Subject: Procedure for Reporting Incidents Involving Recombinant or Synthetic Nucleic Acid Molecules to the NIH Office of Science Policy (OSP)

Procedure:
It is the responsibility of the Institutional Biosafety Committee for Human Subjects to report to OSP incidents involving recombinant or synthetic nucleic acid molecules that may have personnel exposure implications. NIH OSP reportable events include:

- significant problems with or violations of the NIH Guidelines (i.e., failure to obtain IBC-HS 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: IBC-HS Policy XIV.A.2: Reporting Serious Adverse Events and Unanticipated Problems); and/or
- any event that the IBC-HS deems appropriate to report to NIH OSP.

I. Investigator Responsibilities.
A. The Investigator 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 Institutional Biosafety Committee Policy: Responding to Personnel Exposures & Spills Involving Biological Materials.
B. The Investigator 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).
C. In the context of recombinant or synthetic nucleic acid molecules, Investigators 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.

II. IBC-HS Committee Responsibilities.
A. The BSO will be the official contact for all events that meet the criteria of an NIH OSP 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 OSP. (Data to be collected and submitted will minimally include the information fields found in the NIH OSP document entitled Template for Reporting Incidents Involving Recombinant DNA to the NIH Office of Science Policy (OSP).
B. Any event involving recombinant or synthetic nucleic acid molecules requiring BSL-2 containment will be reported to NIH OSP immediately.
C. After initial notification is made to NIH OSP, 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-HS at the next regularly scheduled IBC-HS meeting.

D. The IBC-HS will make its recommendations to address contributing factors and these will be communicated to the Investigator and other affected parties.

E. The Investigator will be requested to provide a written response regarding the status of requested corrective actions.

III. Vanderbilt Occupational Health Responsibilities.

A. Practitioners will notify the BSO of all reported injuries/exposures involving biological materials that occur in a VUMC lab research setting.

B. This reporting is intended to supplement, not replace, the reporting to be completed by the Investigator.