of the IBC Protocol Application will not be granted until the training requirements have been met and verified by the IBC.

Table 1. IBC Training Requirements

Research Involves:	**Training Requirement:**
Recombinant and Synthetic Nucleic Acid Molecules	Office of Regulatory Services Training Site: Recombinant DNA and Transgenic Animals
Chemical Hazards	EH&S Training Site: Hazard Communication and Waste Management – Academic (Course #CEM200)
Radioactive Material & X-Rays	EH&S Training Site: Radiation Awareness (Course #RAD100), Radiation Producing Machine (Xray) – Part 1 (Course #RAD200), & Radiation Producing Machine (Xray) – Part 2 (Course #RAD300)

Lasers	EH&S Training Site: Laser Safety (Course #LSR100)
Animals	Office of Regulatory Services Training Site: IACUC General Training
Human Blood, Body Fluids, or Tissue	EH&S Training Site: Bloodborne Pathogens for Laboratory Research Personnel (Course #BIOL200) & Biosafety Level 2 (BSL-2) (Course #BIOL500)
Human Subjects	UTA's Human Subjects Protection (HSP) Training
PHS Funding (pending or awarded)	UTA's RCOI Training: Conflicts of Interest in Research: Disclosure, Management, and Reporting

I. Experiments with r/sNA requiring BSL-2 or higher containment will require certification of the laboratory to ensure appropriate safety practices, equipment, and facility design. The PI should notify EH&S (817-272-2185 or ehsafety@uta.edu) as soon as possible once determined these levels of containment will be necessary. The laboratory certification process may occur simultaneously with the protocol review process, but final approval of the Protocol Application will not be granted until the BSL-2 laboratory certification by EH&S is complete.

J. Occupational Health and Safety

i. The IBC shall determine the necessity for health surveillance of personnel involved in connection with individual recombinant or synthetic nucleic acid molecule projects; and if appropriate, conduct a health surveillance program for such projects.

ii. The Office of Regulatory Services will work with EH&S to provide oversight for health surveillance of personnel involved in connection with individual r/sNA projects that have been determined, by the IBC, to require a health surveillance program.

iii. The institution shall establish and maintain a health surveillance program for personnel engaged in large-scale research or production activities involving viable organisms containing r/sNA which require BSL-3 containment at the laboratory scale. The institution shall establish and maintain a health surveillance program for personnel engaged in animal research involving viable r/sNA-containing microorganisms that require BSL-3 or greater containment in the laboratory. (BSL-3 containment and above requires prior approval by UTA Administration.)

K. When an IBC protocol involves biohazardous agents such as microbial pathogens, toxins, and/or human blood, body fluids, and cells/tissues, the PI is responsible for completing the

appropriate parts of the Human Pathogen Registration (HPR) and forwarding it to EH&S. After receiving the registration, EH&S conducts a laboratory inspection using Biosafety Level 2 (BSL-2) Commissioning Checklist to ensure compliance with local, state, and federal regulations and to improve safety. The PI is also responsible for notifying EH&S when the project has terminated or when other significant changes occur using the Human Pathogen Registration Update (HPRU). These forms can be found on the EH&S – Biological Safety website under "Forms."

L. Final approval of research protocols will be communicated to PIs via an approval letter issued by the IBC Chairperson.

M. In accordance with the *NIH Guidelines* Section IV-B-2, the IBC will periodically review approved r/sNA research to ensure compliance with the *NIH Guidelines* and UT Arlington Policy RA-PO8 (Policy for Research Involving Recombinant or Synthetic Nucleic Acid Molecules). Periodic reviews will be scheduled at the discretion of the IBC and communicated to the PIs. PIs are responsible for submitting information requested during periodic reviews in a timely manner, meeting the deadlines established by the IBC.

   i. Protocols with a non-exempt determination must complete a Periodic Review every 3 years.
      a) Triennial reports should be submitted to the Office of Regulatory Services at regulatoryservices@uta.edu
      b) The IBC will review the Triennial Report via email. The review period is typically 5 business days. If the IBC requests additional information or modifications to secure approval following review of an Triennial Report, the Office of Regulatory Services will summarize these requests and notify the PI.
      c) The Triennial Report must be completed and approved by the anniversary date of original IBC approval of the protocol.
      d) Approval of Triennial Reports will be communicated to PIs via an approval letter issued by the IBC Chairperson.

   ii. Protocols with an exempt determination will undergo a triennial protocol follow-up (email from the Office of Regulatory Services) to verify project status.

N. The PI is responsible for submitting an Amendment Form to the IBC before implementing major changes in approved r/sNA experiments.

   i. Major changes include:
      a) A change in host or vector.
      b) A change in the donor species or nature of the DNA segment selected.
      c) A change of project title.
      d) A change in funding agency.
      e) A change in the location of work/experiments.
      f) A change of the PI.

ii. Amendment Forms should be submitted to the Office of Regulatory Services at regulatoryservices@uta.edu.

iii. The IBC will review Amendments via email. The review period is typically 5 business days. If the IBC requests additional information or modifications to secure approval following review of an Amendment, the Office of Regulatory Services will summarize these requests and notify the PI.

iv. Approval of Amendments will be communicated to PIs via an approval letter issued by the IBC Chairperson.

v. Laboratory personnel changes will be handled administratively with verification of all appropriate trainings. To make a personnel change on a protocol, PIs should email regulatoryservices@uta.edu.

O. When research covered by UT Arlington Policy RA-PO8 or the *NIH Guidelines* is conducted at or in cooperation with another entity, all provisions of UT Arlington Policy RA-PO8 remain in effect for that research. The UT Arlington IBC may accept, for the purpose of meeting IBC review requirements, the review of an IBC established under another policy of compliance with the NIH. Such acceptance must be in writing, approved and signed by UT Arlington's IBC Chairperson, and approved and signed by correlative officials of each of the other cooperating institutions.