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Reviewed and Approved by: Tyler Ridgeway, CPIA, MBA, ORIE Director	Reviewed and Approved by: Matthew Gordon, PhD, DU IBC Chair	

Section 5: Reporting Requirements

5.0 Reportable Incidents and Violations

Incidents/problems involving recombinant or synthetic nucleic acid molecules and biohazardous materials, agents and toxins must be immediately reported to the Biological Safety Officer (BSO) or the Director of EHS, and the IBC Office. Examples of reportable significant incidents include but are not limited to any overt exposure, such as a needle stick, splash, and contamination due to equipment failure. A significant event may also occur from a containment breach, which may be subsequently determined to pose either an overt or potential exposure to individuals. It should be noted that waste from recombinant or synthetic nucleic acid molecules research is also considered biohazardous and incidents involving improper disposal of recombinant or synthetic nucleic acid molecules must also be reported. Questions regarding reportable incidents should be directed to the BSO.

Failure by research personnel to follow federal and institutional regulations, guidelines, policies and/or procedures may also require reporting to the appropriate institutional, local, state and/or federal agencies. Violations may include but is not limited to conduct of new or ongoing research without appropriate federal or institutional registration, review, approval or oversight.

5.1 Principal Investigator Reporting

The Principal Investigator and their personnel must report any significant incident, violation of the *NIH Guidelines*, or any significant, research-related accidents and illnesses immediately by contacting the BSO. Examples of incidents and violations include:

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

In addition, Principal Investigators must report other information to the IBC as soon as they become aware of the information (must also be reported to OBA):

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

5.2 BSO Reporting

The BSO is required, by the *NIH Guidelines*, to report to the IBC:

- All violations of the *NIH Guidelines* and significant incidents.
- Any significant research-related accidents or illnesses.

5.3 IBC Reporting

The IBC, through the IO, will file an annual report with OBA that includes:

- A roster of all IBC members clearly indicating the Chair, contact person, BSO, and animal expert
- Biographical sketches of all IBC members

The IBC is required, by the *NIH Guidelines*, to report to the appropriate University official(s) and to the NIH/OBA within 30 days any significant incidents, violations of the *NIH Guidelines*, or any significant research-related accidents and illnesses. Copies of these reports should be sent to the Institutional Official and the Director of Research Integrity and Education. The IBC Chair, IBC Administrator, and other University officials will be responsible to determine what actions, if any, are necessary. For example the IBC may choose to change the frequency of lab inspections, or change the Biosafety Level of the protocol, based on results of the incident. The IBC is required to complete a final copy of the Biological Incident Reporting Form which will be signed and dated by the IO.

Other IBC reporting requirements (to OBA and other agencies) include but are not limited to:

- Research involving recombinant or synthetic nucleic acid molecules and biohazardous materials, agents and toxins without prior IBC approval.
- Lax security, unsafe procedures used in a laboratory setting, improper disposal of recombinant waste.
- Significant changes to proposed research risk without prior notification and approval by IBC.
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Certain types of incidents must be reported to OBA on an expedited basis. Spills or accidents in BSL-2 laboratories (involving recombinant or synthetic nucleic acid molecules) resulting in an overt exposure must be immediately reported to OBA. The IBC will report to the Institutional Official, who, in turn will report to OBA, any of the above-described incidents.

Institutional violations that will be reported to the appropriate College or department head may include but are not limited to:

- Lapses in protocol approval.
- Failure to comply with institutional and federal regulations, guidelines, and

policies.

As per Section IV-B-2-a-(7) of the *NIH Guidelines*, if public comments are made on IBC actions, the IBC, through the IO, will forward both the public comments and the IBC's response to the Office of Biotechnology Activities.

5.4 IO Reporting

Upon receiving a report from the IBC, the IO will report:

- In writing any problems with or violations (non-compliance) of the *NIH Guidelines* any significant incident, accidents, or illnesses related to recombinant or synthetic nucleic acid molecules to the NIH/OBA within 30 days or immediately for overt exposure to a BSL-2 agent or potential/overt exposure to a BSL-3 agent.
- Any significant research-related illness or accident that may be hazardous to the public health and cooperate with state and local public health departments.

5.5 Response to External Requests for Information

In accordance with the *NIH Guidelines*, upon request, the institution will make available to the public all IBC meeting minutes and any documents submitted to or received from funding agencies which the latter are required to make available to the public. Redaction of proprietary and private information is allowed but "must be done so judiciously and consistently for all requested documents."