I. Purpose

This policy outlines the incident reporting requirements for Principal Investigators, Biosafety Officer, and departments or divisions whose recombinant Nucleic Acid and/or select agent research is required to be registered and approved by Tulane University IBC.

II. applicability

Any Tulane University Principal Investigator with an IBC application that is approved by the committee must follow the guidance of this policy and the recommendations in the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines).

III. Definitions

A. Biological Agent:

Potentially infectious materials or recombinant agents that are classified as Risk Group1-3 (RG1, RG2 and RG3) under the NIH Guidelines, a Select Agent or Toxin as designated in 42 CFR part 73 or 9 CFR part 121, or a BSL3 non-recombinant, non-select agent.

B. Recombinant DNA Incident:

Section IV-B-2-b-(7) of the NIH Guidelines states that IBCs must report "...any significant problems, violations of the NIH Guidelines, or any significant research-related accidents and illnesses" involving recombinant materials to NIH OBA within 30 days. Appendix G of the NIH Guidelines specifies certain types of accidents that must be reported on a more expedited basis. According to Appendix G-II-B-2-k, spills or accidents in BL2 laboratories resulting in an overt exposure must be immediately reported to NIH OBA (as well as the IBC). According to Appendix G-II-C-2-q and Appendix G-II-D-2-k, spills or accidents occurring in high containment (BL3 or BL4) laboratories resulting in an overt or potential exposure must be immediately reported to NIH OBA (as well as the IBC, and BSO).
a. **Potential Exposure:**
   Any potential contact with a RG3 recombinant biological agent. According to the *NIH Guidelines*, this contact would be reportable to NIH Office of Biotechnology Activities (NIH OBA). Examples of potential exposures to a BL3 agent are any accidents, equipment failure, needle sticks and splashes to intact skin.

b. **Overt Exposure:**
   A definitive contact with a **RG1**, **RG2** and **RG3** recombinant biological agent. According to the *NIH Guidelines*, this contact would be reportable to NIH Office of Biotechnology Activities (NIH OBA). Examples of overt exposures are needle sticks and splashes of rDNA agent on personnel.

IV. **Implementation procedures**

A. **Responsibilities**

   **Principal Investigator:**
   As stated in the Investigator’s Assurance, Section H of the IBC Protocol, signed by the Principal Investigator (PI) of the Tulane University IBC-approved research, PIs are required to report potential or overt exposures to rDNA agents and/or biological agents to the Tulane University Office of Biological Safety.

   **Biosafety Officer:**
   The Office of Biosafety, by notice to the Institutional Biosafety Officer (BSO) is responsible for reporting any incident involving recombinant DNA (rDNA) agents and/or biological agents to Tulane University IBC. The BSO is also responsible for presenting any incident and corrective action plans that have proceeded each Tulane University IBC meeting.

   **Tulane University IBC:**
   The committee is responsible for reviewing and discussing incidents at each committee meeting and ensuring that the institution has complied with all applicable regulations for incident reporting. The committee also requires that each Principal Investigator comply with all applicable regulations for incident reporting.

B. **Reporting Considerations**

   1) **Procedure**
      a. Personnel involved in any personal potential or overt exposure must be provided all appropriate medical evaluation and surveillance.
      b. Upon notification of an incident, the BSO or duly designated representative will notify the Tulane University IBC Chair and the University Research Compliance Officer the initial details of the incident. The BSO, or duly designated institutional official, will then notify all appropriate regulatory agencies as specified in Appendices A and B. Notification of the agencies should take place in accordance with reporting requirements as specified in Appendix A.
c. The BSO should investigate the incident to identify root cause, training needs, and corrective action measures.
d. A verbal summary of the incident shall will be provided by the BSO at the next scheduled Tulane University IBC meeting and will be recorded in the meeting minutes.
e. For incidents involving violations of the Tulane University IBC approval, (or lack thereof), PIs must prepare a written response detailing the laboratory event and corrective actions taken to mitigate the event. The letter should be submitted to the Tulane University IBC one week prior to the next scheduled Tulane University IBC meeting so that it can be discussed during the meeting. The Tulane University IBC will document its review in the meeting minutes.

2) Reporting of Significant reporting events: (See Appendix A)

a. Spills and accidents which result in overt exposures to any organisms containing rDNA and/or RG2 and RG3 biological agents must be immediately reported.
b. Illnesses and/or symptoms potentially related to rDNA and/or biological agents in use in the BSL3 laboratory must be immediately reported.
c. Breach of BSL3 containment which results in potential or overt exposures to organisms containing rDNA and/or biological agents released into the environment must be immediately reported.
d. Breach of containment resulting from failure of mechanical systems (e.g. HVAC, loss of power) and laboratory equipment (Biosafety cabinet, centrifuge, ventilated animal cages) must be immediately reported.

3) Reporting of Incidents at the Tulane University IBC meeting:

BSO must provide a verbal report, which shall include, but is not limited to, the following:
a. The nature of the incident (e.g. personnel exposure, spill, loss of containment, loss of transgenic animal, failure to obtain IBC approval, failure to follow approved containment conditions, other)
b. The Tulane University IBC protocol number.
c. Federal, state or local agencies to which incident is being reported.
d. A description of the incident, including the following information:
   i. The recombinant agent or material involved. (if applicable)
   ii. The incident/violation location (e.g. laboratory biosafety level, vivarium, non-laboratory space).
   iii. The person(s) involved in the incident/violation, including others present at the incident location. [position title only] (e.g., graduate student, post doc, animal care worker, and facility maintenance worker).
   iv. Actions taken immediately following the incident/violation to limit any health or environmental consequences of the event, as well as the [position titles] of the individual(s) who took those actions.
   v. The training received by the individual(s) involved and the date(s) the training was conducted.
vi. The institutional or university biosafety manual for the research and a determination of whether there was any deviation from these procedures at the time of the incident/violation.

vii. Any deviation from the Tulane University IBC-approved containment level or other Tulane University IBC approval conditions at the time of the incident/violation.

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

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

x. Any medical treatment/surveillance provided after the incident.

xi. Any injury or illness associated with the incident.

xii. Any equipment failures that occurred.

xiii. Any other relevant information identified during the review/investigation of the event.

xiv. Measures taken by the Institution to mitigate identified problems (e.g., review by Tulane University IBC, root cause analysis)

V. Policy Authority

The Tulane University IBC shall enforce this policy.

VI. References

A. NIH Guidelines


B. CDC/NIH BMBL 5th edition (see Table 2)

http://www.cdc.gov/biosafety/publications/bmbl5/

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<tr>
<th>Regulatory Agency</th>
<th>Jurisdiction</th>
<th>Reporting Requirements / Procedure</th>
<th>Timing to Report</th>
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<tbody>
<tr>
<td>NIH OBA</td>
<td>All institutions receiving NIH funding for rDNA</td>
<td>BSO, IBC Chair, University Compliance Officer must report Telephone or Email Correspondence to Dr. Kathryn Harris In some cases, it may be appropriate to contact the NIH/OBA by telephone or email to determine if NIH/OBA</td>
<td>Within 30 days. Note: certain types of incidents require immediate reporting. Consult regulation</td>
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Appendix A: Regulatory Agency Reporting Procedure

Appendix B:  Regulatory Agency Contact List for Reporting of incidents:

<table>
<thead>
<tr>
<th>Agency Contact</th>
<th>Regulation</th>
<th>Website/Forms</th>
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<tr>
<td>Mail: Dr. Kathryn Harris National Institutes of Health Office of Biotechnology Activities 6705 Rockledge Dr., Suite 750 Bethesda, MD 20892-7985 Fax: 301-496-9839 Email: <a href="mailto:HarrisKath@od.nih.gov">HarrisKath@od.nih.gov</a></td>
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<tr>
<td>Express mail (FedEx, UPS, etc.): Dr. Kathryn Harris National Institutes of Health Office of Biotechnology Activities 6705 Rockledge Dr., Suite 750</td>
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Tulane IBC Incident Reporting Policy-August 2016
| CDC Select Agent Program  
| 1600 Clifton Road NE, Mailstop A-46,  
| Atlanta, GA 30333  
| Fax 404-718-2096  
| Email: lrsat@cdc.gov | 42 CFR 73.0  
| Select Agent Rule  
| Incidents reported by entity  
| Responsible Official | Form 3 Report of Theft Loss or Release Available at:  
| Regulations:  