



IBC SOP:	Statement on Holding Protocol and Use of Holding Protocol
SOP#410.00	IBC Approval: 11/19/2025

A. Performance Standard

To provide a mechanism for holding biological specimens not assigned to an active Texas A&M University-San Antonio (A&M-SA) IBC approved protocol.

B. Background/Purpose

All biological specimens maintained by A&M-SA for teaching or research purposes must be covered by an active, approved protocol. The IBC has the responsibility to ensure all biological specimens and transgenic species used in teaching and research activity meet federal law, Public Health Service policy, and NIH guidelines. This SOP specifically addresses the holding of biological specimens and materials on a global holding protocol. This Holding Protocol [IBC 9999-00] does not expire and does not require Annual Renewal.

C. Roles

- Researcher/Principal Investigator: The investigator should work with the IBC to ensure that protocols are active and current and will remain so for duration of the research or teaching activity.
- IBC: Provides a mechanism for rapid transfer of biological materials in cases where it is necessary to protect wellbeing, welfare, or prevent infection to the external environment.
- Director of Research Compliance (DRC), or designee: Will maintain the Holding Protocol for the purpose of temporarily holding and maintaining biological specimens that are not covered by an existing protocol. Upon arrival, the storage containers (e.g., freezer(s) and/or refrigerator(s)) will be inspected by the BSO or designee for damage and remedied as required.

D. Guidance

1. Eligibility for Participation Under this SOP:

Use of the Holding Protocol is intended to be temporary. **Permission must be obtained from the IBC Chair, or DRC prior to use of the Holding Protocol.** Situations which may result in the use of this protocol might include:

- a. Materials ordered/acquired without an approved protocol.
 - b. Biological specimens originating from inactivated (or terminated) protocols.
 - c. Biological specimens on a protocol under investigation.
 - d. New Investigators without an approved A&M-SA protocol that have biological specimens needing immediate storage space.
 - e. Investigators who are leaving A&M-SA and do not yet have the necessary approvals for the transfer of materials to the new institution.
2. The PI (or his/her designee) requesting the use of the A&M-SA Holding Protocol must complete the “*Biological specimen Holding Protocol Request Form and email to ibc@tamusa.edu”.*



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3. **Approval:**

Only the DRC, or IBC Chair are authorized to approve the transfer of biological material to the Holding Protocol. All actions involving the Holding Protocol will be reported to the IBC at the next regularly scheduled meeting.

4. **Management of Biological Specimens on the Holding Protocol:**

- a. No data collection, experimental or instructional procedures are allowed with specimens on the Holding Protocol.
- b. Propagation to maintain viability of specific lines may occur under this protocol provided a protocol is in place to govern propagation procedures.
- c. *Any associated safety procedures including use of personal protective equipment* will be maintained as appropriate and in accordance to the IBC approvals as necessary.
- d. *Documentation of Biological Specimens Placed on the Holding Protocol:* When biological specimens are placed in the holding protocol, there will be a note to document release of the specimens in the holding protocol when IBC protocol is approved.
- e. If destruction of samples are required under the Holding Protocol, BSO or designee will perform it using appropriate methods.
- f. Other methods of disposition, as appropriate, may also be pursued to ensure human welfare.
- g. The freezer will be checked periodically by IBC Chair, DRC or designee to verify that the biological materials are safe and secure.
- h. A contingency plan must be in place to respond to a freezer failure that requires the transfer of the materials.

5. **Non-Compliance**

- a. Noncompliance with this holding protocol could result in a shutdown of PI's research program.

6. **Time limit:**

- a. Biological specimens should be removed from the Holding Protocols as soon as possible. The maximum time for the specimens to stay on the Holding Protocol is 2 months. May be extended on case-by-case basis.
- b. Failure to submit an IBC protocol in a timely manner may result in noncompliance and IBC action.

7. **IBC Chair or DRC must be notified** of any special conditions of note for all biological specimens transferred onto the Holding Protocol. Examples include:

- a. Zoonotic and/or infectious disease potential including viral vectors.
- b. Chemical or radiation hazard potential.
- c. Gene Modified Organisms if applicable.

History:

Version 01 - Initial Approval: 10/26/2021; IO Approved 6/4/2024

Version 02- Approved 11/19/2025



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Texas A&M University-San Antonio

Biological Specimen Holding Protocol Request Form

(Please type form, handwritten forms will be returned)

Please Note:

- No experimental or instructional procedures are allowed while biological specimens are on the A&M-SA Holding Protocol. Noncompliance with this holding protocol could result in a shutdown of PI's research program.
- Permission must be obtained from the IBC Chair or Director of the Office of Research Compliance (DRC) prior to placement of specimens onto the Holding Protocol.
- The PI (or his/her designee) must complete this form.

PLEASE COMPLETE ALL OF THE INFORMATION BELOW

Date Submitted: _____ Grant # (if applicable) _____
 Investigator: _____ Current Protocol #: _____
 Submitted by: _____ Phone: _____
 Department: _____ email: _____

Anticipated Length of time on Temporary Holding Protocol: _____ *(2 months maximum)*

Reason for Request (check all that apply):

- Expired/Lapsed Protocol
- IBC requirement
- PI leaving A&M-SA
- Study ended
- New A&M-SA PI
- Other (please explain): _____

BIOLOGICAL SPECIMEN INFORMATION

Please attach a spread sheet with the following information:

1. List of all the biological specimens by strains, including any special care required.
2. Name of the Institution from where the specimen will be shipped _____
3. Name and contact information of the person responsible for the shipment _____
4. If any specimens require special conditions, detail them on the spreadsheet in a new sheet.

Please attach documents with the following information:

5. Compliance Committee approvals from the institution, letters showing the date and protocol number.
6. Funding source for the study
7. Name and contact information of the personnel handling the MTA in the previous institution.
8. Name and contact information of the administrator from the research compliance office.

Storage Location: Building: _____ Room: _____

PI

IBC Chair /DRC