

# **POLICY**

Policy Number: EHS-06	Policy Title: Institutional Biosafety Committee Meeting Minutes	
Section: Environmental Health and Safety	Responsible Office: EHS	Page 1 of 5
Effective Date: June 1, 2025	Supersedes: N/A	

## 1. Purpose

This document outlines meeting minutes and public access policies regarding the Recombinant DNA Committee (RDC) of Texas Biomedical Research Institute (Texas Biomed). The RDC is the equivalent of the Institutional Biosafety Committee (IBC) as directed within the NIH Guidelines for Research Involving Recombinant and Synthetic Nucleic Acids (NIH Guidelines).

### 2. Scope

This policy applies to all faculty, staff, researchers, students, visitors, and contractors conducting or overseeing federally funded or non-federally funded research involving recombinant or synthetic nucleic acid molecules at or sponsored by Texas Biomed.

# 3. <u>Definitions:</u>

**RDC:** Recombinant DNA Committee (Institutional Biosafety Committee per NIH Guidelines) as defined by the NIH Guidelines, "...responsible for review and approval of recombinant/synthetic nucleic acid research protocols conducted at or sponsored by the institution for compliance with the NIH Guidelines and approving those research projects that are found to conform with the NIH Guidelines."

**RDC/IBC Chair:** Individual who is appointed by Texas Biomed's leadership to lead the RDC/IBC and serves as the "contact person" with NIH OSP per NIH Guidelines.

**BSO**: Biological Safety Officer at Texas Biomed who oversees the institutional biological safety program. The BSO is the Vice Chair of the committee.

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NIH OSP: National Institutes of Health Office of Science Policy

**PI**: For the purpose of this policy, Principal Investigator is a lead scientist with an appointment at Texas Biomed who is responsible for overseeing the research projects conducted at Texas Biomed as described in the corresponding RDC protocol.

**Recombinant and synthetic nucleic acids (r/sNA).** As defined by the NIH Guidelines:

- I. "Molecules that a) are constructed by joining nucleic acid molecules and b) that 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 "

## 4. Roles and Responsibilities:

BSO, RDC/IBC Chair and/or designee are responsible for:

- a. Accepting public requests for minutes
- b. Corresponding with NIH OSP regarding public requests for RDC minutes
- c. Suggesting redactions in accordance with NIH Guidelines and NIH OSP Guide notices

Executive Vice President for Research, with advisement from General Counsel and Senior Leadership, is responsible for:

- a. Determining when minutes or information may be released to the requestor
- b. Working with the BSO and RDC Chair on such releases
- c. Assisting with the redaction of minutes as needed
- d. Communicating with the NIH OSP or any sister agencies on any or all of the above

Vice President of Corporate Communications or their designee is responsible for:

- a. Providing guidance on communication with requestors
- b. Serving as a liaison between BSO/RDC/IBC Chair and General Counsel
- c. Publishing minutes on public interfacing Texas Biomed webpage after committee approval and after all allowable redactions have been made. This applies to meetings taking place on or after June 1, 2025.

#### 5. General Policy:

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NIH Guidelines mandate that IBC minutes and related documents regarding research involving r/sNA be available upon request to the public and that attendance at meetings be open when it does not compromise proprietary or privacy interests. Furthermore, IBC meetings taking place on or after June 1, 2025, must be posted to an institution's public-facing website immediately after finalization and approval.

## 6. Procedures:

NIH Guidelines only address research involving r/sNA. All other projects and research are not subject to open records access and, to the extent such information may be incidentally included in IBC minutes, such information shall be redacted from the minutes prior to being made public. RDC/IBC Meeting minutes must reflect oversight by the IBC outlined as prescribed in the NIH Guidelines:

- a. Time, date and place of meeting
- b. Prior meeting minute approval
- c. Principal Investigator (PI) name
- d. Verification that the PI and laboratory staff performing the research have been appropriately trained in the safe conduct of the research.
- e. Committee members and those attending
- f. Whether meeting is open or closed. If closed, then the "Why"
- g. All major motions, major points of order and all approved motions
- h. Summaries of research in front of the committee to include principal investigator, project title, BSL level approved and risk assessment information
- i. Applicable NIH guidelines
- j. Any stipulations contained in committee decisions
- k. Time of meeting adjournment

Upon approval of minutes, the following information involving r/sNA may be redacted in accordance with NIH Guidelines and Federal Select Agent Program guidance:

- a. Information likely to compromise institutional or national security
- Information on work involving Select Agents as directed by Federal Select Agent Program (FSAP)
- c. Locations or layouts of laboratories, animal facilities and material storage areas
- d. Names of IBC Committee members and identifiers if disclosure of the information would endanger public health or safety as defined under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Title II – Enhancing Controls on Dangerous Biological Agents and Toxins.

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- e. Information likely to compromise trade secrets, proprietary work or intellectual advantage
- f. Personnel and human resource matters
- g. Confidential commercial information
- h. Confidential sponsor information and pending patents
- Information prohibited to be released by non-disclosure clauses and/or confidentially clauses

## **Posting of Minutes and Record Requests**

Texas Biomed follows NIH Guidelines in making meeting minutes publicly available for NIH funded research. Minutes will be publicly posted online after formal ratification by the RDC and after appropriate redactions have been made. Consistent with NIH guidelines, Texas Biomed will redact proprietary or private information, to include trade secret information and other confidential commercial information, including home telephone numbers and home addresses of RDC members, and specific information where disclosure would compromise institutional or national security.

When applicable, Texas Biomed will follow all regulations, orders, and guidelines of the Federal Select Agent Program (FSAP) with respect to the publication of RDC minutes involving select agents and toxins. Generally, information that is widely available from other public sources such as institutional webpages, publications describing a principal investigator's (Pl's) research, or public grants databases (e.g. names of RDC's members and Pls, agents used in research, grant numbers) is not generally considered private or proprietary and will not be redacted from the RDC minutes unless determined to be proprietary, private information or in instances where disclosure may endanger institutional or national security or the safety of individuals.

Texas Biomed shall make reasonable efforts to accommodate public attendance upon request and by virtual means at IBC meetings, consistent with Section IV-B-2-a-(6) of the Guidelines, while safeguarding proprietary or sensitive information. For discussions determined to address proprietary or private information or in instances where disclosure may endanger institutional or national security – such as federal select agents or the safety of individuals – Texas Biomed reserves the right to restrict or limit public access.

Any comments received by Texas Biomed from the public review of these documents and any subsequent response(s) by the Recombinant DNA Committee, will be forwarded to the Office of Science Policy, National Institutes of Health, 6705 Rockledge Drive, Suite 750, Bethesda MD 20892.

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#### References:

- I. NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules
- II. Implementation Update: Promoting Maximal Transparency Under the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (Notice # NOT-OD-25-082)
- III. NIH OSP FAQs About IBC Meetings and Minutes: https://osp.od.nih.gov/policies/biosafety-and-biosecurity-policy/faqs-about-ibc-meetings-and-minutes/
- IV. Texas Biomed EHS-03a: Recombinant DNA Policy
- V. Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Public law 107-188) Title II Enhancing Controls on Dangerous Biological Agents and Toxins

# **Date Approved**

June 12, 2025 (EHS-06)