Incident Reporting Policy

Approved on November 18, 2011

I. Purpose

This policy outlines the incident reporting requirements for Principal Investigators, Biosafety Officers, and institutions whose recombinant DNA and/or biological work is covered by the Committee on Microbiological Safety.

II. Applicability

Any COMS application that is approved by the committee must follow the guidance of this policy and the recommendations in the NIH Guidelines.

III. Definitions

A. Biological Agent:

Potentially infectious materials or recombinant agents that are classified as Risk Group1-3 of the NIH rDNA Guidelines.

B. **Biological agent incident**:

Any incident involving a biological agent. These incidents must be reported to COMS. Local health departments (Boston Public Health Commission and/or Cambridge Biosafety Committee) may also require the reporting of a biological agent. Please refer to Appendix A: Regulatory Agency Reporting Procedure for further procedures on reporting to health departments including lists of reportable biological agents.

C. Recombinant DNA Incident:

Section IV-B-2-b-(7) of the *NIH Guidelines* states that IBCs should report "...any significant problems, violations of the *NIH Guidelines*, or any significant research-related accidents and illnesses" 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). Local health departments under COMS (City of Boston and Cambridge) also require reporting recombinant DNA incidents. (See Tables 1 and 2 below).

D. Potential Exposure:

A possible personal contact with a Biosafety Level Three (BL3) recombinant biological agent. According to the NIH rDNA 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, or splash to intact skin.

E. Overt Exposure:

A definitive contact with a Biosafety Level Two or Biosafety Level Three recombinant biological agent. According to the NIH rDNA 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 Memorandum of Understanding and Agreement, signed by the Principal Investigator (PI) of COMS-approved research, PIs are required to report potential or overt exposures to rDNA agents and/or biological agents to their Institutional Biological Safety Officer (BSO). Additionally, the NIH Guidelines state that reporting of accidents or illnesses to the NIH is the responsibility of the PI, the BSO and the Institutional Biosafety Committee (IBC). This policy mandates the reporting through the BSO. The following excerpts from the COMS application memorandum highlight the PI requirements under this policy:

*"By signing this document I agree to **immediately notify COMS** if a member of the laboratory staff **develops symptoms of illness related to an agent** involved in this study and if there is **accidental release of a biohazardous agent into the environment**.*

*And in a separate paragraph, "By signing this document I accept full responsibility for laboratory biosafety training, for the maintenance of a safe workplace **and for immediate reporting of accidental exposures to biohazardous agents."***

Biosafety Officer:

As stated above, the biosafety officer is responsible for reporting any incident involving recombinant DNA (rDNA) agents and/or biological agents to COMS and to the appropriate government agencies, as listed under Appendix A. In some cases, an entity may designate an institutional responsible official to complete said reporting. The BSO is also responsible for presenting any incident and corrective action plans that have proceeded each COMS meeting.

COMS: The committee is responsible for reviewing and discussing incidents at each committee meeting and ensuring that each 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. The BSO or duly designated representative will notify the Associate Director of Biological Safety and/or the COMS Chair 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. BSO should investigate the incident to identify route cause, training needs, and corrective action measures.

d. A verbal summary of the incident shall be provided by the BSO at the next scheduled COMS meeting and will be recorded in the meeting minutes.

e. For incidents involving laboratory acquired infections, breach of containment or overt exposures, and/or violations of the COMS 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 COMS one week prior to the next scheduled COMS meeting so that it can be discussed during the meeting. COMS 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 BL2 or BL3 biological agents must be immediately reported.
b. Illnesses and/or symptoms potentially related to rDNA and/or biological agents in use in the BL3 laboratory must be immediately reported.
c. Breach of BL3 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 COMS meeting:

BSO should provide verbal report, which shall include, but 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 COMS approval 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 laboratory standard operating procedures (SOPs) for the research and a determination of whether there was any deviation from these SOPS at the time of the incident/violation.
vii. Any deviation from the COMS-approved containment level or other COMS 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 COMS, root cause analysis)

4) Multi-institutional research:

There may be circumstances where Principal Investigators are collaborating with other institutions that are not covered by COMS. The Principal Investigator must report to their BSO any incident that occurs under a COMS protocol. PIs should be aware that they may have additional reporting obligations to other institutions should their work be registered at other Institutional Biosafety Committees (IBCs).

V. Policy Authority

The Committee on Microbiological Safety shall enforce this policy.

a. **Related Policies**

VI. References

A. NIH rDNA Guidelines

http://oba.od.nih.gov/rdna/nih_guidelines_oba.html

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

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

Appendix A: Regulatory Agency Reporting Procedure

Regulatory Agency	**Jurisdiction**	**Reporting Requirements / Procedure**	**Timing to Report**
NIH OBA	All institutions receiving NIH funding for rDNA	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 considers the incident to be reportable.*	Within 30 days. Note: certain types of incidents require immediate reporting. Consult regulation
Boston Public Health Commission	City of Boston only 1)rDNA BL3 and BL4 Labs 2) Reportable Infectious	1) Telephone or Email Correspondence 2) For laboratory's with BPHC	1) Within thirty (30) days an institution shall report any significant problems with or violations of the Guidelines and any significant RDNA related accidents or illnesses to the Executive Director and the Boston RDNA Advisory Committee. Any such problems, accidents, or illnesses which have a potential impact on the public health and safety shall be reported immediately.

	Agents and Toxins (see regulation for specific list of materials) 3) Clinical labs 4) Animal Bites	BL3 Permits: a. Employees exhibiting symptoms or may have been exposed to agents in use in the BPHC permitted BL3 laboratory b. Employees absent for two or more consecutive working days, where Institutional Occupational Health personnel have reasonable suspicion that the illness may be related to an exposure to agent in use in the BPHC permitted BL3 laboratory c. Failures, malfunctions, or renovations of major mechanical or security systems of the BPHC permitted BL3 laboratory 3) **Clinical Laboratory Reporting Form** **To Report:** Complete form	2) Immediate reporting 3) Report immediately by phone suspect or confirmed cases 4) Fax Completed Form to BPHC-CDC

		and fax 4) **Animal Bite Reporting Form** **To report:** Complete reporting form and	
Cambridge Public Health Department	1)All institutions receiving NIH funding for rDNA: 2) BL3 Labs	1) Telephone or Email Correspondence to Director of Environmental Health 2) Telephone or Email Correspondence to Director of Environmental Health	
MA DPH	State of MA Biological Waste (see regulation)		
CDC/APHIS Select Agent Program	Select Agents (see regulation for complete list)	Select Agent Responsible Official must report	RO must contact APHIS or CDC immediately upon discovery of a theft, loss, or a release (occupational exposure or release of an agent or toxin outside of the primary barriers of the biocontainment area) of a Select Agent and Toxin not authorized under a federal act.

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

Agency Contact	**Regulation**	**Website/Forms**
Mail: Dr. Kathryn Harris National Institutes of Health	The NIH Guideline for Research	Specific Incident Reporting Template available at: http://oba.od.nih.gov/rdna_ibc/ibc_f

Office of Biotechnology Activities 6705 Rockledge Dr., Suite 750 Bethesda, MD 20892-7985 Fax: 301-496-9839 Email: HarrisKath@od.nih.gov Express mail (FedEx, UPS, etc.): Dr. Kathryn Harris National Institutes of Health Office of Biotechnology Activities 6705 Rockledge Dr., Suite 750 Bethesda, MD 20817-1814 Fax: 301-496-9839 Email: HarrisKath@od.nih.gov	Involving Recombinant DNA Molecules (NIH Guidelines),	aq.html
Boston Public Health Commission, Communicable Disease Control Division 1010 Massachusetts Avenue, Boston, MA 02118 Phone: 617-534-5611 Fax 617-534-5905	1) BPHC Recombinant DNA Technology: Use Regulations 2) BPHC Disease Surveillance and Reporting Regulation 3) BPHC Biological Laboratory Regulation	Reporting Form: Regulations: http://www.bphc.org/programs/cib/environmentalhealth/biologicalsafety/Pages/Home.aspx
Sam Lipson. Director of Environmental Health, Cambridge Public Health Department 119 Windsor Street, Ground Level	Recombinant DNA Ordinance	No Specific Reporting Template. Regulations:

Cambridge, MA 02139 Phone 617-665-3838 Fax 617-665-3888 slipson@challiance.org	Cambridge Biosafety Regulation	http://www.cambridgepublichealth.org/services/regulatory-activities/biosafety/
APHIS Select Agent Program 4700 River Road Unit 2, Mailstop 22, Cubicle 1A07 Riverdale, MD 20737 Fax: 301-734-3652 Email: Agricultural.Select.Agent.Program@aphis.usda.gov	42 CFR 73.0 Select Agent Rule	Reporting Form: Form 3 Report of Theft Loss or Release Available at: http://www.selectagents.gov/TLRForm.html Regulations: http://www.selectagents.gov/Regulations.html
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	Form 3 Report of Theft Loss or Release Available at: http://www.selectagents.gov/TLRForm.html Regulations: http://www.selectagents.gov/Regulations.html
Massachusetts Department of Public Health Office of General Counsel 250 Washington Street, 2nd Floor Boston MA 02108 Phone: 617-624-5213	105 CMR Department of Public Health Minimum Requirements for the Management of Medical or Biological Waste (State Sanitary Code Chapter	No Specific Reporting Template. Regulations: http://www.mass.gov/Eeohhs2/docs/dph/regs/105cmr480.pdf

	VIII)	