Information

Investigating and Reporting Potential Violation(s) of National Institutes of Health Guidelines (NIH Guidelines)

Effective

April 8, 2015

Applicability

This procedure applies to all individuals, including principal investigators (PIs), researchers, instructors, laboratory/clinical managers, students, or other personnel who work in a laboratory or clinic utilizing recombinant nucleic acids (rDNA) or synthetic nucleic acids (SNA).

Administrative Authority

Senior Associate Vice President for Operations

Responsible Unit

Environmental Health and Safety
1800 Arthur Street, Louisville, KY
502-852-6670
biosafe@louisville.edu

History

Revision Date(s): September 2016
Reviewed Date(s): September 2016

Categories

Reason for Procedure:

The University of Louisville is required to report violations of the *National Institutes of Health (NIH) Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines)* to the NIH/Office of Biotechnology Activities (OBA). This document outlines the process for investigating potential violations and the

reporting requirements.

Statement:

Investigation and Reporting Procedures:

Once a potential violation has been identified and reported, the following investigative and reporting procedures should be conducted:

- The receipt of a report of a potential violation of the *NIH Guidelines* will immediately be brought to the attention of the IBC Chair, the DEHS Director, and BSO. These individuals will select an additional IBC member within 2 business days to constitute a subcommittee to investigate and, where concerns are substantiated, take the appropriate steps to address, correct, and/or resolve the reported concern.
- The subcommittee will contact the PI with notice of the reported potential violation thus initiating the investigation (referred to subsequently as the "incident"). Information related to the incident will be requested from the PI and, if necessary, a meeting with the PI will be scheduled. If the PI does not respond or cooperate with the investigation within 2 business days of initial notification, the incident will escalate up the chain of command (i.e. Department Chair, EVPRI, etc.) until the investigation can be completed.
- Upon completion of the investigation, the subcommittee will determine if a violation of the *NIH Guidelines* has occurred. The subcommittee will prepare an incident report using the NIH/OBA "Incident Reporting Template" as guidance.
- The IBC Chair will ensure that notification and the incident report signed by the IBC Chair will be sent to the NIH/OBA at the following address and under the conditions described below:

Kathryn Harris, Ph.D., RBP
Senior Outreach and Education Specialist
Office of Biotechnology Activities
National Institutes of Health
6705 Rockledge Drive, Suite 750
Bethesda, MD 20892-7985 (20817 for non USPS mail)

- The following incidents will be reported **immediately** to the NIH/OBA by the DEHS Director or BSO via email to Kathryn Harris at harriskath@od.nih.gov and a subsequent investigation will be conducted if deemed an exposure. More detailed follow-up reports, if needed, will be sent within 30 days to NIH/OBA at

the above address.

- Spills or accidents in BSL-2 laboratory resulting in an overt exposure, injury, or illness.
- Spills or accidents occurring in high containment (BSL-3) laboratory resulting in an overt or potential exposure, injury, or illness.
- It is recommended that the following incidents be reported **as soon as possible** to the NIH/OBA by the DEHS Director or BSO via email Kathryn Harris at harriskath@od.nih.gov. More detailed follow-up reports, if needed, will be sent **within 30 days of incident occurrence** to NIH/OBA at the above address.
- 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).
- Failure to adhere to the containment and biosafety practices described in the *NIH Guidelines*.
- Any significant incidents of the *NIH Guidelines* and any significant research-related accidents or illnesses will be submitted **within 30 days from notification** of the IBC, DEHS Director, or BSO that an incident has occurred. The DEHS Director or BSO will notify NIH/OBA of any incident(s) requiring reporting via email to Kathryn Harris at harriskath@od.nih.gov; a full report, if needed, will be sent to the above address.
- Copies of the incident report and correspondence with the NIH/OBA will be provided to the PI, IBC Chair, EVPRI, DEHS Director, BSO, IBC, Department Chair, and University Counsel.
- The incident report will be openly discussed at the first available meeting convened of the IBC. The IBC Chair will notify the PI of the date of said meeting and request that they advise the IBC Chair if they plan to appear at that meeting. After open discussion of the incident report, the IBC will determine if refinement of University procedures are necessary to prevent future incidents.

Related Information:

UofL Institutional Biosafety Committee (IBC)

The *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines)* detail safety practices and containment procedures for

basic and clinical research involving recombinant or synthetic nucleic acid molecules, including the creation and use of organisms and viruses containing recombinant or synthetic nucleic acid molecules.

Definitions:

Recombinant and synthetic nucleic acids are defined in the context of the *NIH Guidelines* as:

- Molecules that (a) are constructed by joining nucleic acid molecules and (b) that can replicate in a living cell (i.e. rDNA);
- Nucleic acid molecules that are chemically or by other means synthesized or amplified, including those that are chemically or otherwise modified but can base pair with naturally occurring nucleic acid molecules (i.e. SNA); or
- Molecules that result from the replication of those described in the previous two bullets above.

Potential violations of the *NIH Guidelines* may include, but are not limited to, the following:

- Any significant research related accident, illness, or violation of the *NIH Guidelines*;
- Spills or accidents resulting in overt exposure (e.g. skin punctures with needles containing rDNA or SNA, exposure of broken skin or mucous membranes), injury, or illness at Biosafety Level 2 (BSL-2);
- Spills or accidents occurring in Biosafety Level 3 (BSL-3) laboratories outside of a biosafety cabinet resulting in an overt or potential exposure, injury, or illness;
- Violations of the *NIH Guidelines* containment or biosafety practices, or significant problems leading to a breach of containment (including improper disposal of rDNA or SNA materials or escape of a transgenic animal);
- Failure to register and/or obtain approval of the IBC prior to initiation of research and/or clinical studies involving rDNA or SNA;
- Significant changes to proposed research risk without prior notification and approval by IBC;
- Failure to renew a registration and obtain IBC review and approval, prior to the expiration date, for research and/or clinical studies involving rDNA or SNA (i.e. lapse in protocol approval); or
- Failure to comply with institutional and federal regulations, guidelines, and policies that result in an unsafe condition pertinent to the use of rDNA or SNA.

Responsibilities:

Reporting Responsibilities and Procedures

It is the responsibility of PIs, researchers, instructors, laboratory/clinical managers, students, or other personnel who work in a laboratory or clinic utilizing rDNA or SNA to report any potential violation of the *NIH Guidelines*. Allegations regarding a potential violation of the *NIH Guidelines* can be reported through several different routes:

- Anonymous Reporting: Any student, staff, or faculty member can in good faith report real or perceived University-related misconduct or potential non-compliance to the University's Compliance Hotline toll free at 1-877-852-1167 or online through ULink "Compliance Hotline Reporting". Protection for employees who report non-compliance is available through the University's Duty to Report and Non-Retaliation Policy.
- Verbal Reporting: A verbal report with information that a potential violation of the *NIH Guidelines* has occurred may be made to the IBC Chair or any IBC member using contact information from the IBC Roster located on the DEHS website (https://louisville.edu/dehs/biological-safety) and/or by calling DEHS at (502) 852-6670.
- Written Reporting: A written report with information that a potential violation of the *NIH Guidelines* has occurred may be made to the IBC Chair, any IBC member, and/or DEHS through he Biosafe service account at biosafe@louisville.edu.

Forms/Online Processes:

NIH Incident Reporting Template (Word)