TEXAS A&M UNIVERSITY
SAN ANTONIO

IBC SOP:	Statement on Protocol, Submission, and Review
SOP#400.00	IBC Approval: 11/19/2025

4.0 IBC Forms

All permit applications must be submitted using the posted forms. The IBC forms are posted on the IBC website. Please check the website for any submission deadlines. All research and teaching involving biohazardous materials, and/or r/sDNA, must receive IBC approval prior to initiation of the project.

4.1 Submissions (new and renewals after 3-year approval period)

Forms must be typed and submitted electronically. It is the responsibility of the PI to address all requests for revisions and clarification within 30 days of the date of request. PI may submit a one-time extension request to the DRC in writing. This request will be reviewed and approved by the DRC after consulting with the chair. After this time, the protocol will need to be resubmitted for a *de novo* review. Protocols resubmitted with revisions must be a Microsoft Word document and have track-changes enabled.

4.2 Amendments

All amendments must be submitted in writing, using the appropriate forms found on the IBC webpage, and approved before work can begin. Failure to obtain IBC approval or IBC exemption determination prior to the start of work results in noncompliance. There is no limit to the number of amendments to an approved protocol. For major amendments, at the discretion of the chair, a new protocol may be requested. PIs are encouraged to contact IBC for any clarification.

Administrative Amendments

May be approved by the Office of Research Compliance without further review by chair or committee

1. Change of title to match grant
2. Adding or removing personnel
3. Correction of typos (doesn't significantly change risk level)

Minor Amendments

May be approved by the IBC Chair without further review by committee

1. Change in principal investigator.
2. Changing the campus storing location or laboratory location.
3. Changing the disposal methods of animals, plants, and *in vitro* cultures.

Major Amendments

1. To be reviewed and approved by the full IBC committee
2. Adding a new species, organism or toxin.
3. Changing aspects of the recombinant or synthetic nucleic acid molecules (e.g., host range, nature of DNA, etc.).
4. Addition of a new biohazardous material.
5. Changing or adding objectives to the study.

6. Changing the biosafety level of a study.
7. Changing the inoculation route of a human pathogen.
8. Generation of new transgenic line(s).
9. Moving isolates from long term storage to active research.

   (*Please note: If the changes are considered significant enough, the IBC may require submission of a new Application*)

10. Changing the inoculation route of a non-human pathogen. (major)

4.3 Continuing Review

The Continuing Review form can be found on the IBC website. Continuing Reviews are to be submitted no later than one (1) week before the anniversary date of approval to allow time for review and approval. Courtesy reminders will be sent from the Office of Research Compliance 90, 60, and 30 days before the anniversary date. Failure to submit the continuing renewal one week before the anniversary date will result in termination of that registration. If a registration is terminated, PIs will need to submit a new application for *de novo* review by the Committee if the PI desires to continue work covered by the terminated protocol.

IBC permits are approved for 3 years. After two continuing review renewals have been submitted for registration, PI's are required to resubmit the entire registration for *de novo* review by the Committee. Failure to do so constitutes non-compliance.

4.4 Laboratory Inspections

Environmental Health & Safety (EH&S) is responsible for conducting inspections annually of all teaching and research laboratories on campus. This includes BSL-1 and BSL-2 facilities and certification of biosafety cabinets, hoods etc.

4.5 Protocol Termination

The Principal Investigator will notify the RCC regarding intent to terminate an approved IBC registration. The IBC Chair or designee will conduct a close-out audit. All biospecimens will be transferred to a holding protocol or disposed of in accordance with the approved protocol.

Failure to renew a previously approved IBC protocol before the expiration date, described in Section 4.3, may result in termination of the protocol(s). All biospecimens will be moved into a holding protocol and locked from further use.

Issues of noncompliance with institutional and federal regulations, policies, and guidelines or requirements of the IBC may also initiate protocol termination. Instances of noncompliance will be evaluated, and the IBC may determine if protocol termination is appropriate.

History:

Version 01 - Initial Approval: 12/14/22; IO Approved 3/29/2023
Version 02- Approved 11/19/2025