



IBC Title:	Confidentiality of Records and Access Requests		
SOP #110	IBC	IBC Approval Date:	03/08/2021

1 SCOPE

This SOP applies to confidentiality of IBC records, access requests and redaction of documents.

2 PURPOSE

- 2.1 The purpose of this SOP 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 and ends when the record is properly maintained or the request to access is managed.

3 RESPONSIBILITIES

- 3.1 The university's Research Compliance Coordinator (RCC):
 - 3.1.1 is responsible for ensuring current, consistent and organized documentation is in the IBC Records; and
 - 3.1.2 notifies the IBC in the event of a request for record access.
- 3.2 The Institutional official (IO) is responsible to ensure compliance with this procedure.
- 3.3 The IBC Chair is responsible for assisting the RCC, IO, and IBC in managing access requests and redaction of documents, conducts the preliminary review documents that are responsive to a request, and makes a recommendation to the RCC as to whether the request should be distributed to IBC members for review.

4. DEFINITIONS FOR PURPOSES OF THIS POLICY:

- 4.1 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.
- 4.2 Inspection: All IBC records, whether in paper or electronic form, are readily available for inspection by federal agencies. This policy should not be interpreted to limit the inspection of IBC records. Integral to the NIH Guidelines is public participation and transparency.
- 4.3 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.

5 PROCEDURE

- 5.1 The RCC will inform the IO and the IBC chair when a request for information is received from A&M-Commerce's compliance office.
- 5.2 The IBC chair and the IO will conduct the preliminary review of the request and the IBC chair will consult the PI if the request of information is pertaining to an approved biohazard use protocol.
- 5.3 After the review, the IBC chair and the IO will review the requested materials and redact any information that is not subject to disclosure; if additional help is required, the IBC chair may form an ad hoc committee of selected IBC members.
- 5.4 Redactions must be applied judiciously and consistently for all requested documents.
- 5.5 Questions about redaction practices should be posed to the A&M-Commerce's compliance office and the Office of General Counsel.

6 Compliance with the State Law

- 6.1 State institutions also have to comply with state public disclosure laws, such as the Texas Public Information Act, in making documentation publicly available upon request.
- 6.2 A provision in state law, Federal law, or institutional policy that requires an institution to follow specific procedures in responding to requests for institutional records is not inherently in conflict with any provision of the NIH *Guidelines*.
- 6.3 Should a conflict with the NIH *Guidelines* occur, the Office of General Counsel will be consulted.

7 Delivery of Requested Material

- 7.1 Requiring a member of the public to travel to the site is generally not appropriate since this can often entail significant time, effort, and travel expenses.
- 7.2 Fees. An institution may charge an amount sufficient to cover the costs of providing minutes and other requested documentation or materials. However, charges should not be excessive or used as a deterrent to access.
- 7.3 Delivery of the materials should occur in a timely manner.

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

RELATED SOPS: All.

VERSION HISTORY:

Version 1.0- Approved 03/08/2021