TEXAS A&M UNIVERSITY
SAN ANTONIO

Guidelines for Confidentiality of Records and Access Requests

1. SCOPE

This guideline applies to confidentiality of Institutional Biosafety Committee (IBC) records, access requests and redaction of documents. Requests for information can be received through various routes (ie: IBC chair, DRC, IO, committee members/administrators, lab managers, ethics hotline or FOIA). This guideline applies to any request of IBC documents as outlined in NIH guidelines.

2. PURPOSE

2.1 The purpose of this Guideline is to establish a process to ensure confidentiality of IBC Records and manage requests for access to IBC documents as required by the NIH *Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules.*

2.2 The process begins when a record is created or a request to access an existing record is made either in writing or verbally and ends when the record is properly maintained. Verbal requests must be documented in writing.

2.3 The guideline identifies the administrative units that are involved in receiving and fulfilling the information request.

3. BACKGROUND

3.1 All IBC protocols are considered confidential documents. However, the committee deliberations are open and available to the public per NIH policy and may be requested via open records request.

3.2 Public: Since the NIH Guidelines are nationally applied, and no limitations were placed on the notion of "public" when they were first promulgated, "public" should be interpreted in its broadest sense – as referring to all people and entities.

3.3 Inspection: All IBC records, whether in paper or electronic form, are readily available for inspection by federal agencies.

3.4 Public Access Request to IBC Meeting Minutes and Other Documents:

A. Generally, confidential records are not disclosed to any third party unless disclosure is required by law. The confidential records will include any IBC record and IBC meeting minutes.

B. Public Requests for Rosters. Under the NIH *Guidelines*, IBCs are required to make rosters and biographical sketches of IBC members that have been submitted to NIH available to the public upon request.

C. Meeting minutes and certain other documents must be made available to the public upon request. NIH *Guidelines* Section IV-B-2-a-(7). Documents include:

1. Documents provided to funding agencies (such as NIH) that those agencies would have to make available to the public.
2. Reports of incidents as described under Section IV-B-2-b-(7) and in Appendix G of the NIH *Guidelines*.

D. Redaction is permissible for documents disclosed to address privacy and confidentiality concerns.

E. Access to minutes cannot be overly burdensome to the public.

4. PROCESS AND RESPONSIBLE PARTIES

4.1 The university's IBC Research Compliance Administrator (RCA) is responsible for ensuring, organizing, and keeping the current documentation inspection ready.

4.2 The Director of Research Compliance (DRC) is responsible for ensuring compliance with the procedure as indicated in #5. Upon receipt of the records request, The DRC will notify the IO and the IBC chair.

4.3 The university records request officer (URO) will be notified by the DRC. The URO will correspond with the requestor and request a timeline for responding, and the detail of the kinds of documentation requested. The URO will consult with the Office of General Counsel (OGC) as necessary. They will then compile and redact information after consultation with the OGC.

4.4 The DRC is responsible for advising of any protected and proprietary information.

REFERENCES:

NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines), Section IV-B-2-a-(7) and Section IV-D-5.
NIH, Access to IBC Meeting Minutes and Other Documentation (Nov. 21, 2014)
NIH, Frequently Asked Questions (FAQs) FAQs About IBC Meetings and Minutes

VERSION HISTORY:

Version 1.0- 3/27/2024; IO approved 12/3/2024