



SOP Title	Recombinant DNA, Biohazard and Animal Bite Incident Reporting				
Date Last Revised		Date Created	10/05/2017	Revision #	
SOP Number	7	Required by:	<input type="checkbox"/> OHRP <input type="checkbox"/> Funding Agency <input type="checkbox"/> OLAW		
Applicability	<input type="checkbox"/> RGC Internal		<input checked="" type="checkbox"/> Researcher	<input checked="" type="checkbox"/> Institutional	
Subgroup	<input type="checkbox"/> NKU Compliance	<input type="checkbox"/> IRB	<input type="checkbox"/> IACUC	<input checked="" type="checkbox"/> IBC	

1.0 PURPOSE

The purpose of this SOP is to describe the process for reporting incidents involving recombinant DNA, biohazards, and/or animal bites that occur with personnel on IBC approved protocols.

2.0 GENERAL INFORMATION AND SCOPE

NKU is required to report certain incidents involving recombinant DNA or biohazard research to the National Institutes of Health. This SOP outlines:

- information necessary to determine the nature and extent of the incident
- the process for internally reporting incidents
- the appropriate and process for reporting to National Institutes of Health Office of Science Policy.

A. BITES RECEIVED FROM RATS AND MICE

Rats naturally carry bacteria in their mouth and can transmit them through bite wounds causing infection. A common rat oral bacteria in North America, *Streptobacillus moniliformis*, causes Haverhill Fever approximately 2-10 days after exposure. If untreated, the disease can be fatal due to malignant endocarditis, meningoencephalitis or septic shock.

Symptoms of infection after exposure:

- Inflammation around the bite wound
- high prostrating fevers
- rigors
- headache
- polyarthralgia (pain in multiple joints)

Bites from rodents should be immediately cleaned with warm, soapy water. Any symptoms appearing after exposure should be taken seriously and immediately reported to a physician for medical management.

B. REPORTING RESPONSIBILITIES

The following individuals and departments must be notified:

1. The Principal Investigator
2. The Department of Safety and Emergency Manager
3. The NKU Institutional Biosafety Chair

4. The NKU Manager of Research Compliance
5. If applicable, the National Institutes of Health, Office of Science Policy

C. REPORTABLE INCIDENTS AND TIMELINES

1. Report Internally - immediately to the Principal Investigator and Department of Safety and Emergency Management:
 - 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 (NIH Guidelines G-II-C-2-q).
 - 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)
 - 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).
 - Failure to adhere to the containment and biosafety practices described in the NIH Guidelines.
2. Reporting to NIH Office of Science Policy
 - A. The following incidents must be reported to the NIH Office of Science Policy:
 - Any spill or accident involving recombinant DNA research (described below) or otherwise leads to personal injury or illness or to a breach of containment must be reported to OSP. This might include skin punctures with needles containing recombinant DNA the escape or improper disposition of a transgenic animal, or spills to high risk recombinant material occurring outside of a biosafety cabinet.
 - Failure to adhere to the containment and biosafety practices articulated in the NIH Guidelines must be also reported to OSP.
 - Any significant problems, violations of the NIH Guidelines, or any significant research-related accidents and illnesses.
Timeline: Report to NIH within 30 days.
 - Spills or accidents in BL2 laboratories resulting in an overt exposure.
Timeline: Report to NIH immediately.
 - B. What does not warrant reporting to OSP?
Minor spills of low-risk agents not involving a breach of containment that were properly cleaned and decontaminated generally do not need to be reported. OSP should be consulted if the Institutional Biosafety Committee (IBC), investigator, or other institutional staff are uncertain whether the nature or severity of the incident warrants reporting; OSP can assist in making this determination.

3.0 PROCEDURES

When an incident occurs that requires reporting (see above), the following procedures should be followed:

- If not already involved, the Principal Investigator should be notified immediately.
- PI and others involved must complete the NKU Department of Safety and Emergency Management Incident Form.

- The NKU Department of Safety and Emergency Management will notify the IBC Chair and the Manager of Research Compliance immediately.
- The Manager of Research Compliance will log the incident in the IBC Incident Report Log
- The IBC Chair will contact the PI.
- The PI and the IBC Chair Recombinant DNA Biohazard Incident Report Form or the Animal Bite/Exposure Report Form
- If the incident requires reporting to the NIH OSP:
 - the PI and IBC Chair will complete the NIH Incident Reporting form
 - the PI and the IBC Chair will decide who should submit the formal report to NIH OSP
 - 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.
- Copies of the incident report will be provided to NKU Legal Department, the Director of Research, Grants, and Contracts, Manager of Research Compliance, and the Chair of the appropriate department.
- The report will be provided to the IBC for review either via email or at an in-person meeting.
- Procedures required to rectify the issue should be completed and documented.
- Additional Reporting Requirements
 - If a faculty or staff are injured, NKU Human Resources must be notified 859-572-6063 or the 24-hour access line at 1-800-440-6285
 - If a student is injured, the Student Office of Student Conduct, Rights and Advocacy must be notified 859-572-5147
 - If a visitor, contractor or volunteer is injured, Procurement services must be notified 859-572-5265.

4.0 REFERENCES

5.0 FORMS OR ATTACHMENTS

NKU Recombinant DNA and Biohazard Incident Reporting Form

NKU Animal Bite/Exposure Form

[NKU Department of Safety and Emergency Management Incident Reporting](#)

[NIH Incident Reporting FAQs](#)

[NIH Incident Reporting](#)

6.0 DEFINITIONS

Approvals

Title	Approved	Date Approved	Not Applicable
Manager of Research Compliance	<input checked="" type="checkbox"/>	06/12/2018	<input type="checkbox"/>
IBC Chair	<input checked="" type="checkbox"/>	06/12/2018	<input type="checkbox"/>
Institutional Official	<input type="checkbox"/>		<input checked="" type="checkbox"/>

Revisions

Title	Approved	Date Approved	N/A	Summary
Manager of Research Compliance	<input type="checkbox"/>		<input type="checkbox"/>	
IACUC Chair	<input type="checkbox"/>		<input type="checkbox"/>	
Institutional Official	<input type="checkbox"/>		<input type="checkbox"/>	