TTUHSC

RECOMBINANT DNA

BIOSAFETY COMMITTEE (RDBC)

PROCEDURAL MANUAL

Version: June, 2017

TABLE OF CONTENTS:

Section 1.0—Introduction

This Texas Tech University Health Sciences Center Recombinant DNA Biosafety Committee ("TTUHSC RDBC" or "RDBC") Procedural Manual provides the TTUHSC research community with an overview of the federal regulations and institutional policies that govern the conduct of research utilizing recombinant or synthetic nucleic acids. It is the responsibility of the TTUHSC RDBC to approve and oversee the use of recombinant or synthetic nucleic acid molecules in all teaching, research, or testing activities conducted at TTUHSC facilities or by TTUHSC research personnel. The information in this manual is intended to provide procedural detail to accompany TTUHSC OP 73.05; Research Involving Hazardous Chemical and Biological Materials and Recombinant or Synthetic Nucleic Acid Molecules

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

(i) molecules that a) are constructed by joining nucleic acid molecules and b) can replicate in a living cell, i.e., recombinant nucleic acids;

(ii) 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

(iii) molecules that result from the replication of those described in (i) or (ii) above.

1.1—Charge and Authority of the RDBC

Because TTUHSC receives NIH funding for research involving r/sNA molecules, all activities involving these materials must follow the NIH Guidelines. Failure to adhere to these guidelines can result in suspension or termination of NIH funding, or to a requirement for 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 RDBC 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 RDBC regardless of the funding source for the work.

The Senior Vice President for Research (SVPR) has charged the TTUHSC RDBC with review, approval and oversight of research involving r/sNA. Responsibilities of the RDBC include training of research personnel to assure compliance with NIH/OBA and other pertinent guidelines and regulations. The RDBC 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. The RDBC receives administrative support from the TTUHSC Research Integrity Office which is part of the TTUHSC Office of Research. The RDBC works in conjunction with other TTUHSC offices and committees, including the Office of Safety Services, the Institutional Biosafety Committee (IBC) which oversees the use of biohazardous materials, agents and toxins, the Institutional Animal Care and Use Committee (IACUC) and the Institutional Review Board (IRB) in order to help ensure the health and safety of all personnel working with r/sNA

1.2—Scope

The RDBC policies and procedures apply to all research personnel engaged in activities and/or research involving r/sNA, regardless of funding source if those personnel or activities are:

- Sponsored by TTUHSC (unless this is the only connection to TTUHSC).
- Conducted by TTUHSC faculty, staff or students as part of his or her responsibilities to the institution.
- Conducted using TTUHSC's property, facilities or non-public information belonging to or under the control of TTUHSC.
- Received, stored, used, transferred or disposed of at any of TTUHSC facilities.

1.3—Confidential Medical Committee

The RDBC is a committee of the TTUHSC established for the purpose of carrying out requirements governing research involving r/sNA under federal law and TTUHSC policies and procedures. The RDBC is a "medial committee" as defined under Texas Health and Safety Code Chapter 161. All documents generated by, submitted to, or for the purposes of fulfilling RDBC duties are confidential and privileged as "medical committee documents."

Section 2.0—Responsibilities related to the RDBC

2.1—RDBC Responsibilities

The responsibilities of the RDBC include, but are not limited to:

- Review, approval and oversight of research utilizing recombinant or synthetic nucleic acid 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

- Notifying the Principal Investigator of the results of the RDBC's review, approval, or disapproval.

- Reviewing and reporting of any significant problems, violations of the NIH Guidelines and any significant research-related accidents or illnesses to the IO and to the NIH/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 RDBC 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.

2.2—Institutional Official Responsibilities

The responsibility for the Recombinant DNA Biosafety Committee rests with the Senior Vice President for Research (SVPR) who is the Institutional Official. The Institutional Official:

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

2.3—Research Integrity Office Responsibilities

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

- Serve as liaison between research personnel, the RDBC, federal and regulatory agencies.
- Provide documentation, forms, regulatory guidelines and regulations to Principal Investigators.
- Maintain RDBC 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 RDBC-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 RDBC by scheduling meetings, arranging for meeting space and taking/disseminating/maintaining meeting minutes.

The Research Integrity Office will provide annual updates of the RDBC to the NIH Office of Biotechnology Activities (OBA). The TTUHSC RDBC is registered with the OBA for purposes of r/sNA research. An annual report is filed with OBA, which includes an updated list of RDBC

members indicating the role and institutional affiliation of each member and biosketches for each member. The Research Integrity Office notifies OBA of changes in RDBC membership and submits the annual report on behalf of TTUHSC using the online IBC Registration and Management System.

2.4—RDBC Chair Responsibilities

The IBC Chair responsibilities include, but may not be limited to:

- Serving as a potential contact for all regulatory agencies;
- Acting as liaison between the research personnel and RDBC;
- Assigning *ad hoc* subcommittees as needed to review an issue prior to official committee decisions made at a convened meeting;
- Calling RDBC meetings to order, directing meeting deliberations, requesting motions and seconds, and closing the meeting once it has concluded business.

2.5—Biological Safety Officer (BSO) responsibilities:

The BSO is a federally required member of the RDBC. The principal function of the BSO should be to advise the research personnel and the RDBC concerning the most appropriate safety practices that will assure the safe conduct of research with r/sNA.

The 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 and personnel contamination and investigate laboratory accidents involving r/sNA.
- Provide advice on laboratory security to the RDBC research personnel.
- Provide technical advice to research personnel and the RDBC on research safety procedures.

2.6—Principal Investigator Responsibilities:

The Principal Investigator is responsible for following the NIH Guidelines and institutional policies and procedures when using r/sNA. Along with this understanding, the Principal Investigator will also have the following responsibilities:

- Make the initial risk assessment and determination of required biosafety levels (including physical containment) in accordance with the NIH Guidelines.
- Be adequately trained in good laboratory techniques.

- Provide laboratory research personnel with descriptions of potential biohazards and necessary precautions.
- 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.
- 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 RDBC 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 RDBC 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 can be found below in Section 6.0.
- 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 RDBC can make the decision as to whether or not they are exempt.

Section 3.0—RDBC Membership

The RDBC is composed of at least five members that collectively have experience and expertise in r/sNA technology and the capability to assess the safety of r/sNA research and identify any potential risk to public health or the environment. All members, including the Chair, shall be appointed by, serve at the discretion of, and report to the Senior Vice President for Research (SVPR). Recommendations for appointees may be made to the SVPR by current RDBC members or administrative staff. In general, appointments will be for two years and made effective September 1 of each even-numbered year. Members will be expected to complete training regarding r/sNA, laboratory safety, and biosafety upon appointment to the RDBC. Currently approved online training for TTUHSC RDBC members consists of the NIH Guidelines course provided by CITI (www.citiprogram.org).

The appointed members will represent all TTUHSC campuses at which research with r/sNA materials takes place. The composition of the RDBC shall consist of:

- At least one individual with expertise in each of the following areas: genetics, micro-organisms, and r/sNA technology,
- At least one member representing the laboratory technical staff,
- Two committee members who are not affiliated with TTUHSC (including family members) who represent the interests of the West Texas area with respect to health and protection of the environment, and,
- The TTUHSC Biological Safety Officer,
- The TTUHSC Institutional Veterinarian.

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 Chairperson of the TTUHSC Institutional Biosafety Committee will be an *ex-officio,* non-voting member of the RDBC.

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

Appointment to the RDBC 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.

Section 4.0—RDBC Meetings

The Committee will meet at least bi-annually, and more often if deemed necessary by the RDBC Chair in order to resolve matters requiring immediate attention. Prior to each meeting, all voting RDBC members shall receive copies of the meeting agenda, draft minutes of the previous meeting, and any necessary materials required for discussion of agenda items. When possible, and consistent with protection of privacy and proprietary interests, RDBC meetings shall be made open to the public in accordance with the NIH Guidelines.

4.1—Quorum

A majority of the voting members must be present (teleconference is acceptable) to conduct the business of the RDBC. The final approval or disapproval of registration of each non-exempt research request requires a majority vote of RDBC members present and voting. If a quorum is lost at any time during the meeting, no further action shall be taken by the RDBC until a quorum is attained.

4.2—Attendance

Members are expected to attend a majority of RDBC meetings. Anticipated absences from an RDBC meeting should be communicated to the RDBC Chair and the RDBC Administrator at least 24 hours before a meeting.

4.3—RDBC Member Conflict of Interest

An RDBC member engaged, 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 RDBC. RDBC 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 RDBC 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, and
- A personal belief system that would preclude acceptance of any research in a particular area even though permitted under existing regulations or policies.

4.4—Research review at convened meetings

Research classified as Exempt, and minor amendments (such as personnel or room changes) can be submitted at any time, without regard to the posted deadlines or meeting dates. These profiles and amendments will be reviewed on a rolling basis

For research to be reviewed at a convened meeting of the RDBC, there must be sufficient time for the RDBC members to review the research profile. These profiles must be submitted in accordance with the submission deadlines posted on the RDBC website: http://www.ttuhsc.edu/research/hrpo/rdbc/default.aspx. The RDBC Chair may make exceptions to the deadline on a case-by-case basis if there are compelling circumstances.

When conducting initial or periodic review of ongoing research activities, the RDBC 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.).

4.5—Review Outcomes

Non-exempt research profiles are presented and discussed individually, and the RDBC votes on the disposition of the profile. Possible outcomes include:

- Approval – When the RDBC has determined that all review criteria, based on institutional policies and federal regulations have been adequately addressed, the RDBC may approve the research, though further review by other institutional committees (IACUC, IBC, etc.) may still be required.
- Modifications required – This status is used for research which does not yet meet all requirements for approval but may be revised, resubmitted and approved without further review at the convened meeting. This status will be used when only minor modifications or clarifications are required.
- 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.
- Disapproval – If a profile has not adequately addressed all of the requirements of the institutional policies and federal regulations, the convened RDBC may disapprove it. Profiles may only be disapproved at a convened RDBC meeting. An RDBC 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 RDBC vote to disapprove. The SVPR shall be copied on the correspondence to the PI.

  The written RDBC disapproval notification to the PI will include reasons for the decision of the RDBC. The PI may request reconsideration of the decision of the RDBC 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 RDBC Chair who shall schedule a meeting of the RDBC. The PI may also address the RDBC in person at the next scheduled RDBC meeting. The RDBC 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 RDBC made on reconsideration.

Generally within 3 business days of the completion of the review process, the Principal Investigator will receive written notification of the review decisions and whether any special conditions for approval of work is required. Included in the notification of approval will be the RDBC 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/end dates).

4.6—Meeting Minutes

Minutes of RDBC 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 RDBC 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, and
- Thorough discussion of research related issues and their resolution.

Meeting minutes will be maintained for three years.

Section 5.0—Profile submission and review

RDBC profile submissions—new applications or modifications to previously approved profiles must be submitted for review and RDBC approval to the RDBC administrator. Contact information can be found here. No new research involving r/sNA or changes to previously approved research can be initiated until the Principal Investigator has received approval by the RDBC in writing.

5.1—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 RDBC is aware of the activities and can verify they are exempt. For more information on exemptions,

visit: http://osp.od.nih.gov/sites/default/files/Experiments_that_are_Exempt_from_the_NIH_Guidelines.pdf (PDF).

Submitted r/sNA Research Profiles for Exempt research will be reviewed by an experienced RDBC 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 from the NIH Guidelines will require submission of a project update at least once every five years. Exempt research will not require review at a convened meeting of the RDBC, but these determinations will be presented and ratified at the next convened meeting.

5.2—Projects requiring RDBC 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.

Studies that will be reviewed at a convened meeting must be submitted using the r/sNA Research Profile form found here at least four weeks prior to the scheduled meeting. 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 RDBC (the Primary Reviewer) and the BSO to present at the next scheduled RDBC meeting. The Primary Reviewer and BSO will make every effort to contact the Principal

Investigator regarding the need for clarifications or corrections to the application **prior to** the RDBC meeting in order to expedite the review process.

The Primary Reviewer will review the application for completeness, with a special emphasis on safety concerns relevant to the application. This will include a review of the materials to be used, the investigator's plans for safe use and disposal of the materials, and a brief review of the studies in which the materials will be used. The BSO or designee will review the application to verify the laboratory license and that appropriate training has been completed by all laboratory personnel.

At the RDBC meeting, the Primary Reviewer will present a summary of the Research Profile form and then open the item for discussion. Once the review is complete, the RDBC will vote on the application, with possible outcomes as indicated above in Section 4.5.

5.3—Modifications to approved research

Principal Investigators shall not initiate or implement any changes or modifications of RDBC approved research without the prior review and approval of the RDBC. This includes, but is not limited to, a change in the types of materials, changes in personnel, location, procedures or changes that increase the risk of the project and/or the Biosafety Level. All requests to modify an approved project should be submitted using the Renewal/Amendment/Termination (R/A/T) form found here.

- *Minor changes* to the research (typically personnel changes for which appropriate training has been verified and location changes) may be approved by expedited review by the RDBC Administrator in consultation with the RDBC Chair.
- *Major changes* to the research (including changes in scope, procedures, or principal investigator) require review and approval at a convened meeting of the RDBC. Once completed, the amendment form should be submitted to the RDBC Administrator at least one week prior to a scheduled RDBC meeting.
- *Material Transfer Agreements (MTAs):* Incoming Material Transfer Route Sheets submitted to the Office of Sponsored Programs to add material from Risk Group 3 or 4 organisms, or that encode toxic molecules will require an amendment on the R/A/T form for RDBC review.

5.4—Annual and Three-Year Renewals of Approved Research and Notice of Termination

- *Annual Renewals of non-exempt projects*: Principal investigators who wish to continue their **non-exempt** RDBC project for more than one year will be required to submit a Renewal on the R/A/T form here to the RDBC for review at least 10 days before the anniversary date of the approval. Annual review of exempt research will not be required.
- *Three year Renewal of non-exempt projects:* Non-exempt research will require a new Research Profile be submitted to the RDBC for committee review and vote in a convened meeting at least 30 days before the three-year anniversary date of the previous Research Profile approval. Approximately two months before the end of the third research year, the PI may receive a courtesy notice of the upcoming required

registration, a web address to the r/sNA Research Profile form and a deadline for submitting the completed form.

- *Five year renewal process for exempt projects:* Exempt research will require a new Research Profile be submitted to the RDBC after five years from the previous approval. This review will be identical to the initial review of the protocol, requiring re-submission of the r/sNA Research Profile form as described above.
- *Termination of research:* Principal Investigators who will be leaving TTUHSC or who will no longer be using r/sNA materials are required to notify the RDBC Administrator in writing of their intent to terminate their protocol, using the R/A/T form. The investigator should also work with the RDBC and Safety Services to ensure that any r/sNA materials in the lab are properly destroyed or transferred to a different TTUHSC laboratory as approved by the RDBC. The RDBC will be informed of terminations at the next regularly scheduled RDBC meeting. Investigators who are closing a laboratory for any reason should also refer to HSC OP 73.10 Faculty Laboratory Space Check-Out Procedures.
- *Transfer of r/sNA Materials to another TTUHSC laboratory:* Principal investigators who wish to transfer materials to another faculty member must notify Safety Services of their intent to do so. The investigator who is to receive the transferred materials is responsible for submitting an amendment to the RDBC for review and approval prior to the transfer of the materials. No materials shall be transferred until RDBC approval has been granted for the submission(s) related to the requested transfer. Investigators may also need to refer to HSC OP 73.02 Ownership and Transfer of Externally Sponsored Projects and Research Records.

Section 6.0—Reporting unanticipated events

Incidents/problems involving r/sNA molecules must be immediately (within 24 hours) be reported 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 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 RDBC in a timely manner (through email or phone call to the RDBC Chairperson and/or RDBC Administrator).

The RDBC 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. The RDBC, 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 RDBC 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 RDBC reporting requirements (to OBA and other agencies) include but are not limited to:

- Research involving r/sNA molecules without prior RDBC 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 RDBC.

Certain types of incidents must be reported to OBA on an expedited basis. Spills or accidents in BL2 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 RDBC will report to the Senior Vice President for Research, who, in turn will report to OBA, any of the above-described incidents.

Section 7.0—Non-compliance

Any allegations of non-compliance or unsafe working conditions shall be made to the RDBC Chair, to any member of the RDBC, the Research Integrity Office (RIO) to the Senior Vice President for Research (SVPR) or through the TTUHSC EthicsPoint Hotline. In all instances, allegations shall be immediately forwarded to the RDBC Chair. The RDBC Chair is responsible for investigation and resolution of all allegations of non-compliance. The allegations and resulting investigations will remain confidential to the extent possible.

7.1—Investigation and Review of allegations

The RDBC Chair will appoint a subcommittee to investigate the allegation. Subcommittee members should be free of any actual or perceived conflict of interest with either the complainant or the respondent of the allegation. The subcommittee will inform all persons involved in the investigation of the purpose and the manner in which it will be conducted. The subcommittee, in its investigation, will examine all documents and procedures relating to the allegation and will interview individuals who are named in the allegation and others who may have knowledge of the circumstances surrounding the allegation and determine if there is a basis in fact to support the allegation. The subcommittee will provide a written report its findings to the full RDBC for the final determinations. The written report may include recommendations for possible outcomes/required plans of correction if it appears that the allegation has been substantiated.

Possible outcomes that may be recommended by the subcommittee include, but are not limited to:

a) additional training required for lab personnel

b) suspension or termination of approval of use of r/sNA

c) confiscation or destruction of r/sNA

d) notification to the department chair or Dean of the incident of non-compliance

e) written report to TTUHSC Human Resources regarding the incident

f) other actions deemed necessary to protect the public and/or TTUHSC, including restricting access to the laboratory in order to suspend activities.

The RDBC will discuss the subcommittee report at a convened meeting and make final determinations as to

a) whether the allegation of non-compliance is substantiated,

b) the seriousness of the incident (if the allegation is substantiated) and

c) the actions to be taken by the respondent and other relevant personnel in order to correct the issue or to ensure that it will not recur.

The respondent may be asked to attend the meeting to respond to the allegation or the findings before the RDBC takes a final vote on the incident. (The respondent shall not be present at the time of the final vote by the RDBC).

If the RDBC determines that the allegation has been substantiated, a final written report will be sent to all parties involved including the complainant (if known) the respondent, the Department Chair of the respondent, the Assistant Vice President for Research Integrity and the Senior Vice President for Research. The Research Compliance Officer in the Research Integrity Office will ensure that any required plan of correction is carried out. Any necessary reporting to outside agencies, including the OBA or the NIH, will be directed by the Senior Vice President for Research.

Section 8.0—Training

The NIH Guidelines (Section 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 RDBC.

8.1—RDBC Chair and Member training:

The RDBC Chairperson and all voting members of the RDBC are required to complete the NIH Recombinant DNA Guidelines course offered through www.citiprogram.org. Voting members who are TTUHSC employees must also complete NESOP and annual refresher training offered through TTUHSC Safety Services. Instructions for signing in to and accessing the CITI course can be found here.

The RDBC 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 RDBC meetings;
- Reviewing relevant books, periodicals or handouts furnished to RDBC 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.

*8.2—Principal Investigators and laboratory staff conducting **non-exempt research** under the purview of the RDBC:*

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 www.citiprogram.org. Instructions for signing in to CITI and accessing this course can be found here. **Completion of these training programs will be required for all staff listed on the protocol prior to RDBC approval of a new non-exempt protocol.**

8.3—*Principal Investigators conducting **exempt** research under the purview of the RDBC:*

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 RDBC Administrator. Completion of these training activities will by the PI will be required prior to RDBC approval of a new, exempt protocol.

8.4—Continuing Education (Re-training).

Annual Refresher training through the TTUHSC Office of Safety Services will be required for all TTUHSC employees. The CITI NIH Recombinant DNA Guidelines course will be required every three years by the RDBC Chair and members, Principal Investigators and laboratory staff conducting non-exempt research using r/sNA materials.

Section—9.0 Access to Laboratories

Principal Investigators shall allow access to their laboratories to members of the RDBC conducting business on behalf of the RDBC, 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.