Institutional Biosafety Committee
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Title: Institutional Biosafety Program Policy: Mandatory Incident Reporting
Effective Date: 09-October, 2018
Authorized by: Institutional Biosafety Committee, Office of Laboratory and Field Safety, Office of Research Compliance
Revision History: 6-March-2018, 09-October-2018 (JC)

I. Background

The Central Michigan University Biosafety Program Policy (Policy 3-47) charges the Vice President for Research and the Institutional Biosafety Committee (IBC) with ensuring compliance with applicable federal and state laws and regulations, including the National Institutes of Health Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines), The Federal Select Agent Program (7 C.F.R. Part 331, 9 C.F.R. Part 21 and 42 C.F.R. part 73) and The United States Government Policy for Oversight of Dual Use Research of Concern (DURC) and consistent with the guidance found in the Centers for Disease Control's Biosafety in Microbiological and Biomedical Laboratories (BMBL).

II. Purpose

NIH Guidelines section IV-B-1-j defines the following responsibilities of the Institution with regard to ensuring appropriate reporting of incidents or adverse events related to the conduct of covered research to the NIH Office of Science Policy (OSP): "Report any significant problems, violations of the *NIH Guidelines*, or any significant research related accidents and illnesses to NIH OSP within thirty days, unless the institution determines that a report has already been filed by the Principal Investigator or Institutional Biosafety Committee. Reports shall be sent to the Office of Science Policy, National Institutes of Health, preferably by e-mail to: NIHGuidelines@od.nih.gov; additional contact information is also available here and on the OSP website (www.osp.od.nih.gov)." This policy defines incident reporting requirements that comply with NIH Guidelines and other applicable laws and regulations.

III. Definitions

Institution: The designated entity listed on the IBC registration with the National Institutes of Health Office of Science Policy. For the purposes of this policy, the Institution is Central Michigan University (CMU).

Principal Investigator (PI): The faculty or staff member listed on the CMU Biosafety Registration Form as the individual responsible for overseeing the conduct of the research described in the registration, including supervision of research personnel.

Researcher(s), Research Personnel, Research Staff or Laboratory Personnel: any faculty, student, staff member, contracted employee or volunteer conducting research under the supervision of a PI under the auspices of CMU and/or the CMU IBC (an individual acting as an "agent" of CMU in the conduct of biohazardous research).

Incident: Any significant problems, violations of the *NIH Guidelines*, or any significant research related accidents and illnesses.

Adverse events: Any incident that occurs during the conduct of human subject research (e.g. human gene trials).

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IV. Policy

It is the policy of Central Michigan University and the CMU Institutional Biosafety Committee (IBC) that all incidents must be reported to the IBC, the Biosafety Officer (BSO), the Office of Laboratory and Field Safety (OLFS) and the NIH OSP.

V. Procedures

A. All PIs and personnel working with biohazards are obligated to report any incident, as defined in section III, related to the conduct of biohazardous research.
   1. Personnel should report any incident to their PI or supervisor when practicable.
   2. The PI is responsible for informing the IBC, BSO and OLFS unless it is determined that research personnel have already done so.
   3. PIs and research personnel need only inform one CMU entity listed above to facilitate informing all of them, however steps should be taken to verify they have received the report (i.e. a response if the report is submitted via e-mail).
   4. Incident reports must be submitted to the IBC as soon as is safe and practicable.
   5. It is expected that any incident that poses an immediate or ongoing threat to personnel, CMU or the surrounding community will be reported immediately to the BSO, OLFS and CMU Police Department as appropriate.

B. The IBC, BSO and OLFS will keep other institutional offices informed as appropriate (e.g. Risk Management Environmental Health and Safety, Office of General Counsel, Office of Research Compliance and the Vice President for Research).

C. The Vice President for Research is responsible for ensuring that appropriate reporting to external agencies has occurred.
   1. Incidents must be reported to NIH OSP within 30 days of the incident
      i. Reports may be submitted by the PI so long as the IBC and BSO have also been informed
      ii. If a report has not already been submitted by the PI, the IBC or BSO will submit a report in coordination with the PI.
      iii. Reports should be submitted using the Template for Reporting Incidents Subject to the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules to the National Institutes of Health Office of Science Policy (OSP) or a similar format containing all of the relevant information found in this template.

   2. Adverse Event reports (e.g. related to human gene transfer) must be submitted to:
      i. The IRB within 5 days if the event requires immediate intervention to prevent serious harm to participants or others.
      ii. The IRB within 10 days for all other unanticipated problems
      iii. The NIH OSP as well as the FDA if determined by the IRB to be reportable. Reports should be submitted utilizing the Template for Reporting Adverse Events In Human Gene Transfer Trials or a similar format containing all relevant information listed in the template.
      iv. The funding agency and/or sponsor based on agency and sponsor reporting requirements.

Additional Information:
For questions, additional details or to request changes to this policy, please contact the IBC IBC@cmich.edu or Office of Research Compliance RESCOMPLIANCE@cmich.edu