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Section 1.0 Introduction

Texas Tech University Health Sciences Center

require modification as these guidelines, or other federal, sta-6.6 (r .6v4 (,)-1 (o)-6.6 (lin)2. (s)-1.3 (t)-i (a-6.6 u (d)2. (a-6

- 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.

- 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 IBCChairperson 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.

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 MemberResponsibilities

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:

- ƒ Review Initial Submissions, 3-Year Renewals, Amendments, and Designated Review Submissions as assigned
- ƒ Offer individual expertise during meetings or to other members as needed
- ƒ 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 oITnepCbeA nn he rnbletp9-6 (t)-6 ((t)-5.9 ( )]TJ(l)-3.2i)-3.2 (7-6.7 (1-0.8 (n

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)

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

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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 s.8 (e)173 (i)-3.2 (a)-3.3 (l)7.[(fc2cTd(r73 (o)4.2 (t2/P3 (t)-3 (in)2.2)10.8 (ete5(w)-3.4 (in)2.2 y)6.

- 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 agenh (j)-1.2 (-0.002p(r)11 [s)21.3 (u32.3 (b)2.2 (m9)2.2(is)-1.3 (s4.)13.4 (e)-2 (h)2.3 (w)a[s)21.(ro)-6.6 (t)7.9 ( )10.6

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

Toxin: any

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 facilite2eAL

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 credent[illegible]***

5.5.1Access 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 r

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*

7.2 Students

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 pote6.6 (t)7.9 (10.6 (an)2.v)- (e(a)1091 (o)36.6 (s)-1.3 (e)-34 (t)-3 ((n)2.2 (e)-3 (6(s)-1.3 (c)-2 (l)]
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Section 9.0 Safety Services

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