Policy Statement

Per the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (Section IV-B-1-j), it is the responsibility of the Vanderbilt University (VU) Institutional Biosafety Committee (IBC) to report incidents involving recombinant or synthetic nucleic acid molecules that may have personnel exposure implications to the NIH Office of Biotechnology Activities (OBA) as outlined in applicable sections of that standard. To that end, the IBC will take action via the VEHS Biosafety Team to assure that researchers are aware of the necessary response and reporting actions through various communication mechanisms and training materials.

Definition

NIH OBA reportable events include:

- significant problems with or violations of the NIH Guidelines (i.e., failure to obtain IBC approval, failure to follow prescribed containment conditions)
- significant research-related accidents or illnesses including:
  - spills resulting in an exposure incident involving recombinant or synthetic nucleic acid molecules,
  - exposure incidents involving recombinant or synthetic nucleic acid molecules,
  - releases/losses of viable materials (including animals) containing recombinant or synthetic nucleic acid molecules outside of the institution.
- serious adverse events (SAEs) occurring on human gene transfer clinical trials (covered under the IBC policy document entitled: Policy and Procedure for Reporting Serious Adverse Events Occurring on Human Gene Transfer Clinical Trials
- any event that the IBC deems appropriate to report to NIH OBA.

Although the NIH Guidelines charges several parties with the responsibility of reporting such events, at Vanderbilt, the Institutional Biosafety Officer will be the designated party to report these events to NIH OBA within the applicable prescribed timeframes.

Procedure

This procedure focuses specifically on the reporting actions related to the IBC Best Practices for Research Laboratories: Responding to Personnel Exposures and Spills Involving Biological Materials, an emergency planning document adopted by the IBC intended to fulfill the requirements of Section IV-B-2-b-(6) of the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules.

Principal Investigator’s (PI) Responsibilities

1. The PI must assure that they and their research staff are aware of, and received training on, the exposure and spill response and reporting requirements outlined in the document entitled IBC Best Practices for Research Laboratories: Responding to Personnel Exposures and Spills Involving Biological Materials.
2. PI’s must assure that these procedures are implemented in the lab and that a spill kit is assembled and maintained if applicable. (This will be verified by VEHS Biosafety during ongoing lab surveillance visits.)
3. In the context of recombinant or synthetic nucleic acid molecules, PI’s must report to the BSO as soon as the scene is secured, or medical follow-up has been initiated (as applicable) any spill that may have resulted in personnel exposure, or any other exposure incident.

IBC Responsibilities

The BSO will be the official contact for all events that meet the criteria of an NIH OBA reportable event as described above. Upon receiving notification of an event, the BSO will take action to collect details about the event necessary to describe the event to NIH OBA. (Data to be collected and submitted will minimally include the information fields found in the NIH OBA document entitled Template for Reporting Incidents Involving Recombinant DNA to the NIH Office of Biotechnology (OBA).

1. Any event involving recombinant or synthetic nucleic acid molecules requiring BSL-2 containment will be reported to NIH OBA immediately.
2. After initial notification is made to NIH OBA, the BSO will take action to coordinate and facilitate an incident analysis with the parties involved in the event. A summary of the event and findings of the incident analysis will be presented to the IBC at the next regularly scheduled IBC meeting.
3. The IBC will make its recommendations to address contributing factors and these will be communicated to the PI and other affected parties.
4. The PI will be requested to provide a written response regarding the status of requested corrective actions.

Vanderbilt Occupational Health

1. Practitioners will notify the BSO of all reported injuries/exposures involving biological materials that occur in a Vanderbilt lab research setting.
2. This reporting is intended to supplement, not replace, the reporting to be completed by the PI.

Policy Endorsement & Revision

This policy was reviewed and approved by the Vanderbilt IBC on July 24, 2012. The policy will be reviewed periodically when determined appropriate by the Biosafety Officer for purposes of compliance with regulatory requirements.