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| IBC SOP: | Statement on Reporting Requirements | |
| SOP#600.00 | IBC Approval: 9/14/2022 | IO Approval: 6/6/2023 |

6.0 Reporting to NIH—Recombinant or Synthetic Nucleic Acids

The DRC on behalf of the Institution, shall report to the NIH OSP:

- Per Section IV-B-1-j of the *NIH Guidelines* any significant problems with or violations of the NIH Guidelines, System regulations (15.99.06 Use of Biohazards in Research, Teaching, and Testing), the A&M-SA IBC rule, A&M-SA IBC SOPs, and/or any significant research-related accidents or illnesses to the NIH OSP within 30 days;
- A report will be written and will include:
 - the date(s) of the incident;
 - a description of the incident;
 - the section(s) of the *NIH Guidelines* violated, if applicable;
 - the sections of the Biosafety in Microbiological and Biomedical Laboratories (BMBL) violated, if applicable
 - the personnel involved in the incident;
 - a description of the investigation of the incident, if any;
 - a description of the measures implemented by the Institution to rectify the situation.
- The report will be sent to the NIH OSP (NIHGuidelines@od.nih.gov) and copies sent to other appropriate personnel i.e. BSO, Chair, PI and IO.
- For BSL-2 studies, per Appendix G–II-B-2-k, any spills and/or accidents which result in **overt exposures of personnel** to organisms containing recombinant or synthetic nucleic acid molecules are **immediately reported (within 24 hours)** to the Institutional Biosafety Committee (ibc@tamusa.edu), EHS (vpantusa@tamusa.edu), and NIH OSP (NIHGuidelines@od.nih.gov)

The DRC, on behalf of A&M-SA and the IBC, shall file an annual report with NIH OSP which includes:

- A roster of all IBC members clearly indicating the Chair, contact person, Institutional Biosafety Officer, plant expert (if applicable), animal expert (if applicable), human gene therapy expert (if applicable), or ad hoc consultant (if applicable).
- Biographical sketches of new IBC members, including community members.

6.1 Principal Investigator Reporting

6.1.1 The Principal Investigator and other research personnel must report any significant incident, violation of the *NIH Guidelines*, or any significant, research-related accidents and illnesses immediately by contacting the DRC, BSO, and RCC. The PI is required to fill out an [Adverse Event Form](#). Examples of incidents to be reported are:

- Overt exposures. Defined as exposures that result in direct personnel exposure to biohazardous materials such as injection, spills, splashes, or aerosol inhalation associated with BSL-1 or BSL-2 registrations.
- Potential exposures. Defined as exposures that have a high risk of exposing personnel to biohazardous materials such as spills, containment failure while working with an agent, or equipment failure that may produce aerosols associated with BSL-1 or BSL-2 registrations.
- Any illness that may be caused by the agents used in the laboratory incidents involving the improper disposal of rDNA.

6.1.2 Principal Investigators must also report other information to the IBC as soon as they become aware of the information (must also be reported to BSO):

- Information to support a new host-vector system **Section IV-B-7-b-(1)**.
- Petitions for proposed exemptions to the NIH Guidelines **Section IV-B-7-b-(2)**.
- Petitions for approval to conduct experiments specified in Sections III-A-1 and III-B **Section IV-B-7-b-(3)**.
- Petition for determination of containment for experiments not covered by the NIH Guidelines **Section IV-B-7-b-(5)**.

History:

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