LSU Inter-Institutional Biological and Recombinant DNA Safety Committee (IBRDSC)

Policy: Recombinant DNA and Biohazard Incident Reporting

Adopted April 26, 2012

All University personnel (Louisiana State University A&M and the Louisiana AgCenter) are required to report incidents (spills) and exposures (inhalation, inoculation, ingestion or skin contact) involving recombinant DNA (rDNA) or biohazards to the LSU Office of Environmental Health and Safety (EHS). The EHS after review by the LSU Inter-Institutional Biological and Recombinant DNA Safety Committee (IBRDSC) must report these incidents to the National Institutes of Health, Office of Biotechnology Activities (NIH OBA). This policy describes this requirement and the appropriate process.

Responsibilities

(1) University personnel involved in the incident will immediately report the incident to their Principal Investigator and the Office of Environmental Health and Safety (*immediately means by the end of the work shift at the latest*):

Office of Environmental Health & Safety (EHS) Copy & Mail Center Corner of South Stadium Drive and CEBA Lane 225-578-5640 OR

Sarah Keeton, PhD Biological Safety Manager Phone: 225-578-4658 sorlik1@lsu.edu Abbie Fish, PhD Assistant Director of Research Safety Phone: 225-578-4658 <u>afish5@lsu.edu</u>

- (2) University personnel will also complete the LSU/NIH incident Reporting Form located on the EHS web site at: <u>https://lsu.edu/ehs/safety/research/biological-safety.pcf</u>
- (3) The report will be provided to the Institutional Biosafety Committee (IBRDSC) for review.
- (4) Following review by the IBRDSC the biosafety manager will submit the report to NIH on behalf of the University. Copies of the incident report will be provided to the LSU A&M Vice Chancellor of Research and

Economic Development, AgCenter Vice Chancellor & Director Louisiana Agricultural Experimental Stations, and the Chair of the Department involved.

Reportable Incidents

- (1) 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.
- (2) 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.
- (3) 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)
- (4) 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).
- (5) Failure to adhere to the containment and biosafety practices described in the NIH Guidelines.

TimeLines and Authority:

Institutional incident reporting to NIH

Section IV-B-2-b-(7). Reporting any significant problems with or violations of the NIH Guidelines and any significant research-related accidents or illnesses to the appropriate institutional official and NIH/OBA within 30 days, unless the Institutional Biosafety Committee determines that a report has already been filed by the Principal Investigator. Reports to NIH/OBA shall be sent to the Office of Biotechnology Activities, National Institutes of Health, 6705 Rockledge Drive, Suite 750, MSC 7985, Bethesda, MD 20892-7985 (20817 for non-USPS mail), 301-496-9838, 301-496-9839 (fax).

Appendix G-II-B-2-k. Spills and accidents which result in overt exposures to organisms containing recombinant DNA molecules are immediately reported to the Institutional Biosafety Committee and NIH/OBA.

Form Attached:



Return to: LSU Office of Environmental Health & Safety Room 212, Copy & Mail Center Phone: 225-578-5640 Fax: 225-578-7489 E-mail: <u>ghayes@lsu.edu</u>

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 NIH OBA within 30 days. Certain types of incidents must be reported on a more expedited basis. Spills or accidents in BL2 laboratories resulting in an overt exposure must be immediately reported to NIH OBA. Spills or accidents occurring in high containment (BL3 or BL4) laboratories resulting in an overt emust be immediately reported to NIH OBA.

This form is intended to facilitate the reporting of incidents that occur during the conduct of research subject to the NIH Guidelines.

| Does this incident involve research subject to the NIH Guidelines? | | Yes | | No | | | | |
|--|--|------------|-------------|--------|--|--|--|--|
| | If no, this incident does not have to be reported to OBA | | | | | | | |
| Department Name | | | | | | | | |
| Date of Report | | | | | | | | |
| Name & Position of Person Reporting | | | | | | | | |
| Telephone Number | | | | | | | | |
| E-mail Address | | | | | | | | |
| Date of Incident | | | | | | | | |
| Name of Principal Investigator | | | | | | | | |
| Is this an NIH funded project? | | Yes | | No | | | | |
| If yes, please provide: | NIH gra | int or con | ntract num | iber: | | | | |
| | NIH fur | ding inst | itute or ce | enter: | | | | |
| | NIH program officer contact information (name, e-mail, etc.) | | | | | | | |
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| What was the nature of the incident? | Personnel exposure | | | | | |
|---|--|--|--|--|--|--|
| | Spill | | | | | |
| | Loss of containment | | | | | |
| | Loss of transgenic animal | | | | | |
| | Failure to obtain IBC approval | | | | | |
| | Failure to follow approved containment | | | | | |
| | conditions | | | | | |
| | Other - please describe | | | | | |
| | | | | | | |
| | | | | | | |
| Did the Inter-Institutional Biological and | Yes 🗖 No 🗖 | | | | | |
| Recombinant DNA Safety Committee | | | | | | |
| (IBRDSC) approve this research? | | | | | | |
| | If yes, on what date? | | | | | |
| If yes, please provide: | Approval date: | | | | | |
| 5 SED UT | Approved biosafety level for the research: | | | | | |
| | Additional approval requirements: | | | | | |
| | | | | | | |
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| What section(s) of the NIH Guidelines is the | | | | | | |
| research subject to? | | | | | | |
| Has a report of this incident been made to | CDC | | | | | |
| other federal or local agencies? If so please | <u> </u> | | | | | |
| indicate by checking the appropriate box. | | | | | | |
| | | | | | | |
| | USDA | | | | | |
| | 🗖 FDA | | | | | |
| | EPA | | | | | |
| | OSHA | | | | | |
| | Research Funding Agency/Sponsor | | | | | |
| | 🔲 (name) | | | | | |
| | State/Local Public Health | | | | | |
| | Federal/State/Local Law Enforcement | | | | | |
| | Other, Please describe | | | | | |
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Please provide a narrative of the incident including a timeline of events. The incident should be described in sufficient detail to allow for an understanding of the nature and consequences of the incident. Include the following information as applicable.

A description of:

• The recombinant agent or material involved.

• The incident/violation location (e.g. laboratory biosafety level, vivarium, non-laboratory space).

• Who was involved in the incident/violation, including others present at the incident location? Note – please do not identify individuals by name. Provide only position titles (e.g., graduate student, post doc, animal care worker, facility maintenance worker).

 Actions taken immediately following the incident/violation, and by whom, to limit any health or environmental consequences of the event.

• The training received by the individual(s) involved and the date(s) the training was conducted.

• The institutional or laboratory standard operating procedures (SOPs) for the research and whether there was any deviation from these SOPS at the time of the incident/violation.

• Any deviation from the IBC approved containment level or other IBC approval conditions at the time of the incident/violation.

• The personal protective equipment in use at the time of the incident/violation.

• The occupational health requirements for laboratory personnel involved in the research.

• Any medical advice/treatment/surveillance provided or recommended after the incident.

Any injury or illness associated with the incident.

• Medical surveillance results (if not available at the time of initial report please indicate when results will be available).

Equipment failures.

DESCRIPTION OF INCIDENT: (use additional space as necessary)

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| DESCRIPTION OF INCIDENT (continued) | |
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| Has a root cause for this incident been identified? | Yes | | No | |
|---|--------------------|----------------|------------|-----------------------|
| | If yes please des | cribe: | | |
| | | | | |
| Describe measures taken by the Principal In | vestigator to miti | igate any prol | olems ider | ntified. For measures |
| identified but not yet taken, please include necessary) | | | | |
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