IBC GUIDELINE:	Managing reported concerns related to the use of recombinant DNA, biohazard agents, and toxins in research, teaching, and other activities		
SOP #	102	IBC Approval:	March 23, 2020

Purpose:
The IBC must review and address any reported concerns related to the use of biohazardous materials at Texas A&M University-Commerce (A&M-Commerce) to ensure the safety of faculty, staff, students, visitors, the general public and the environment as well as to ensure compliance with relevant federal, state, The Texas A&M University System regulations and Texas A&M University-Commerce rules, regulations and Institutional Biosafety Committee (IBC) requirements. This SOP outlines the process for managing such concerns.

Scope:
This procedure applies to all faculty, staff and students, affiliated researchers or other individuals who are affiliated with A&M-Commerce.

Noncompliance is any failure or refusal to comply with relevant federal laws and regulations, A&M System regulations, and A&M-Commerce rules, regulations and practices regarding the use of biohazardous materials.

A. Reporting Criteria, methods and procedures:
All A&M-Commence faculty, staff and students have a responsibility to report any of the following:

i. An actual or suspected concern related to biohazardous material possession or use can be reported to the Research Compliance office directly, in writing (researchcompliance@tamuc.edu) by phone (903-886-5766), or anonymously via the Texas A&M University System Risk, Fraud and Misconduct Hotline. Reports may also be made to any member of the IBC. If a concern is reported orally, the individual who receives the phone call should document the circumstances fully to ensure that the issues are clear and to prevent any potential misunderstandings. The report will be shared with the IBC chair, the Institutional Officer (IO) and the biosafety officer (BSO) for further action.

ii. Information relating to an open inquiry or investigation will be shared only with others at the University (or at a University-affiliated organization whose biohazard and recombinant DNA use program is covered by the IBC) who have a need to know, those who are involved in or necessary to the investigative process, and federal agencies, as required.

iii. It should be understood by all University personnel that participation in the biosafety program is a privilege that is extended to PIs and other individuals by the IBC under conditions of voluntary compliance and submission to IBC authority, and an implied or explicit promise to cooperate with the IBC and abide by their instructions.

B. Initial evaluation and actions by the IBC:
Upon review of the reported concern, the IO or IBC Chair, in cooperation with the Research Compliance Coordinator (RCC), will determine if immediate action is required or if routine IBC investigative procedures will be followed.

i. If the reported concern falls into any of the categories listed below, immediate action is required and must be initiated by the IO, IBC Chair or a designee to mitigate safety, security or health concerns:

- Conditions that may jeopardize the health or well-being of employees, laboratory workers, or students be evaluated and acted upon immediately. In such cases, in consultation with the IO, the IBC Chair shall halt the relevant procedure, including procedures listed on approved Biohazard Use Protocols (BUPs), that, in their judgment, do not comply with institutional policies or that represent an unexpected or unpredicted level of risk to well-being of workers or environment, until the IBC can be convened to review the matter.

- Situations that may involve potential criminal activity, human safety or security of A&M-Commerce property are evaluated immediately by the institution's compliance or occupational health and safety officials, or law enforcement authorities, as appropriate. In this case, the IBC retains authority over biohazard agents and use aspects of the potential

violations, and will work in tandem and in
cooperation with other University entities and other appropriate authorities.

ii. Allegations of other ongoing policy or procedural matters, or other situations that do not involve apparent immediate danger to workers and environment may not require such immediate attention, but nonetheless must be investigated promptly.

iii. After an initial action, a report must be submitted to the IBC for review of concerned issues related to biohazard agent and recombinant DNA use. Emergency meetings of the IBC may be called as necessary.

Investigation

Upon receipt of the initial action report, the IBC Chair will appoint a subcommittee of one or more individuals with at least one a member of the IBC (subcommittee may have non-IBC members) to investigate the allegation. The subcommittee will inform all persons involved in the investigation of the purpose and the manner in which it will be conducted. The subcommittee will examine all documents and procedures relating to the allegation and will interview individuals named in the allegation and others who may have knowledge of the circumstances surrounding the allegation and determine if there is a basis in fact to support the allegation. The subcommittee will report its findings to the full IBC, including any recommendations for the IBC's consideration.

The investigative process may include consultation with the PI, research staff(s), and any other individuals who may have information pertinent to the incident. Depending on the circumstances, information required by the IBC will vary but may involve:

a. Interviewing complainants (if known), any persons against whom allegations were directed, members of the research team, the PI's department head, and any other pertinent program officials;

b. Visiting the laboratory and observing the work performed;

c. Obtaining or reviewing any pertinent records, (e.g., laboratory notebooks, protocols, and instrument sign-in sheets, training records, and other documents); and

d. Consulting with appropriate experts. Appropriate experts may include the BSO, research subject matter experts, regulatory experts, law enforcement personnel, University-retained attorneys, or others.

The University should make all reasonable attempts to assist the IBC in requesting and receiving any and all physical, documentary, and testimonial evidence that is pertinent to cases being investigated by the IBC.

Investigation Report

At the conclusion of the investigation, the subcommittee will create a report detailing the investigators' findings and recommendations.

The report will include:

i. A description of the concern(s);
ii. The results and records of any interviews that were conducted;
iii. The condition of the laboratory and working environment;
iv. The results of document reviews;
v. Copies of all supporting documentation including correspondences, reports, biohazard use records, and any other pertinent materials;
vi. One of the following determinations of whether the facts support the allegation(s) of noncompliance:
    - Sustained: evidence satisfies burden of proof
    - Not sustained: evidence does not satisfy burden of proof
    - Inconclusive or unable to determine
vii. Determination of the root cause(s) of the noncompliance and recommendations for correction and/or prevention of re-occurrence.

Once the subcommittee approves their report, it will be sent to the IBC to be reviewed at the next convened IBC meeting for determination review and approval.

IBC Review

The subcommittee's investigation report must be reviewed and approved at a convened meeting of the IBC. During the IBC meeting, the Chair of the Investigative Subcommittee will describe the methodology and results of the investigation as well as the recommendation made. After discussion, the IBC may approve the report as is, with modifications or table the approval and request further action by the subcommittee or others.

Notification

The PI responsible for the protocol shall be provided with outcomes of the investigation.

Final Actions

The IBC has the authority to address non-compliance in accordance with the *NIH Guidelines*, the BMBL, A&M–Commerce policies and procedures, and other legal requirements. Findings of non-compliance may result in one or more of the following actions:

- Suspension of use of rDNA and/or biohazardous materials;
- Requirement to amend the protocol to correct noncompliance;
- Termination of approval for use of biohazardous materials;
- Confiscation or destruction of the biohazardous materials; and
- Increased post approval monitoring.