UNIVERSITY OF TEXAS AT ARLINGTON

INSTITUTIONAL BIOSAFETY COMMITTEE

REVIEW OF CONCERNS, INCIDENTS, AND POTENTIAL NON-COMPLIANCE

I. Regulatory Authority and Responsibility

A. In accordance with the NIH Guidelines, the University of Texas at Arlington has established an Institutional Biosafety Committee (IBC) responsible for the review of all research involving recombinant and synthetic nucleic acid molecules and transgenic animals. The IBC is a university-wide standing committee advisory to the Vice President for Research.

B. On behalf of the Institution, and in accordance with the NIH Guidelines, the Institutional Biosafety Committee is responsible for oversight and review of research including independent assessment of: containment levels, laboratory facilities, procedures, practices, health surveillance, and training and expertise of personnel involved in the research.

C. The IBC also provides consultation to the Institution's research community including faculty, staff, and students, concerning issues of biohazards, laboratory biosafety procedures, and appropriate biological techniques (best practices) to minimize risk and hazard.

II. Definitions

A. Noncompliance is defined as research conducted in a manner that is not approved by the UTA IBC to include a range of actions from relatively minor violations resulting from inadvertent errors, inattention to detail, or inadequate training and supervision of research staff, to more serious violations that pose a risk to the health and/or safety of humans, animals, plants, and the environment.

A. Serious noncompliance is defined as any activity or deviation from the approved protocol, institutional policies and procedures, federal regulations, or provisions of the NIH Guidelines that have the potential to pose a risk to the health and/or safety of humans, animals, plants, and the environment.

B. Continuing noncompliance is defined as multiple similar violations over time, either on the same protocol or for the same investigator across multiple protocols.

C. Concerns and Incidents (CI) are defined as a report regarding regulatory compliance, safety issues, spills/accidents, potential exposures, or any actual or perceived incident involving research under the purview of UTA's IBC. Any spill or accident involving recombinant or synthetic nucleic acid molecule research of the nature described above or that otherwise leads to personal injury or illness or to a breach of containment must be reported. These kinds of events might include skin punctures with needles containing recombinant or synthetic nucleic acid molecules, the escape or improper disposition of a transgenic animal, or spills of high-risk recombinant or synthetic materials occurring outside of a biosafety cabinet. Relevant incidents would include spills and accidents which result in overt exposures to organisms containing

recombinant or synthetic nucleic acid molecules in the laboratory. Failure to adhere to the containment and biosafety practices articulated in the *NIH Guidelines* must also be reported. Minor spills of low-risk agents not involving a breach of containment that were properly cleaned and decontaminated generally do not need to be reported.

D. The CI Review Team is defined as the group designated by the IBC to perform review of CIs that are potentially serious/continuing to determine actions for resolution. The CI Review Team is comprised of the IBC Chair, Vice Chair, a representative from the Environmental, Health, and Safety (EH&S) office, and a representative from the Office of Regulatory Services (ORS).

III. Reporting Concerns and Incidents

A. A CI report can be made in the following manner:

1. The Office of Regulatory Services, 817-272-3723, regulatoryservices@uta.edu
2. The IBC Chair, ibc@uta.edu
3. The Institutional Official (Vice President for Research), 817-272-6791
4. EH&S, 817-272-2185
5. UT Arlington Campus Police, 817-272-3381
6. The University Ethics Hotline, 877-507-7314 (report can be anonymous)

B. CI may include:

1. Adverse events or unanticipated outcomes during a research study.
2. Potential non-compliance to research (IBC protocol), IBC policy, EH&S policy, federal regulations, or other institutional requirements.
3. Accident or mishap resulting in personnel harm, overt or potential exposure, or death.
4. Concerns or complaints made by a non-UTA researcher, including a member of the public.

C. CIs as defined above in Section II must be reported to the IBC within 5 business days. Certain types of accidents must be reported on a more expedited basis:
    1. Spills or accidents in BL2 or BL3 laboratories resulting in an overt or potential exposure must be immediately reported to the IBC within 24 hours.

IV. Office of Regulatory Services (ORS) Initial Assessment of CI

A. Reports of CI shall be submitted to ORS.

B. ORS will conduct fact-finding which may involve discussions with the PI and research team, review of protocols or evidence submitted, discussions with other employees, and unannounced laboratory inspections. Information gathered may include:

1. The Complainant's name (voluntary)
2. The name of the PI and other individuals involved
3. Description of the CI including the dates of observation
4. Copies of any written, photographic, or taped documentation to substantiate the CI
5. Names of any other witnesses to the CI

6. Funding source
7. Personnel training records
8. Corrective actions already initiated

C. Following review of initial evidence and information gathered, ORS will determine if the CI constitutes potential non-compliance and/or poses a potential risk to personnel safety or the environment. If the CI constitutes non-compliance, ORS will determine if it is potentially serious and/or continuing. ORS will then facilitate full review and resolution of the CI according to Section V.

V. Review and Resolution of CI

A. For CIs that constitute **minor/non-continuing non-compliance and do not pose potential risk to personnel safety or the environment**, ORS will (as the IBC's designee) facilitate resolution of the CI through the following actions:

1. Document review findings to support the determination that the non-compliance is not serious and not continuing.
2. Determine corrective actions.
3. Inform the PI of the review of the CI, the findings, and the corrective actions for resolution, if applicable. The PI may receive a summary of the CI without reference to the Complainant name(s) who filed it.
4. At its discretion, provide a confidential written response to the Complainant, if known, explaining the findings of the review.
5. Submit a report of the non-compliance and corrective actions to the IBC at the next convened meeting.

B. For CIs that constitute **potentially serious or continuing non-compliance and/or a potential risk to personnel safety or the environment**, the following actions will be taken:

1. ORS will notify the Institutional Official (IO) of the initiation of the review.
2. The CI will be reviewed and evaluated by the CI Review Team utilizing the initial facts and information gathered by ORS. In the event of a conflict of interest or unavailability of a member of the CI Review Team, another voting member of the IBC may be called upon as a replacement.
3. The CI Review Team will determine if a CI requires further investigation by the IBC.
    i. CIs that require further investigation will be reviewed in accordance with Section VI. CIs received from the public will automatically proceed to an investigation.
    ii. For CIs that do not require further investigation, the CI Review Team will facilitate resolution of the CI through the following actions:
        1. Determine whether the CI constitutes non-compliance that is either serious and/or continuing.
        2. Develop corrective actions. Corrective actions deemed to be immediately necessary to protect personnel will be communicated to the PI to be implemented.
        3. Submit a report to the IBC via email describing the CI, the findings, and the recommended corrective actions (including any already

implemented). The IBC will be given 5 business days to respond with additional input, recommendations, or a request for further investigation under Section VI.

4. Following review of the CI report by the IBC (via the email report or at a convened meeting), the CI Review Team will finalize and document the review and findings and any details that support the determination of serious or continuing non-compliance.
5. Inform the PI of the review of the CI, the findings, and the corrective actions for resolution, if applicable. The PI may receive a summary of the CI without reference to the Complainant name(s) who filed it.
6. At its discretion, provide a confidential written response to the Complainant, if known, explaining the findings of the review.
7. Summarize CI reviews and findings at the next convened IBC meeting for recording in the meeting minutes.

VI. IBC Investigations

A. When a CI requires further investigation, it will be conducted by a designated Subcommittee of the IBC.

B. ORS will assign the Subcommittee members which will include, at minimum, a representative from EH&S and at least one voting member that is faculty.

C. ORS will notify the IBC and the Institutional Official (IO) of the initiation of the investigation.

D. The Subcommittee will review the initial facts and information compiled by ORS and/or the CI Review Team.

E. Additional information may be collected by the Subcommittee using a variety of methods. These may include, but are not limited to:

1. Unannounced visits to the laboratory in question to review procedures, lab/facility documents, or talk with personnel.
2. Submission of documentation from the PI, research team personnel, or staff. Such documentation could include: research records relating to rDNA experimentation, purchase orders, standard operating procedures, diagnostic laboratory reports, quality assurance reports, or others that provide information which may assist in the investigation.
3. Documentation supporting the CI reported by the Complainant.
4. Review of IBC protocols, IBC inspection reports, incident reports or any other pertinent IBC records.
5. Interviews with the PI, Complainant or other individuals who can provide information for the investigation.

F. The Subcommittee will review all evidence and information gathered and take the following actions:

1. Determine whether the CI constitutes non-compliance that is either serious and/or continuing.
2. Develop corrective actions. Corrective actions deemed to be immediately necessary to protect personnel will be immediately communicated to the PI to be implemented.
3. The Subcommittee may elect to either have the full IBC review and discuss its CI investigation findings during a convened meeting (for example, when significant committee input may be needed), or to finalize its findings and recommendations and submit those in a report to the full IBC via email. When an emailed report is utilized, it will describe the CI, the findings, and the recommended corrective actions (including any already implemented). The IBC will be given 5 business days to respond with additional input, recommendations, or a request for review of the CI by the full committee at a convened meeting.
4. Following review of the CI investigation by the IBC (via the email report or at a convened meeting), the Subcommittee will finalize and document the review and findings and any details that support the determination of an incident and/or serious or continuing non-compliance.
5. Inform the PI of the review of the CI, the findings, and the corrective actions for resolution, if applicable. The PI may receive a summary of the CI without reference to the individual(s) name(s) who filed it.
6. At its discretion, provide a confidential written response to the Complainant, if known, explaining the findings of the review.
7. Summarize CI reviews and findings at the next convened IBC meeting for recording in the meeting minutes.

VII. Corrective Actions

A. When corrective actions result from the review of a CI, they may include but are not limited to:

1. Requiring an amendment to the IBC approved protocol
2. Requiring a change in procedures previously approved in an IBC protocol
3. Requiring a re-submission of a currently approved IBC protocol
4. Conducting announced or unannounced laboratory inspections to observe procedures, conditions, and/or review programs
5. Requiring the PI to provide a written plan that defines how the incident will be prevented from reoccurring
6. Training which may include “hands-on” training, online training, conferences/webinars/workshops, or other targeted training
7. Increased monitoring
8. Suspension or termination of the IBC protocol or rDNA research activity in accordance with UTA Policy RA-PO-08, Policy for Research Involving Recombinant or Synthetic Nucleic Acid Molecules.

VIII. Documentation and Notifications

A. Upon completion of a CI review and/or investigation by the IBC, ORS shall carry out the following documentation and communication:

1. CIs found to be incorrect or insufficiently substantiated during any part of the review/investigation process will be reported to the IBC at the next convened meeting.
2. Required notifications to the PI. If a finding of non-compliance is determined to be serious and/or continuing, the Chair or supervisor of the PI and the IO shall also receive a notification of the conclusion and findings of the review/investigation, a description of violations (if any), and the required corrective actions (if any).
3. Notifications to the Complainant as determined necessary.
4. Required notifications and prompt reporting to NIH and sponsoring agencies, as applicable, and in accordance with the NIH Guidelines incident reporting requirements.

IX. Appeal Opportunity

A. The PI can appeal the findings of a CI review. The appeal must be submitted to the IBC Chair according to the IBC Appeal of an IBC Decision SOP.

X. Confidentiality of the Complainant

A. The confidentiality of any Complainant will be maintained by all individuals involved in the review and/or investigation of CIs or potential non-compliance. Information on any documentation which is provided to individuals other than ORS or members of the IBC which would identify the Complainant shall be redacted.