IBC SOP:	Statement on Biosafety and Biohazards Noncompliance Investigation	
SOP#800.00	IBC Approval: 7/12/2023	IO Approval: 8/22/2023

8.0 Purpose

To help ensure the safety of laboratory personnel as well the public, the Institutional Biosafety Committee (IBC) must review and address all reports of biosafety concerns. Procedures are established to ensure that concerns are communicated to the IBC by the Investigators and the general public. The form for reporting biohazardous concerns can be found here. The Chair of the Committee or its designees must review each concern in a timely and systematic manner and when necessary, take prompt and appropriate corrective actions.

8.1 Definitions

Noncompliance: Conducting research in a manner that is not in compliance with federal regulations, laws, required guidelines, A&M-SA IBC policies and procedures, university rule, or the decisions of the A&M-SA IBC to the policies and procedures page on the website.

Non-serious noncompliance: An isolated incident that is not serious or continuing in nature. Includes unintentional mistakes, oversights, or misunderstandings resulting in inadvertent errors, inattention to detail, or inadequate training and supervision of research staff.

Serious noncompliance: An intentional violation of IBC or university policy or willful noncompliance with applicable federal regulations, laws, and/or required guidelines including, but not limited to, the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acids (and/or the United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern). Some unintentional violations that could pose a risk to the health and/or safety of humans, animals, plants, and the environment could be considered as serious noncompliance.

Continuing noncompliance: A pattern of repeated actions or omissions taken by investigator or research personnel that indicates a lack of ability or willingness to comply with federal regulations, laws, required guidelines, A&M-SA policy, A&M-SA IBC policy and procedures, or the determinations and requirements of the IBC.

8.2 Examples of Noncompliance

8.2.1 Below is a non-comprehensive list of examples that may indicate noncompliance:

- Violation of laboratory safety rules that align with the approved BSL designation (examples: working with a BSL-2 organism in a BSL-1 lab, not using swing bucket covers when centrifuging BSL-2 samples, etc.)
- Conducting experiments not covered by a specific protocol.
- Non-registered personnel performing procedures.

- Use of unauthorized microbial strains or cell lines
- Moving or sharing specimens without authorization.
- Failure to self-report incidents in an appropriate time period.
- Other infractions as they arise.

8.2.2 All researchers are encouraged to self-report or report any adverse events within 24 hours using the Adverse Events Form (click here.)

There are several options available to report adverse events concerning biosafety at A&M-SA.

DRC (Director of Research Compliance) [rani.muthukrishan@tamusa.edu or 210-784-1223],
BSO (Biosafety Officer) [victor.pantusa@tamusa.edu or 210-784-2822],
IO (Institutional Official) [vijay.golla@tamusa.edu or 210-784-1215],
TAMUSA Campus Coordinator [john.wickline@tamusa.edu or 210-784-2003].

In addition to the A&M-SA personnel, Ethics Point (click here, (888) 493-1870), a risk, fraud, and misconduct hotline utilized by the Texas A&M University System, may also be used when reporting concerns.

Public members who are concerned about Biohazard research or safety can use Reporting Biohazardous Concerns Form here.

8.2.3 If the complaint is received verbally, the BSO/DRC/IO will document the report with details such as date and location of the event, names of the personnel involved and depending on the incident will forward to appropriate personnel. For example, if the incident involves safety, campus police and other responsible personnel will be notified.

8.2.4 Texas A&M system regulation and TAMUSA rule is to prohibit unlawful retaliation against employees as a consequence of good faith actions in the reporting of, or the participation in an investigation pertaining to, allegations of wrongdoing. A&M-SA will treat concerns submitted from the general public in the same manner.

8.3 Investigation of Alleged Noncompliance

8.3.1 Further Actions

The BSO/DRC and IBC Chair/Designee will form a subcommittee to screen the initial reports. A determination will be made whether a risk persists.

8.3.2 Investigation

An Investigative Committee will be formed to follow up on the adverse event and will consist of one or more members. The members will be appointed by the IBC Chair and their expertise will be appropriate for the allegation, with care taken to avoid potential conflicts of interests. *Ad hoc* members may be appointed, as appropriate.

The Investigative Committee will be tasked with information gathering, drafting a report of the investigation, and determining a completion date. The assigned completion date will depend on the IBC's determination of whether immediate remedial action may be required. The nature of the investigation will vary depending on the circumstances, but often involves:

- Interviewing complainants (if known), potential witnesses, any persons against whom allegations were directed, and relevant administrators.
- Interviews may be done in-person, via live-streaming platforms (WebEx, Microsoft Teams, etc.), or by email.
- More than one member of the Investigative Committee shall be present during the interview.
- Reviewing any pertinent records.
- Identify relevant rules and regulations.
- As part of the investigation, additional allegations found may be investigated and could result in an additional investigation or maybe in included in the original investigation.
- As part of the investigation, the Investigative Committee may sequester evidence if it is appropriate and needed to conduct the investigation. If evidence is to be sequestered, interested parties will be notified and provided with copies of the evidence and the Investigative Committee will take possession of the originals until the investigation is completed, at which time the original documents will be returned.

The report presented to the IBC should review:

The allegation(s) and may include:

- who was involved
- what happened
- where the alleged noncompliance occurred
- when the alleged noncompliance occurred
- the root cause of the alleged noncompliance
- the results of interview(s)
- the condition of the laboratory
- the results of records and other document reviews

The report reviewed should also contain:

- Any supporting documentation such as correspondence, reports, and records
- Requirements of the NIH, funding agencies, institutional policies and procedures
- Recommended corrective actions, if appropriate, ensure the non-compliance issue will not occur in the future.

8.3.3 Outcomes and Final Actions

- Upon receipt and evaluation of the report, the IBC may request further information or find that the allegation was:

  Not sustained: an allegation is not sustained when an investigation reveals that the evidence does not satisfy the required burden of proof. The concern or complaint was not substantiated, but related aspects require further review, or

  Sustained: an allegation is sustained when an investigation reveals that the evidence satisfies the burden of proof in support of the allegation.

  Inconclusive: the evidence collected during the investigation was unable to render a verdict of sustained or not sustained.

- Other institutional programs (IRB, IACUC or export controls) may require review.

8.4 Noncompliance with IBC Permit, Policies, Procedures, or Decisions

Noncompliance occurs when procedures or policies approved by the IBC are not being followed. When the investigation results in a determination of permit noncompliance, the IBC's first step will be to notify the PI that the work must be brought into compliance.

If allegations of noncompliance are verified, the IBC will review corrective actions put in place by the PI to ensure the safety of all individuals. A clearly minor and unintentional misinterpretation of an IBC policy that has created no additional risk for an individual is an example of where a verified allegation of noncompliance might lead to an explanation, not a corrective action.

Non-compliance			
Compliant		Non-compliant	
Non-serious Halted	Non-serious continuing	Serious Halted	Serious continuing

8.5 Consequences of Noncompliance

Subsequent actions of the IBC will include:

- Implementing measures to prevent recurrence.
- Notifying the PI's academic supervisor.
- Notifying the Vice Provost for Research and Health Sciences of its actions.
- Notifying funding or regulatory agencies, as required.
- Notifying the complainant, any persons against whom allegations were directed, and pertinent program officials (appropriate supervisory and management staff, the public affairs office, A&M-SA attorneys, A&M-SA Office of Research Compliance, etc.).
- Suspending privileges on a case-by-case basis resulting of a PAM (post approval monitoring)

8.6 Incident Reporting to NIH

The following incidents must be reported to NIH's Office of Science Policy (OSP) within 30 days. Reports should be emailed to: NIHGuidelines@od.nih.gov.

- Any significant problems or violations of the NIH Guidelines (e.g., failure to adhere to the containment and biosafety practices in the guidelines); and
- Any significant research-related accidents and illnesses (e.g., spill/accident leading to personal injury or illness, breach in containment, escape or improper disposition of a transgenic animal).

The following incidents require immediate reporting to NIH OSP:

- Spills or accidents involving rDNA requiring BSL-2 containment resulting in an overt exposure (e.g. needle-stick; splash in eyes, nose, mouth; or accidental aerosolization / inhalation).

Minor spills of low-risk agents, contained and properly disinfected, generally do not need to be reported, but researchers should consult the BSO or IBC if uncertain.

Any incident reports to the NIH OSP will be submitted by the DRC/BSO. The report should include the nature of the spill, the response made to mitigate the problem, and all steps taken to preclude its reoccurrence.

History:
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