TEXAS TECH UNIVERSITY
HEALTH SCIENCES CENTER™

Institutional Biosafety Committee Bylaws

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Section 1.0 Introduction

Texas Tech University Health Sciences Center has fulfilled state and federal laws for regulation of hazardous biological agents, hazardous chemical agents, toxins, and recombinant or synthetic nucleic acids by creating the Institutional Biosafety Committee (IBC), a governing body charged with reviewing and monitoring the ethical and safe use of said agents. The responsibilities of the IBC include communication between the IBC, Principal Investigator (PI), Safety Services, and other institutional committees to ensure the safety of personnel, staff, and the local environment. The information in this manual is intended to provide procedural detail to accompany the HSC Operating Policy 73.05 Research Involving Hazardous Chemical and Biological Materials, and Recombinant or Synthetic Nucleic Acid Molecules.

1.1 Institutional Biosafety Committee

The Senior Vice President for Research (SVPR) has charged the TTUHSC IBC with review, approval, and oversight of research involving recombinant/synthetic nucleic acids and use of hazardous materials. IBC procedures apply to all personnel and faculty involved in research and/or activities involving hazardous biological materials, hazardous chemical materials, toxins, and the use of recombinant or synthetic nucleic acid molecules used in experimental studies or animal studies that are:

- Carried out by TTUHSC faculty, staff, students or volunteers;
- Conducted using TTUHSC property, facilities;
- non-public information belonging to or under the control of TTUHSC;
- Received, stored, used, transferred or disposed of at any of TTUHSC facilities.

Recombinant/synthetic nucleic acid (r/sNA) molecules are defined as:

- molecules that a) are constructed by joining nucleic acid molecules and b) 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 (i) or (ii) above.

The IBC receives administrative support from the TTUHSC Research Integrity Office which is part of the TTUHSC Office of Research. The IBC works in conjunction with other TTUHSC office and committees including the Office of Safety Services, the Institutional Animal Care and Use Committee (IACUC), and the Institutional Review Board (IRB) in order to ensure the health and safety of all personnel.

1.2 Charge and Authority of the IBC

As TTUHSC receives funding from the National Institutes of Health (NIH) for research involving r/sNA molecules, all activities involving these materials must follow NIH Guidelines. Failure to adhere to these guidelines can result in suspension or termination of NIH funding, or require prior NIH approval of any or all r/sNA projects at the institution. These policies and procedures are based upon information found in the NIH Guidelines. Applications approved under any version of the IBC Policies and Procedures may

require modification as these guidelines, or other federal, state, or institutional rules change. TTUHSC requires all activities that involve the use of r/sNA to be reviewed and approved by the IBC regardless of the funding source for the work.

Responsibilities of the IBC include training of research personnel to assure compliance with National Institutes of Health/Office of Biotechnology Activities (OBA) and other pertinent guidelines and regulations. 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. Please consult the HSC Operating Policy 73.05 Research Involving Hazardous Chemical and Biological Materials, and Recombinant or Synthetic Nucleic Acid Molecules for more information regarding the IBC.

1.3 Responsibilities

The TTUHSC Institutional Biosafety Committee is responsible for carrying out institutional policies that will safeguard our community and the well-being of our laboratory personnel. The IBC reviews DURC and all research involving hazardous biological, hazardous chemical agents, and toxins; hereafter referred to as hazardous materials. Any faculty member at TTUHSC who oversees a research lab will be required to have an approved protocol from the TTUHSC IBC. The approved protocol serves as a broad inventory of all hazardous agents in the lab, approved laboratory personnel and provides a general scope of the activities taking place in the research lab. The TTUHSC IBC is not involved in the oversight of clinical laboratories. Further duties of the IBC include:

- Review, approval and oversight of research utilizing r/sNA molecules for adherence with the NIH Guidelines. This pertains to initial reviews and ongoing reviews and modifications to currently approved research. Initial and ongoing reviews shall include:
    - an independent assessment of the biosafety level (including appropriate physical containment) required by the NIH Guidelines for proposed research;
    - an assessment of the facilities, procedures, practices, training and expertise of all personnel involved in the research;
    - at such time as any human gene transfer research may be proposed to take place at TTUHSC, ensuring that all aspects of the NIH Guidelines, Appendix M are fully addressed
- Periodically review and modify institutional procedures the possession for the safe use, handling, and storage of hazardous chemical, biological materials, and use of r/sNA molecules as required by NIH/OBA and other federal or state regulations or institutional requirements;
- Notifying the Principal Investigator of the results of the IBC's review, approval, or disapproval;
- Advise the Institution/Investigators on regulations & policies involving hazardous materials and recombinant or synthetic nucleic acid molecules;
- Advise the Laboratory Animal Resource Center on safe practices involving hazardous materials and r/sNA molecules;
- Certify to granting agencies that facilities, procedures, personnel training/expertise, and practices have been reviewed and approved;
- Monitor institutional educational programs on the use of hazardous materials and r/sNA molecules;
- Review the Laboratory Safety Manual every 3 years;

- Reviewing and reporting of any significant problems, violations and any significant research-related accidents or illnesses to the Institutional Official (IO) and to the National Institutes of Health/Office of Biotechnology Activities (OBA) per the NIH Guidelines.
- Periodically reviewing and modifying institutional procedures as required by NIH/OBA and other federal or state regulations or institutional requirements to oversee the possession and/or use of recombinant or synthetic nucleic acid molecules.
- Suspending or terminating approval for the possession or use of r/sNA if 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. Enforce punitive measures, including lab closure, when necessary to safeguard employees, the public, and the environment.

1.4 Institutional Official Responsibilities

The responsibility for the IBC rests with the Senior Vice President for Research (SVPR) who is the Institutional Official. The institutional Official:

- Appoints IBC members;
- Periodically evaluates IBC members with input from the IBC Chair and IBC Administrator;
- Annually evaluates the allocation of resources to the IBC and adjusts as necessary.

Section 2.0 Committee Composition

The IBC must have a Chair, Co-Chair, and Biosafety Officer. The committee must have a minimum of 5 members though any member may serve multiple roles. New members are appointed by the Senior Vice President of Research but may also be nominated by committee members. A member's appointment is an annual term, coinciding with the institution's fiscal year and automatically renewed on a year to year basis. The membership of this committee consists of the following:

- A minimum of five TTUHSC faculty members. Attempts will be made to include representation from each TTUHSC school and campus whose faculty conduct basic laboratory research;
- At least one member with expertise in each of the following areas: genetics, microorganisms, r/sNA technology;
- The TTUHSC Biological Safety Officer (BSO);
- The TTUHSC Institutional Veterinarian;
- Two committee members who are not affiliated with TTUHSC who represent the interests of the West Texas area with respect to health and protection of the environment;
- For the general purposes of the committee at least one representative from the Office of Safety Services from each TTUHSC campus where basic laboratory research is conducted;
- At least one member representing the laboratory technical staff.

An individual may meet more than one of the above criteria. Further, the Committee may seek the advice of non-voting consultants from other disciplines as needed to carry out its duties.

The committee shall make recommendations to the SVPR for officers to the positions of Chairperson and Co-Chairperson. They shall perform the duties described by IBC Bylaws and by the parliamentary authority adopted by the IBC. Until notice is given to the officers by the SVPR or the SVPR by the officers, these appointments shall be automatically renewed on a year to year basis.

An individual with expertise in plant, plant pathogens, or plant pest containment principles will be appointed to the IBC as a voting member, if ever any TTUHSC researchers wish to begin conducting such r/sNA research.

Appointment to the IBC may be rescinded at the sole discretion of the SVPR. Removal of members will generally be for cause, but not, in any case, for purposes of retaliation or for unconstitutional reasons. Members may also be removed and replaced for more than three unexcused absences during a fiscal year.

2.1 Committee Responsibilities

The IBC advises the institution on regulations and policies involving biologically and chemically hazardous materials. In conjunction with TTUHSC Safety Services, the IBC maintains and enforces standard operating procedures for research involving biologically and/or chemically hazardous material. The committee also serves as a resource for the Laboratory Animal Resource Center when evaluating the use of hazardous chemicals or biologics in human or animal studies.

- As a committee, members will review initial applications, 3-Year Renewals, Amendments, and Designated Review Submissions to assist a PI in the set-up and maintenance of their laboratories;
- Continuing review of existing protocols is the responsibility of the IBC to enforce standard operating procedures and comply with NIH Guidelines.

2.2 Research Integrity Office Responsibilities

The Assistant Vice President in the Research Integrity Office will appoint a Research Integrity Office (RIO) staff member to provide overall administrative support of the IBC. The IBC administrator will coordinate IBC reviews and meetings. The IBC administrator's responsibilities include but are not limited to the following:

- Serve as liaison between research personnel, the IBC, federal and regulatory agencies;
- Provide 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;
- Provide copies of meeting minutes, incidents of non-compliance, suspensions or terminations of IBC-approved research to the Institutional Official and Assistant Vice President for Research Integrity;
- Communicate with IRB or IACUC when research involves human subjects or animals; provide administrative support for the IBC by scheduling meetings, arranging for meeting space and taking/disseminating/maintaining meeting minutes.

RIO will provide annual updates of the IBC to the NIH Office of Biotechnology Activities (OBA). The TTUHSC IBC is registered with the OBA for purposes of r/sNA research. An annual report is filed with OBA, which includes an updated list of IBC members indicating the role and institutional affiliation of each member and biosketches for each member. RIO notifies OBA of changes in IBC membership and submits the annual report on behalf of TTUHSC using the online IBC Registration and Management System.

2.3 IBC Chairperson Responsibilities

The Chairperson will approve meeting agendas, call meetings to order, direct deliberations, request motions and seconds, and close the meeting once business has concluded. In addition, the IBC Chair acts as liaison between the IBC and Investigators when needed. Enforcement of decisions taken by the committee will require the support of the Chairperson if needed. The Co-Chairperson will provide additional support by stepping in as Interim Chairperson in case the Chairperson is unable to fulfill their duties. In addition, responsibilities may include but may not be limited to:

- Serving as a potential contact for all regulatory agencies;
- Assigning *ad hoc* subcommittees as needed to review an issue prior to official committee decisions made at a convened meeting.

2.4 Biological Safety Officer Responsibilities

The Biological Safety Officer (BSO) is a federally required member of the IBC per NIH Guidelines (§ IV-B-3-c). The principal function of the BSO should be to advise the research personnel and the IBC concerning the most appropriate safety practices that will assure the safe conduct of research with r/sNA.

BSO responsibilities include:

- Performance of periodic inspections of laboratories conducting research using r/sNA to ensure that laboratory standards are rigorously followed;
- Perform and review the required risk assessment;
- Develop emergency plans for handling accidental spills, personnel contamination, and investigate laboratory accidents involving r/sNA;
- Provide advice on laboratory security to the IBC research personnel;
- Provide technical advice to research personnel and the IBC on research safety procedures.

2.5 Member Responsibilities

Committee members are volunteers who represent either the Safety Services department or Research Faculty. As a member duties include but may not be limited to the following:

- Review Initial Submissions, 3-Year Renewals, Amendments, and Designated Review Submissions as assigned
- Offer individual expertise during meetings or to other members as needed
- Attend IBC meetings once a month

Members may also serve on a sub-committee if called upon for review of specific projects or development of policy. If there is a conflict of interest (COI) members may not vote on approval/disapproval of a submission.

2.6 IBC Chairperson & Member Training

The IBC Chairperson and all voting members of the IBC are required to complete the NIH Recombinant DNA Guidelines course offered through CITI. Voting members who are TTUHSC employees must also complete NESOP and annual refresher training offered through TTUHSC Safety Services.

The IBC Chair and members are also encouraged to participate in at least two hours of continuing education annually regarding the research uses of r/sNA and the implementation of the NIH Guidelines. This additional training can include, but is not limited to:

- Attending educational presentations as part of regularly scheduled IBC meetings;
- Reviewing relevant books, periodicals or handouts furnished to IBC members;
- Attending TTUHSC training seminars focusing on relevant topics;

Attending local, regional or national seminars or conference related to institutional biosafety or r/sNA materials. A stipend to offset travel costs may be available from the TTUHSC Office of Research.

2.7 Principal Investigator Responsibilities

The Principal Investigator (PI) is responsible for full compliance with NIH Guidelines and institutional policies and procedures when using r/sNA. As part of the general responsibility the PI will:

- Make the initial risk assessment and determination of required biosafety levels (including physical containment) in accordance with the NIH Guidelines;
- Obtain adequate training in best laboratory techniques/practices, including 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;
- Provide laboratory research personnel with descriptions of potential biohazards and necessary precautions; 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 r/sNA and/or biohazardous materials, agents or toxins;
- Develop and obtain IBC approval of and adhere to biosafety plans for handling accidental spills and personnel contamination;
- Inform the research personnel of the Occupational Health & Safety Program and provisions for any precautionary medical practices advised or requested (e.g., vaccinations);
- Obtain and maintain IBC approval prior to initiating or modifying any research involving use of r/sNA;
- Immediately (within 24 hours of becoming aware of the event) report any significant problems or any research-related accidents and/or illnesses to the Biological Safety Officer (BSO) in the Office of Safety Services. Details regarding reporting of significant problems, unanticipated events, research-related accidents or illnesses (see Section 8.0);
- Comply with permit and shipping requirements for biohazardous materials;
- Although federal regulations allow exemptions for some types of r/sNA use, the Principal Investigator must submit an application for all projects using r/sNA and biohazardous materials, agents and toxins so the IBC can make the decision as to whether or not they are exempt.

Clarification of these responsibilities is provided in section 6.0.

Section 3.0 Meetings

The IBC will meet monthly to conduct official business, prior to each meeting all voting IBC members shall receive copies of the meeting agenda, draft minutes of the previous meeting, and any necessary materials required for discussion of agenda items. A quorum of members must be present in order (teleconference is acceptable) to conduct the business of the IBC. The IBC defines "quorum" as fifty percent of members plus one of the regular voting members. If quorum is not attained at any time during the meeting, no further action shall be taken to the IBC until a quorum is reached.

At a minimum the IBC will meet once every fiscal quarter if monthly meetings may not be held. Meetings will be held on the second Tuesday of each month unless other arrangements are made by the Chairperson, and may be subject to changes due to the holiday schedule. When possible, and consistent with protection of privacy and proprietary interests, IBC meetings shall be made open to the public in accordance with the NIH Guidelines.

3.1 Attendance

Members are expected to attend a majority of IBC meetings. Anticipated absences from an IBC meeting should be communicated the IBC Chair and the IBC Administrator at least 24 hours before a meeting. Absences exceeding 3 meetings, may result in termination of IBC membership.

3.2 IBC Member Conflict of Interest

An IBC member engaged in, expects to be engaged, or has a direct financial interest in a particular project may not be involved in the review or approval of that project, except to provide information as may be requested by the IBC. IBC members with a conflict shall leave the meeting during the discussion and voting on research in which any conflict exists. Their absence will be noted in the IBC meeting minutes. A conflict of interest includes, but is not limited to:

- Involvement in the research as principal investigator or co-investigator;
- Personal relationship with the PI (such as spouse) or strong positive or negative interactions that may be perceived as a possible conflict;
- A personal belief system that would preclude acceptance of any research in a particular area even though permitted under existing regulations or policies.

3.3 Expedited Meeting

Expedited meetings may be called by the Chairperson to review a new application, renewal of established protocol or amendment if a grant transfer or grant award is pending and approval must be granted prior to the next scheduled IBC meeting. All members are invited and a minimum of four members are required to approve the protocol under review. Action is approved by majority vote and business conducted at an expedited meeting is reported to the full committee at the next scheduled meeting.

3.4 Special Meeting

Special meetings may also be called by the Chairperson and may be requested by any members of the IBC. Purpose of the meeting must be declared in the communication and except in case of emergency, at least three days' notice shall be given. Quorum must be achieved for a vote on a special meeting (teleconference is accepted). The minutes of business conducted at a special meeting will be separate from regular monthly meetings.

3.5 Minutes

Meeting minutes will be retained for three years following the meeting. Any printed or electronic documents related to a protocol will be retained for three years following termination of the protocol.

Minutes of IBC meetings shall be completed in sufficient detail to demonstrate the following:

- Date, time and location of the meeting;
- Attendance at the meetings and presence of a quorum;
- Actions taken by the IBC regarding each agenda item (identified by project number, title and/or Principal Investigator);
- Notation of members who were not present during deliberations and voting due to a conflict of interest;
- The basis for requiring changes or disapproving any initial review or renewal of any research profile;
- Thorough discussion of research related issues and their resolution.

3.6 Protocol Review

The IBC provides a schedule that is used for the timely review of protocols prior to the convened meeting to provide PIs' time to respond to comments or any stipulations. Submission deadlines are posted on the TTUHSC IBC website. For research to be reviewed at a convened meeting of the IBC, there must be sufficient time for the IBC members to review the research profile. These profiles must be submitted in accordance with the submission deadlines posted on the TTUHSC IBC website.

When conducting initial or periodic review of ongoing research activities, the IBC is responsible for:

- Determining the containment levels required by the NIH Guidelines.;
- Evaluating the facilities, procedures, practices, training and expertise of personnel involved in research with r/sNA;
- Assuring compliance with the NIH Guidelines.

In reviewing proposed r/sNA research, the NIH Guidelines cite a number of matters that the IBC should consider that include:

- Agent characteristics (e.g. virulence, pathogenicity, environmental stability);
- Types of manipulations planned;

- Source(s) of nucleic acid molecules sequences (e.g., species);
- Nature or function of the gene encoded by recombinant or synthetic nucleic acid molecule 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;
- Change in biosafety risk for organism formed through combination of sequences from multiple sources or synergistic effect of combining transgenes resulting in new phenotype;
- Containment conditions to be implemented;
- Applicable section(s) of the NIH Guidelines (e.g., Section II-D-1, Section III-E-1, etc.).

3.6.1 Full Committee Review

Full committee review will be required for any submissions making major changes to an existing protocol, 3-Year Renewal, or Initial Application submissions. The IBC Chairperson and the IBC Coordinator will assign at least one member to review and present the submission during monthly meetings. If more than one member is assigned to review, one member will be designated the primary reviewer and one the secondary reviewer. These committee members may provide stipulations or queries concerning new protocols, continuing reviews, or amendments. A PI must respond to any query or stipulation within the allotted time, if the deadline is missed this will move their submission to the following meeting to allow sufficient time for review.

3.6.2 Designated Review

Designated review may be applied to minor changes in a PI's agents, such as addition of additional chemicals to an existing addendum on Proprietary Compounds of Unknown Toxicity. A PI may request designated review for submissions (Initial Application, 3-Year Renewal, or Amendment), the decision to use designated review is at the discretion of the IBC Chairperson and Committee. A PI must respond to any query or stipulation within the allotted time, if the deadline is missed this will move their submission to the following meeting to allow sufficient time for review.

3.6.3 Administrative Review

Administrative review is applicable to minor changes that do not require a comprehensive review, such as adding new personnel. Further detail is available in section 4.2 as to how amendments may be approved administratively.

Section 4.0 Submissions

The IBC reviews the registration of r/sNA molecules, hazardous biological agents, hazardous chemical agents, and toxins. These fall under:

- Initial Protocol Submission
- Amendment
- 3-Year Renewal
- Annual Status Review

4.1 Initial Submissions

An Initial Protocol submission is an important step for a PI in setting up their laboratory. Within iRIS, the PI will complete a study application that will serve as their IBC protocol and which may be changed in future to add/delete agents, location, personnel or modify r/sNA molecule work. All versions are saved within iRIS for future reference. All Initial Protocols are automatically designated a full review submission.

4.2 Amendments

Adding a new agent will require full committee vote and as such will be assigned as a full review submission. When adding an agent similar to other agents already approved for a protocol they may be assigned as designated review. Amendments making changes to personnel, deleting agents, and/or location are administratively approved If any of these changes are done in conjunction with the addition of an agent, the submission will automatically be a full review submission.

4.3 3-Year Renewal

Every 3 years a PI must renew their IBC protocol. Their renewal is viewed as an Initial Protocol Submission and reviewed as such. At the time of renewal, the IBC re-evaluates the protocol and updated addenda submitted for review. Stipulations of any of the attached documents or Renewal form may be sent to a PI prior to the meeting and the PI must respond 3 days after notice. If renewals are not submitted prior to the expiration date, the protocol will be terminated unless the PI requests an extension 5 business days prior to the expiration date. The committee and the institution are committed to meeting NIH Guidelines, maintaining current and updated protocols are essential to meeting these guidelines.

4.4 Annual Status Review

An Annual Status Report (ASR) is required in year 1 and year 2 of your IBC protocol, year 3 is a 3-Year Renewal. Reminders will be sent out via iRIS to a PI and their Study Contact when an ASR is due. The annual status report must be submitted prior to the expiration date; extensions may be requested to avoid termination. The committee and the institution are committed to meeting NIH Guidelines, maintaining current & updated protocols are essential to meeting these guidelines.

4.5 Protocol Termination

A PI who is separating from the institution or terminating research must terminate their protocol via iRIS. The process to close a laboratory are clearly stated in HSC OP 73.10 Faculty Laboratory Space Check-Out Procedures.

4.6 Review Outcome

The IBC can make the following determinations regarding a submission.

- Administrative Approval
- Designated Review Approval
- Approval
- Pending
- Tabled
- Disapproved

Designated Member and Administrative approval are usually done prior to a meeting as they do not require a full committee vote.

4.6.1 Administrative Approval

Submissions that fall under administrative approval are personnel changes, deleting agents, location changes and terminations. If the IBC Chairperson or an IBC member determine that an administrative review is insufficient, as the change is not compliant with NIH Guidelines, then that submission will be reviewed at the next meeting by the IBC.

4.6.2 Designated Review Approval

Minor changes in PI's agents are reviewed by a designated committee member, and approved by the same committee member. Full committee vote is not required, but any committee member can object to Designated Review approval, and request full committee review and approval instead.

4.6.3 Approval

When the IBC has determined that all review criteria, based on institutional policies and federal regulations have been adequately addressed, the IBC may approve the research, though further review by other institutional committees (IACUC, IRB, etc.) may still be required.

4.6.4 Pending

The status of Pending may be issued to submitted research which requires clarifications or modifications of the research or procedures, and substantive revision(s) of the submission and/or related document(s). The PI must respond to the identified concerns, clarifications, modifications or revisions requested by the full committee and/or Designated Reviewer, and resubmit the revised research proposal and/or related documents for another full committee review or designated member review.

4.6.5 Tabled

If the research cannot be fully reviewed because of incomplete information provided, the need for outside consultation, loss of quorum during the meeting, or any other reason, the review will be tabled until the next convened meeting.

4.6.6 Disapproval

If a profile has not adequately addressed all of the requirements of the institutional policies and federal regulations, the convened IBC may disapprove it. Profiles may only be disapproved at a convened IBC meeting. An IBC vote to disapprove an investigator's use of r/sNA indicates that there shall be no further review of the research. The Principal Investigator shall be notified in writing of any IBC vote to disapprove. The SVPR shall be copied on the correspondence to the PI.

Written IBC disapproval notification will be sent to the PI and will include reasons for the decision of the IBC. The PI may request reconsideration of a Tabled or Disapproved outcome in writing within 10 days of the date of notice. The PI shall provide a rationale for the request to reconsider and any other relevant supporting documentation to the IBC Chair who shall schedule a meeting of the IBC. The PI may also address the IBC in person at the next scheduled IBC meeting. The IBC shall notify the PI in writing of its decision after reconsideration and the reasons for its decision. No further request for reconsideration by the PI is permitted following the final decision by the IBC made on reconsideration.

Included in all notifications of approval 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 and the approval period (begin/renewal dates).

4.7 Definitions

The IBC defines biohazardous materials as either hazardous biological agents, hazardous chemical agents, or toxins, which must be registered via the IBC protocol application. Other criteria to determine agent registration include the Globally Harmonized System of Classification and Labelling of Chemicals (GHS) and classifications as determined by the U.S. Department of Health & Human Services in the current edition of the Biosafety in Microbiological and Biomedical Laboratories (BMBL).

Hazardous biological agent: refer to an infectious agent or pathogen that poses a danger to personnel or the community, either through exposure in the laboratory due to lack of proper containment or a waste disposal method that exposes the community at large. These are registered per federal regulations of the CDC 9 C.F.R. Part 121: Animals and Animal Products and the OSHA Bloodborne Pathogens Standard 29CFR1910.1030.

Hazardous chemical agent: refer to a chemical agent that has a GHS rating of 1 or 2 oral; 1 dermal; 1 inhalation or HMIS rating of 4 or an animal LD50 of ≤ 50mg/kg.

Toxin: any biological toxin or toxin producing organism; it is mandatory to register these agents with the IBC.

Dual Use Research of Concern (DURC): as defined by the U.S. Department of Health & Human Services is "…life sciences research that, based on current understanding, can be reasonably anticipated to provide knowledge, information, products, or technologies that could be directly misapplied to pose a significant threat with broad potential consequences to public health and safety, agricultural crops and other plants, animals, the environment, materiel, or national security."

4.7.1 Biosafety Levels

The CDC defines appropriate biosafety levels in the following manner per Biosafety in Microbiological and Biomedical Laboratories –

BSL-1 – Biosafety Level 1 is suitable for work involving well-characterized agents not known to consistently cause disease in immunocompetent adult humans, and present minimal potential hazard to laboratory personnel and the environment. BSL-1 laboratories are not necessarily separated from the general traffic patterns in the building. Work is typically conducted on open bench tops using standard microbiological practices. Special containment equipment or facility design is not required, but may be used as determined by appropriate risk assessment. Laboratory personnel must have specific training in the procedures conducted in the laboratory and must be supervised by a scientist with training in microbiology or a related science.

BSL-2 – Biosafety Level 2 builds upon BSL-1. BSL-2 is suitable for work involving agents that pose moderate hazards to personnel and the environment. It differs from BSL-1 in that: 1) laboratory personnel have specific training in handling pathogenic agents and are supervised by scientists competent in handling infectious agents and associated procedures; 2) access to the laboratory is restricted when work is being conducted; and 3) all procedures in which infectious aerosols or splashes may be created are conducted in BSCs or other physical containment equipment.

BSL-2+ – Biosafety Level 2+ builds upon BSL2 by brining BSL3 operations into a BSL2 laboratory space. Persons entering the laboratory must be advised of the potential hazards. Laboratory personnel must demonstrate proficiency in microbiological practices before working with infectious agents. All manipulations of infectious materials must be in a biological safety cabinet. Incidents that may result in exposure to infectious materials must be immediately evaluated and treated. This definition is more appropriately described as the level of BSL3 an individual laboratory may require and may vary by laboratory. Check with your IBC to determine the needs of your laboratory if using agents requiring extra security/safety measures.

BSL-3 – Biosafety Level 3 is applicable to clinical, diagnostic, teaching, research, or production facilities where work is performed with indigenous or exotic agents that may cause serious or potentially lethal disease through the inhalation route of exposure. Laboratory personnel must receive specific training in handling pathogenic and potentially lethal agents, and must be supervised by scientists competent in handling infectious agents and associated procedures.

There are currently no BSL-3 laboratories at TTUHSC Abilene/Amarillo/Dallas/Lubbock/Permian Basin.

4.7.2 Animal Biosafety Levels

The CDC defines appropriate animal biosafety levels in the following manner per Biosafety in Microbiological and Biomedical Laboratories –

ABSL-1 – Animal Biosafety Level 1 is suitable for work in animals involving well-characterized agents that are not known to cause disease in immunocompetent adult humans, and present minimal potential hazard to personnel and the environment. Facilities should be separated from general traffic areas and restricted as appropriate. External doors should not be propped open and should be secured at all times. Personnel must have specific training in animal facility procedures and must be supervised by an individual with adequate knowledge of potential hazards and experimental animal procedures.

ABSL-2 – Animal Biosafety Level 2 builds upon the practices, procedures, containment equipment, and facility requirements of ABSL-1. ABSL-2 is suitable for work involving laboratory animals infected with agents associated with human disease and pose moderate hazards to personnel and the environment. It also addresses hazards from ingestion as well as from percutaneous and mucous membrane exposure. ABSL-2 requires that: 1) access to the animal facility is restricted; 2) personnel must have specific training in animal facility procedures, the handling of infected animals and the manipulation of pathogenic agents; 3) personnel must be supervised by individuals with adequate knowledge of potential hazards, microbiological agents, animal manipulations and husbandry procedures; and 4) BSCs or other physical containment equipment is used when procedures involve the manipulation of infectious materials, or where aerosols or splashes may be created. Appropriate personal protective equipment must be utilized to reduce exposure to infectious agents, animals, and contaminated equipment.

ABSL-2+ – Biosafety Level 2+ builds upon BSL2 by brining BSL3 operations into a BSL2 laboratory space. Persons entering the laboratory must be advised of the potential hazards. Laboratory personnel must demonstrate proficiency in microbiological practices before working with infectious agents. All manipulations of infectious materials must be in a biological safety cabinet. Incidents that may result in exposure to infectious materials must be immediately evaluated and treated. Plus contact the TTUHSC LARC for additional information on specific animal protocol(s). This definition is more appropriately described as the level of BSL3 an individual laboratory may require and may vary by laboratory. Check with your IBC to determine the needs of your laboratory if using agents requiring extra security/safety measures.

ABSL-3 – Animal Biosafety Level 3 involves practices suitable for work with laboratory animals infected with indigenous or exotic agents, agents that present a potential for aerosol transmission, and agents causing serious or potentially lethal disease. ABSL-3 builds upon the standard practices, procedures, containment equipment, and facility requirements of ABSL-2. The ABSL-3 laboratory has special engineering and design features. ABSL-3 requires that: 1) access to the animal facility is restricted; 2) personnel must have specific training in animal facility procedures, the handling of infected animals, and the manipulation of potentially lethal

agents; 3) personnel must be supervised by individuals with adequate knowledge of potential hazards, microbiological agents, animal manipulations, and husbandry procedures; and 4) procedures involving the manipulation of infectious materials, or where aerosols or splashes may be created, must be conducted in BSCs or by use of other physical containment equipment. Appropriate personal protective equipment must be utilized to reduce exposure to infectious agents, animals, and contaminated equipment. Employee occupational health programs must be implemented.

OHS - *yearly reminders concerning vaccines sent to PI's and personnel separately declination forms must be in lab safety manual; posters informing personnel staff of available OHS provided in all labs; emails of Occupational Health and Safety (OHS) reminders on all ASR's and Renewals*

LARC – animal biosafety level should be designated by IBC

Section 5.0 Principal Investigator: Role & Responsibility

TTUHSC identifies a Principal Investigator as an individual that has the appropriate level of authority and responsibility to direct a research project program or grant and who is responsible for the scientific and technical direction, and all compliance requirements for a research project, sponsored program or grant per TTUHSC OP 73.08 Requirements for Principal Investigator Status.

A PI is responsible for the ethical and safe use of their laboratory space and reagents. An IBC protocol should be registered and maintained accordingly, with updated lists of agents, personnel, and laboratory space. Researchers are required to:

- Register their protocols with the IBC via iRIS
- Prepare a Biosafety manual
- Complete appropriate Biosafety & Laboratory Safety Essentials Training
- Ensure biosafety cabinets are certified annually
- Correction of any deficiencies identified during a safety inspection
- Provide laboratory safety training for all personnel

5.1 Safety Training

All personnel that will work in a research laboratory must complete Laboratory Safety Essentials Training per Safety Services. The IBC requires that all PI's complete this training and any other training necessary for their work. Contact Safety Services for questions regarding Laboratory Safety Essentials training or issues with completion. See Section 6.0 for further information.

The PI is also responsible for ensuring all personnel, volunteers, and students working under their supervision complete safety training for r/sNA molecule research. If the PI plans on shipping any hazardous materials they or appointed shipper must complete a Shipping Hazardous Materials training per TTUHSC OP 75.13 Shipment of Hazardous and Infections Materials.

5.1 Submitting IBC Applications

The IBC protocol application is found on iRIS, which is an online database used by TTUHSC to maintain a record of your protocol and used to make changes to the application. A guide to submit an IBC application via iRIS may be found on the Research Integrity Office website under the IBC Forms link . For the purpose of IBC, only the PI, Study Coordinator, and Study Contact need an iRIS account, all other personnel are considered External Personnel and do not require access to iRIS. ***Log into iRIS with eRaider credentials.*** If you do not have an iRIS account, you may request an iRIS account online via the iRIS website or contact the IBC Coordinator – Beatriz Velez at beatriz.velez@ttuhsc.edu or (806) 743-2897.

5.3 Determination of Exemption from NIH Guidelines

Although federal regulations allow exemptions for some types of r/sNA used, the Principal Investigator must submit an application for all projects using r/sNA molecules so that the IBC is aware of the

activities and can verify they are exempt. For more information on exemptions see the NIH FAQs About Experiments that are Exempt from the NIH Guidelines.

Submitted r/sNA Research Profiles for Exempt research will be reviewed by an experienced IBC member (more than 1 year of service to the Committee). If the review confirms the research is exempt from the NIH Guidelines, the PI will be notified. TTUHSC projects determined to be Exempt or Non-Exempt from the NIH Guidelines will require submission of a project update once every 3 years per IBC policy.

5.4 Projects requiring IBC review and approval at a convened meeting:

- The deliberate transfer of a drug resistance trait to micro-organisms that are not known to acquire the trait naturally;
- The deliberate transfer of r/sNA or DNA or RNA derived from r/sNA into human research participants (human gene transfer);
- The deliberate formation of r/sNA containing genes or sequences 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 r/sNA or DNA derived into the germ-line (transgenic animal);
- Viable micro-organisms or cell lines with modified r/sNA - tested on whole animals;
- Genetically engineered plants by r/sNA methods;
- More than 10 liters' culture of organisms or cells containing r/sNA in a single vessel;
- The formation of r/sNA containing one-half or more of the genome of a eukaryotic virus or from the same virus family;
- Biohazardous chemicals and/or biohazardous biologicals, including toxins or select agetns.

Studies that will be reviewed at a convened meeting must be submitted using the electronic forms found in iRIS by the 15th. Incomplete Profile forms will be returned to the Principal Investigator for completion.

The completed Profile form and all attachments will be forwarded to a designated member of the IBC (the Primary Reviewer) and the BSO to present at the next scheduled IBC meeting. The

5.5 Laboratory Space

Any space designated by an institutional department - for research purposes - to a faculty member designated as a Principal Investigator must be registered with the IBC and Safety Services. Laboratory space may be shared with permission of the department of a PI. It must be declared on an IBC application that a space is shared by addition of an "s" to the end of room numbers (e.g., 1A234s).

5.5.1 Access to Laboratories

Principal Investigators shall allow access to their laboratories to members of the IBC conducting business on behalf of the IBC, to the BSO, to the SVPR or designee, or to the Director of Safety Services for routine or for-cause laboratory inspections. In the event of a significant laboratory accident or exposure, additional personnel shall be given laboratory access. This may include, but is not limited to, law enforcement or medical personnel as necessary to ensure the safety of faculty, staff, students or the environment.

Section 6.0 Training

The NIH Guidelines (§IV-B-1-h) require each institution that conducts or sponsors recombinant or synthetic nucleic acid molecule research to ensure that appropriate training for Committee Chair and members including the Biological Safety Officer and other containment experts, Principal Investigators and laboratory staff regarding laboratory safety and the implementation of the NIH Guidelines. The TTUHSC Office of Research is responsible for ensuring that Principal Investigators have the resources necessary for obtaining sufficient training, but the responsibility for ensuring that training is completed is delegated to the IBC.

TTUHSC policy also requires that the PI, laboratory staff, and students complete Laboratory Safety Essentials (LSE) per HSC OP 75.10 Biological and Chemical Hazards Policy for Research Facilities and Personnel. Safety Services in conjunction with the IBC Administrator verify and maintain a record of completed basic LSE and training for r/sNA molecule research.

6.1 Safety Training

Any laboratory conducting research must complete safety training, including volunteers, visiting scholars, and students. Each school or department may require additional trainings outside the purview of the IBC, check with your school or department. Volunteers will obtain training information from their campus volunteer coordinator. Any visiting scholar/visiting student must compete LSE training, they may obtain information from their respective department chair. Laboratory personnel may obtain further information from the IBC website or Safety Services website.

6.2 Non-exempt Research with r/sNA Molecules

PIs and laboratory staff conducting non-exempt research will be required to provide evidence of completion of the New Employee Safety Orientation Program or Annual Refresher training offered through the TTUHSC Office of Safety Services and the NIH Recombinant DNA Guidelines course offered through CITI.

6.3 Exempt Research with r/sNA Molecules

PIs and laboratory staff conducting non-exempt research will be required to provide evidence of completion of the New Employee Safety Orientation Program or Annual Refresher training offered through the TTUHSC Office of Safety Services and to review a summary of the NIH Guidelines provided by the IBC Administrator. Completion of these training activities will by the PI will be required prior to IBC approval of a new, exempt protocol.

6.4 Continuing Education/Recertification

Refresher training through the TTUHSC Office of Safety Services will be required for all TTUHSC employees involved in shipping hazardous materials from a research lab. The CITI NIH Recombinant DNA

Guidelines course will be required every three years for the IBC Chair and members, Principal Investigators and laboratory staff conducting non-exempt research using r/sNA materials.

Section 7.0 Laboratory Personnel

Laboratory personnel are expected to be properly trained by the PI and complete training set forth by Safety Services. Roles that are filled by laboratory personnel but not limited to the following:

- Principal Investigator
- Post-Doctoral Fellow
- Research Assistant/Aide
- Technician
- Student
- Volunteer
- Co-Investigator
- Adjunct Professor
- Visiting Scholar/Professor

Any personnel working in a research laboratory must be registered with the IBC and complete Laboratory Safety Essentials training provided by Safety Services. It is the responsibility of the PI to assure themselves that all lab personnel have read the Lab Safety Manual, are aware of any hazards in the lab, be able to identify exits, locate safety showers/eye wash stations, and have signed the Laboratory Safety Manual.

7.1 External Personnel and Key Study Personnel

Laboratory personnel are compartmentalized into two groups, Key Study Personnel or External Personnel for IBC protocols, defined as follows:

- Key Study Personnel: comprised of Study Coordinator, Study Contact, and Departmental Reviewer, these roles have access to iRIS and may be exempt from LSE training.
    - *Study Coordinator – this role has access to iRIS and they may create forms. This role may be laboratory staff (i.e. Post-Doc, Technician, Research Associate, and Research Assistant) or departmental coordinator. If they are not laboratory staff, they are exempt from LSE training (e.g. Departmental Administrative Assistant). Volunteers are not eligible to be listed as a Study Coordinator.*
    - *Study Contact – this role has access to iRIS and may receive communications from the IBC. This role may be laboratory staff (i.e. Post-Doc, Technician, Research Associate, and Research Assistant) or departmental coordinator. If they are not laboratory staff, they are exempt from LSE training (e.g. Departmental Administrative Assistant). Volunteers are not eligible to be listed as a Study Contact.*
    - *Departmental Reviewer – role is specific to the Department Chair, they receive some IBC correspondence and are used for reporting purposes when creating IBC Reports.*

- External Personnel: Principal Investigators, laboratory personnel, administrators, students, Co-Investigators, and volunteers must be listed as external personnel to verify training dates.

7.2 Students

Students are expected to complete all of the LSE training prior to joining a laboratory. It is the responsibility of the PI to verify training for a student before allowing them to rotate through a laboratory or join their laboratory. If a student has not completed their LSE, they have a grace period of 14 days in which to complete all training and register with the IBC. If a student fails to complete LSE training, departmental access may be revoked until their training requirements have been completed.

Students who are rotating through a laboratory for 12 consecutive weeks or less do not need to be registered on an IBC license but it is mandatory they complete LSE prior to beginning their rotation. If a student's work is 12 weeks or less but not consecutive weeks, they must be registered on an IBC license.

A student that is shadowing a PI/Post-Doc will have to complete LSE but does not need to be registered on an IBC license. However, if the student wishes to engage in learning research techniques they will have to be added to the IBC license.

7.3 Volunteers

Volunteers are for the purposes of IBC any person who is not a paid employee, student of TTUHSC, or visiting fellow, but not limited to these roles. For more information regarding the definition of a volunteer and their registration please see HSC OP 10.28 Volunteer Policy.

The IBC requires that all volunteers be processed via their campus volunteer services coordinator. Volunteers must also complete LSE training prior to joining any laboratories and a PI is responsible for ascertaining LSE completion prior to allowing a volunteer to enter their research laboratory. As a general guideline, if the volunteer is in the lab for 12 consecutive weeks or less they do not have to be listed on an IBC license. However, LSE training and volunteer training is mandatory. If a volunteer's work is 12 weeks or less but not consecutive weeks, they must be registered on an IBC license.

7.4 Study Programs

In the case of study programs that are designed for the enrichment of local students (e.g. SABR) or visiting scholars, PI's are not required to register those students/scholars if they are here for 12 consecutive weeks or less. LSE training is mandatory for these visiting students/scholars, also alerting the IBC Coordinator and Safety Services of their guests.

7.5 Minors

Minors are allowed to volunteer in a research laboratory for college experience but limitations may be placed on the type of work and time a minor may spend in a laboratory per departmental or institutional policy.

A minor is defined as an individual under the age of 18 years who may be an employee (including student employees), student, or visitor (including a volunteer or guest of the institution). Any volunteer that falls between the ages of 14 and 17 years of age must follow the guidelines set forth in HSC OP 73.15 Minors in Research Laboratories. All minors must have written consent from their parent(s),

institutional Office of Research, sponsoring investigator and department chairperson. Training for minors includes NESOP, STEPS and/or Volunteer Orientation Programs, LSE, Radiation Safety. If a minor is participating in special observatory experiences they may be exempt from some training requirements, contact the IBC Administrator for further information.

Section 8.0 Reporting Unanticipated Events

Incidents/problems involving r/sNA molecules must be reported immediately – within 24 hours – to the Biological Safety Officer (BSO). Examples of reportable significant incidents include, but are not limited to, any overt exposure, such as a needle stick, splash, and/or contamination due to equipment failure. 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 r/sNA research is also considered biohazardous and incidents involving improper disposal of r/sNA must also be reported. Questions regarding reportable incidents should be directed to the BSO in the Office of Safety Services.

The BSO is required, by the NIH Guidelines, to report any violations of the NIH Guidelines and/or significant research-related accidents or illnesses to the IBC in a timely manner (through email or phone call to the IBC Chairperson and/or IBC Administrator).

The IBC is required, by the NIH Guidelines, to report to the Senior Vice President for Research and to the NIH/OBA within 30 days any significant incidents, violations of the NIH Guidelines, or any significant research-related accidents and illnesses (§ IV-B-2-b). The IBC, with input from the Office of Safety Services and the Research Integrity Office, will be responsible to determine what corrective actions are necessary. For example, the IBC may choose to increase the frequency of lab inspections by Safety Services, or change the Biosafety Level of the research, based on results of the incident.

Other IBC reporting requirements (to OBA and other agencies) include but are not limited to:

- Research involving r/sNA molecules 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 BSL2 laboratories (involving r/sNA molecules) resulting in an overt exposure must be immediately reported to OBA. In addition, spills or accidents involving r/sNA molecules occurring in high containment (BL3 or higher) laboratories resulting in an overt or *potential* exposure must be immediately reported to OBA. The IBC will report to the Senior Vice President for Research, who, in turn will report to OBA, any of the above-described incidents.

Section 9.0 Safety Services

The department of Safety Services is committed to providing a safe and healthy workplace for faculty, staff, students, volunteers, patients, and visitors through compliance with applicable federal, state, and local rules and regulations, and the safety policies and procedures established by the institution. These policies are applicable to all three campuses – Abilene, Amarillo, Dallas, Lubbock and Odessa.

The IBC and Safety Services – Laboratory Safety work closely together to ensure that there is no undue burden or hindrance is placed on researchers but maintain a safe work environment. If there are any questions regarding operating policies for Safety Services please view their Safety Services Operating Policies on the TTUHSC website.

9.1 Radiation Safety Services

The IBC has no oversight over the procurement, use, and/or disposal of radioactive material used in research. Radiation Safety Services provides support to the Radiation Safety Committee (RSC) and enforces the requirements set forth by the RSC. See the Radiation Safety Services website and Radiation Safety Manual for more information for the use of radioactive materials in research.

9.2 Waste & Chemical Disposal

Safety Services provides waste disposal of hazardous chemicals, disposal of expired chemicals, disposal of hazardous wastes (e.g. biological, chemical, and radiological), and ethanol distribution. The HSC OP 61.14 Facilities and Safety Services Fees provides information for disposal and associated fees for disposal.

9.3 Resources

Safety Services provides information via their website and have kindly provided the following information, also found on their site.

9.3.1 Biosafety Resources

- American Biological Safety Association
- Biosafety in the Laboratory (Handling/Disposal of Infectious Materials)
- Biosafety in Microbiological and Biomedical Laboratories (BMBL) 5th Edition | (Download)
- Bloodborne pathogens (OSHA, 29 CFR 1910.1030)
- National Select Agent Registry
    - Facility Inspection Videos
    - Select Agents and Toxins List
- Public Health Agency of Canada MSDS for Infectious Substances

9.3.2 Additional Resources

- Approaches to Safe Nanotechnology
- Centers for Disease Control and Prevention (CDC)
- Incompatible Chemicals in the Laboratory
- Prudent Practices in the Laboratory (Handling/Disposal of Chemicals)

9.3.3 State & Federal Laws Governing Hazardous Substances

- Hazard Communication - Texas Laws
- Occupational exposure to hazardous chemicals in laboratories (OSHA, 29 CFR, 1910.1450)
- Hazard Communication Worker Right-to-Know Program Notice to Employees
- EPA - Defining Hazardous Waste: Listed, Characteristic and Mixed Radiological Wastes