TEXAS A&M UNIVERSITY
SAN ANTONIO

IBC SOP:	Statement on Post Approval Biosafety Monitoring	
SOP#700.00	IBC Approval: 9/14/2022	IO Approval: 6/6/2023

7.0 Post Approval Monitoring

The purpose of conducting post approval monitoring is to ensure that all work approved in IBC registrations is performed in accordance with the current editions of *NIH Guidelines*, the BMBL, A&M-SA and A&M System regulations, policies and procedures. Compliance with other applicable federal, state, and local regulations is also required. Monitoring will gather information for continuous improvement of the IBC processes, promoting the safe use of biohazardous materials, ensuring compliance, and accurately describing the research being conducted.

7.1 Methods of Monitoring

The IBC utilizes several methods to monitor the conduct and progress of approved protocols and the safety of A&M-SA personnel and approved non-A&M-SA personnel, including faculty, staff, and students working with biohazardous materials. Monitoring includes, but is not limited to, observation of procedures, agent audits, laboratory/facility inspections, IBC application modifications, and annual updates, etc.

7.1.1 Approved protocols will provide baseline information regarding PPE, storage and usage of agents, personnel, and other details relevant for the safety of personnel and the environment. If an amendment is submitted to make necessary adjustments and modifications to approved processes, the amendment must be approved prior to implementation.

7.1.2 Observation of high risk procedures and other procedures as directed by the IBC may be monitored by the BSO/IBC Chair/DRC to ensure the safety of personnel and/or the environment. Post-approval observation of some procedures may be requested by funding agencies. In some instances, procedures involving new equipment may also be monitored.

7.1.3 Agent audits will be performed by the BSO/RCC on an annual basis by sending a memo to all PI's. Follow up will include clarification from the PI's. Physical inspection of the agents will be conducted during the annual lab inspections.

7.1.4 Laboratory/facility inspections will be done on all laboratories listed on active, approved, IBC protocols on an annual basis. Additional inspections will be performed after an accident, spill, unanticipated event, or biological release.

7.1.4.1 Lab inspections of facilities utilizing biological materials occur annually, as conducted by the BSO utilizing a checklist (Biosafety Inspection Report for BSL-1 Laboratory or Biosafety Inspection Report for BSL-2 Laboratory). The BSO provides inspection information, particularly any significant problems noted, to the IBC to ensure that all laboratory space linked to IBC protocols utilizing biological agents meet the necessary standards set forth in the *NIH Guidelines* and the *BMBL*.

7.1.4.2 Any issues found during the annual inspections and the actions taken to resolve the issues will be reported to the IBC at a convened meeting. The IBC may aid the BSO in resolving the issues, if needed.

7.1.4.3 During the lab inspections, the certification status of each biological safety cabinet is checked and verified.

7.1.5 IBC registration modification. PI's are able to modify, monitor, and report all IBC related incidents using the Adverse Event Form or Amendment or Modification to Previous IBC-approved Protocol form. This self-monitoring effort may be followed by post approval monitoring.

7.1.6 Annual Renewal. Confirms the approved personnel (A&M-SA and non-A&M-SA) who are working on the project, the location of the work, the progress on the work, and whether there have been any adverse events or other problems during the conduct of the work.

7.2 Major Biosafety Hazards or Violations of NIH Guidelines

In case of major biosafety hazards or violation of *NIH Guidelines*, an emergency executive session of the IBC committee will be convened as quickly as possible, to discuss corrective and preventive action plans and confirming or amending any actions already taken by the BSO or IBC Chair.

History:
Version 01 - Initial Approval: 9/14/2022; IO Approved: 6/6/2023