XII. Accident and Incident Reporting

Rapid and accurate reporting of accidents and incidents involving occupational exposures to biohazard material is important in identifying potentially hazardous operations and procedures. Furthermore, it allows personnel to be treated appropriately and minimizes the potential for actually contracting a disease associated with the infectious agent.

- Report all accidents involving potential exposures to biohazard material and occupational illnesses to supervisory personnel, the appropriate administrative unit (department, division, etc.), the Institutional Biosafety Officer and Employee Health Services. An accident report form (available at [www.ehs.osu.edu](http://www.ehs.osu.edu)) must be completed and sent to Employee Health Services.

- An investigation of any incident or accident may be performed in accordance with University and EHS policy (see Appendix E for more information).

- Additional information relating to biohazard/rDNA incident reporting requirements is available at: [http://orrrp.osu.edu/ibc/osuibcpolicies/incidentreporting/](http://orrrp.osu.edu/ibc/osuibcpolicies/incidentreporting/)

**The Ohio State University Recombinant DNA / Biohazard Research Incident Reporting Policy and Process**

The Ohio State University is required to report certain incidents involving recombinant DNA or biohazard research to the National Institutes of Health. This policy outlines the information necessary to determine the nature and extent of the incident, as well as the appropriate reporting requirements and process.
Reporting Responsibilities

1. The University personnel involved will immediately report the incident to the Institutional Biosafety Officer, who will contact the Senior Director of Environmental Health and Safety, the Director of University Lab Animal Resources, the Chair of the Institutional Biosafety Committee and the Offices of Responsible Research Practices and Research Compliance as needed.

2. The Institutional Biosafety Officer and the Principal Investigator will collectively complete a rDNA / Biohazard Incident Report Form or an Animal Bite/Exposure Report Form, whichever is appropriate. The form will be completed in a timely manner as determined by the nature of the incident and agency reporting timelines. The report will be provided to the Institutional Biosafety Committee (IBC) for review.

3. Following review by the IBC and the University’s Office of Research Compliance, the Chair of the IBC and Office of Responsible Research Practices will submit the final incident report with the Chair’s signature to the respective federal agency on behalf of the university. Copies of the incident report will be provided to the University Office of Legal Affairs, the Associate Dean for Research of the College involved, and the Chair of the Department involved.

Reportable Incidents and Timelines

1. The following incidents should be reported immediately to the Principal Investigator, the Institutional Biosafety Officer, and the Chair of the Institutional Biosafety Committee:

   a. Spills or accidents in a BSL2 laboratory resulting in an overt exposure, injury or illness of personnel, including bites/exposures to animals intentionally infected with RG2 agents or potential zoonotic diseases.

   b. Spills or accidents in a BSL3 laboratory resulting in an overt potential exposure, injury or illness of personnel, including
bites/exposures to animals intentionally infected with RG3 agents or potential zoonotic diseases.

c. Release of a Risk Group 2 or 3 agent / genetic material from a primary containment device (e.g., biological safety cabinet, centrifuge, or primary container into the laboratory)

d. Spills or accidents that lead to personal injury or illness or breach of containment (e.g., aerosols released outside of containment, skin punctures with needles containing Risk Group 2 or 3 agents or genetic material from these agents).

e. Failure to adhere to the containment and biosafety practices described in the NIH Guidelines.

2. The following timelines will be used for institutional incident reporting for human gene therapy adverse events to the agency:

1. Section IV-B-2-b-(7) of the NIH Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines) states that “...any significant problems, violations of the NIH Guidelines, or any significant research related accidents and illnesses” must be reported to the Office of Biotechnology Activities (OBA) within 30 days.

2. Appendix G of the NIH Guidelines specifies that certain types of accidents / incidents (i.e., 1.a and 1.b) must be reported immediately. A follow-up report will then be submitted as needed.

3. Appendix M-I-C-4-b of the NIH Guidelines specifies that any serious adverse event that is fatal or life-threatening, that is unexpected, and associated with the use of the gene transfer product must be reported to the NIH OBA as soon as possible, but not later than 7 calendar days after the sponsor’s initial
receipt of the information (i.e., at the same time the event must be reported to the FDA).

Serious adverse events that are unexpected and associated with the use of the gene transfer product, but are not fatal or life-threatening, must be reported to the NIH OBA as soon as possible, but not later than 15 calendar days after the sponsor’s initial receipt of the information (i.e., at the same time the event must be reported to the FDA).
Institutional Laboratory Biosafety Manual

rDNA / BIOHAZARD INCIDENT REPORT FORM

1. List the name(s) of the employee(s) involved:

2. List the date, time and location in which the accidental exposure occurred:

3. As thoroughly as possible, describe the circumstances of the exposure incident:

4. List the biological agent / genetic material and route(s) of possible exposure (e.g. inhalation, subcutaneous, etc.):

5. What is the nature of the organism strain to which the employee has been exposed? (strain name and history, complete drug-resistance/susceptibility profile, any other information that might be pertinent to treatment):

6. List steps taken to evaluate employee’s health, and action taken to prevent recurrence of a similar incident:

(Attach additional pages as necessary)
Employee Signature _________________________________ Date ________________
Principal Investigator Signature ________________________________

Submit to Chair of the Institutional Biosafety Committee for review via the Office of Responsible Research Practices (fax number 614-688-0366).

12.5 May 2014
The Ohio State University
ANIMAL BITE / EXPOSURE REPORT FORM
WILD CAUGHT & USDA SPECIES
(To be completed by employee and supervisor)

Employee’s Name: ________________________________

Principal Investigator’s Name: ________________________________

Date of incident: ________________________________ Time of incident: ______ AM/PM
Location of incident: ________________________________

Animal species involved: ________________________________

Describe the circumstances of the exposure incident: ________________________________

Possible risks of exposure: ________________________________

What first aid / medical attention was given to employee following exposure: ________________________________

What action has been taken to prevent recurrence of a similar incident (if any): ________________________________

(Attach additional pages as necessary)
Employee Signature: ________________________________ Date: ________________
Principal Investigator Signature: ________________________________

Submit completed form to the Institutional Biosafety Officer for review via fax at 614-292-6404.

12.6
May 2014
The Ohio State University