Cornell University
Office of
Research Integrity and Assurance
Institutional Biosafety Committee

395 Pine Tree Road Suite320
Ithaca, NY 14850
Phone: 607-255-7219
Fax: 607-255-0758
Email: oria@cornell.edu
www.oria.cornell.edu

# Institutional Biosafety Committee
# Annual Report, 2014-2015

## Contents



## 1. *Charge to the IBC*

Cornell University's (Ithaca –Geneva campuses) Institutional Biosafety Committee (IBC) is responsible for reviewing all University research and teaching activities that are conducted by faculty, staff, students, and/or visiting scientists at, or under the auspices of Cornell University, and that involve the use of recombinant or synthetically derived nucleic acid molecules (r/sNA) or other biohazardous materials (regulated human, animal and plant pathogens and biological toxins). The purpose of these reviews is to ensure that all activities involving r/sNA or other biohazardous materials and the facilities used to conduct such work are in compliance with all applicable external regulations and University policies. The IBC's objective is to ensure that such activities meet standards of good biological safety practice emphasizing protection of personnel, the general public, and the environment. The IBC assists researchers in meeting their responsibilities; imposes requirements and review and approve policies, procedures, programs, and facilities pursuant to the safe use of (r/sNA) or other biological materials.

For complete document: http://www.ibc.cornell.edu/documents/IBC_Charge.pdf

## 2. *Committee Membership*

The committee is Co-Chaired by Professors Colin Parrish and Keith Perry. Over the course of the year three new members were appointed, three appointments were renewed and 1 member left the committee. The committee membership list is found in ***Appendix A.***

## 3. *Active Projects*

The IBC reviews and approves the following categories of projects (detailed explanation of these classifications is provided in ***Appendix B***):

**a. Projects with r/sNA use:**

- Exempt from the NIH guidelines (Class F)
- Non- Exempt, subject to NIH guidelines (classified as Class D or E)

**b. Projects with Biohazardous Materials**

- Infectious/pathogenic agents classified in the following categories: Risk Group 2, 3, and 4 bacterial, fungal, parasitic, viral, rickettsial or chlamydial agents as defined by the National Institutes of Health (NIH) **or**,
- Other agents that have the potential for causing disease in healthy individuals, animals, or plants, and
- Biological toxins include metabolites of living organisms and materials rendered toxic by the metabolic activities of microorganisms (living or dead).

**c. Active Projects registered with the IBC:**

There were 283 active MUA's at BSL1 and BSL2 and 3 MUA's at BSL3 as of May 31, 2015.

| Classification | Type | MUAs Active |
|---|---|---|
| Exempt | Class F | 44 |
| | Class F with Biohazards | 35 |
| Non Exempt | Class D | 11 |
| | Class D with Biohazards | 84 |
| | Class E | 40 |
| | Class E with Biohazards | 27 |
| | Biohazards only | 42 |
| Biosafety Level 3 practices | | 3 |
| **Active as of May 31, 2015** | | **286** |

## 4. *New IBC System Implemented –November 10, 2014*

In November of 2014, a much revised and updated version of the electronic Memorandum of Understanding and Agreement (e-MUA) system for IBC registrations was released. The resulting changes are intended to improve the structure of the questions, reduce administrative burden for researchers in submitting and maintaining their MUAs, and for IBC committee members in reviewing MUAs. In designing the upgrade we consulted with faculty who submit and manage MUAs, IBC reviewers, and other subject matter experts who use the IBC system, and benchmarked the forms and processes in place at peer institutions. Feedback on the usability and features included in the new system has been positive.

Key system changes implemented:

- Updates to the MUA questions, format, and flow of questions to make them more relevant to the considerations important to the IBC in making decisions;
- System logic that controls sections of the application that require response based on previous responses;
- An expandable "Table of Contents" (TOC) for ease of navigation throughout the application;
- Visual indicators in the TOC to provide feedback on required, changed, and/or missing information;
- Waterfall numbering to support the flow of the application and the review cycle;
- "Track changes" features for PIs, Reviewers, and Administrators;
- For 3 year renewals, information from the current, approved MUA is brought forward into the 3 year renewal application for editing and updating; all changes will be visible in "track changes"
- Amendments to current, approved applications build off the existing MUA, and approved changes are incorporated into the current, approved version;
- Robust history and audit trail, tracking previous versions and history of the MUA

Migration/conversion from the old to the new:

Since the structure and content of the form have changed significantly in the new system, the MUA information in the original system needs to be "migrated" over to fit the new form. The IBC office is in the process of bringing this information over for all approved MUAs. The IBC Administrator is working on a one on one basis with all MUA holders to ensure that information migrated to the converted MUA accurately reflects the work that was approved by the IBC. Once the MUA is converted, it will be available to start amendments, annual reviews, or 3-year renewals.

## 5. *Significant events managed by the IBC*

- **Notice of National Biosafety Stewardship Month in September 2014 by the NIH:** the IBC office reached out to all individuals holding an MUA requesting participation and reviewing and updating inventories of biohazardous material used and contact information if they needed assistance in disposing of materials.
- **U.S. Government Policy for Oversight of Life Sciences Dual Use Research issued on September 24, 2014:** No impact to the Ithaca campus at this time since no such agents are being used here
- **Request for release of IBC documentation and subsequent publication of a report:** Under the public access provisions of the NIH Guidelines the IBC received the following request from a reporter from the Democrat and Chronicle based in Rochester
    - All minutes of the IBC meetings from Jan. 1, 2013 to October 31, 2014
    - All NIH-OBA incident reports from Jan. 1, 2013 to October 31, 2014

  All documents were provided and information was redacted per the Cornell IBC Redaction Policy. Several universities and research centers across the US received this type of request from this publication. The report was recently published in the USA Today. http://www.usatoday.com/story/news/2015/05/28/labs-fight-for-secrecy/26530719/. Cornell specific information can be found here http://www.usatoday.com/pages/interactives/biolabs/#lab/NY05. Despite the somewhat sensational nature of the overall report, information specific to Cornell's program was balanced and accurate.

- **Response to a partial stop work order for gain of function research:** The NIAID issued a "Partial Stop Work Order" for a research project that could be construed as "Gain of Function" defined by the NIAID as "*scientific research that increases the ability of any of these infectious agents to cause disease by enhancing its pathogenicity or by increasing its transmissibility among mammals by respiratory droplets"*. The committee conducted a review of the research and determined that the work did not fall in the category of research subject to the Partial Stop work order. This determination was sent on to the Program Officer at the NIAID, which agreed with the committee's assessment and revoked the stop work order for the project.
    - Additionally, in response to the government's call for voluntary review and hold on projects that could be "gain of function", the IBC conducted an internal review of three other projects for gain of function, determined that the research did not fall under the US Government Gain-of – Function as described in the deliberative process and that therefore work on these projects could continue.

## 6. *MUA (Project) review activities*

During the reporting year July 1, 2014-May 31, 2015, the IBC held 9 duly convened meetings to review new Memoranda of Understanding and Agreements (MUA), amendments to approved MUAs and applications for renewal of approved MUAs.

- Review of Exempt projects: The Chair of the IBC or designate or the Biosafety Officer review and approve Exempt projects. The approvals are reported to the IBC at a subsequent meeting.

- Review of Non Exempt MUAs and MUAs with Biohazards: These projects are assigned for review to a subcommittee of three members and approval is issued by the full committee at a convened meeting. Approvals are granted for a period of three years and are contingent upon the successful completion of a continuing review (annual questionnaire).

- Review of Biosafety Level 3 (BSL3) Application: BSL3 Applications are first reviewed by the BSL3 Advisory Committee (BAC), which is composed of the Biosafety Officer and Biosafety team members, Biosafety Engineer, Occupational Medicine Physician and 2 IBC members. The BAC makes recommendations for modification to the application to the Principal Investigator (PI) and determines training and other requirements before the project can be approved. Accordingly, appropriate class room and facility on-site training is delivered. An Occupational medicine evaluation is conducted and a corresponding plan is put into place. The IBC reviews all the recommendations and actions undertaken to address those recommendations and determines if the project can be approved for BSL3 work.

- Annual questionnaires and MUA amendments: These applications are reviewed by the Chair of the IBC or Biosafety Officer and the IBC administrator. Amendments with personnel and facility changes are approved administratively. Amendments that add a new line of research or work that requires a more thorough review are reviewed at a regularly scheduled full committee meeting.

  A total of 176 MUAs or continuation requests (amendments and annual questionnaires) were reviewed during 2014-15. A breakdown of projects submitted for review during the same timeframes in 2012-2013 and 2013-2014 is below:

| Classification | Type | Number reviewed during 2012-13 | Number reviewed during 2013-2014 | Number reviewed during 2014-2015 |
|---|---|---|---|---|
| Exempt | Class F | 5 | 3 | 5 |
| | Class F with Biohazards | 21 | 10 | 2 |
| Non-Exempt | Class D | 6 | 2 | 1 |
| | Class D with Biohazards | 33 | 14 | 13 |
| | Class E | 33 | 11 | 0 |
| | Class E with Biohazards | 12 | 4 | 2 |
| BSL3 Application | | 1 | 1 | 2 |
| BSL3 Amendment | | 2 | 2 | 0 |
| Biohazards only | | 11 | 11 | 16 |

| | | | | |
|---|---|---|---|---|
| Annual Reviews | | 123 | 171 | 69 |
| Amendments | | 89 | 60 | 66 |
| | | | | |
| **Total reviewed** | | 336 | 289 | 176* |
| | | | | |
| MUAs Terminated | | 102 | 47 | 11** |
| | | | | |

*Note that total number reviewed is significantly lower than normal, as the expiration date for all MUAs were extended by six months to allow for migration of the information to the new system.
** 6 MUAs were terminated when the PI filed a new 3 year renewal, 2 left the institution and 3 no longer using r/sNA or biohazardous materials in their research

## 7. *Adverse Events*

**Biosafety Adverse Events and exposures:** The following incidents were reported at full committee meeting, and the outcomes, prevention and follow-up were discussed. The incident was handled according to applicable Cornell policies and regulatory requirements.

Lab incidents – no recombinant or synthetic nucleic acids were involved.

- Bonassar lab: A researcher was using a glass pipette to aspirate human stem cells, and during the process broke the pipette and poked herself through her glove with the sharp edge of the pipette. The grad student followed appropriate protocol, performed first aid, notified her PI who reported the incident to the Biosafety officer, and the individual reported to Cayuga Medical ER as it was after hours. The following day the incident was also reported to Gannett Health Services. The BSO visited the lab and spoke about situational awareness and substitution of the glass tube with a plastic tube.

- March lab: A researcher was cutting into a bag of human blood and cut herself with the scissors. The researcher followed the appropriate protocol, performed first aid, and notified her PI who reported the incident to the IBC. The researcher reported to Gannett Health Services. The BSO visited the lab and reiterated the importance of situational awareness and taking care when performing experimental procedures.

**Adverse Events reported to the NIH:**

- None of the above events was reported to the NIH as they did not involve use of recombinant materials.

## 8. *Ongoing Education and Training for IBC members and Biosafety team:*

- New members attended training focused on the NIH guidelines, risk assessment of use of biohazardous materials and committee functions.

- The committee was kept informed of the many occurences and reports in the media about spills and accidents and possible exposures happening elsewhere in the US:

    - CDC statement on Small pox samples found in FDA freezer and CDC report on accidental release of anthrax at CDC facility.
    - gain of function research study using a 1918 avian influenza virus in ferrets which initially resulted in publication of work being stopped.
    - congressional hearing of the House Energy and Commerce Committee and letters to CDC, FDA, NIH and HHS OIG regarding safety lapses involving Select Agents. http://energycommerce.house.gov/letter/letters-cdc-fda-nih-and-hhs-regarding-recent-safety-lapses-involving-select-agents
    - Discussed report in CDC: Morbidity and Mortality weekly report concerning a laboratory acquired infection and subsequent death of the laboratory worker in 2012 from meningococcal disease. Several breaches in recommend practice of safe handling of N. meningitides were discussed. Additionally the laboratory workers had not been offered meningococcal vaccine in accordance with Advisory Committee on Immunization Practices (ACIP) recommendations.

## 9. *Appendix A: Committee Membership*

**Voting Members**

| | |
|---|---|
| Colin Parrish (Chair), | Professor, James A Baker Institute for Animal Health |
| Perry, Keith (Vice Chair) | Assoc. Professor, Plant Pathology & Plant Microbe |
| Angert, Esther | Assoc. Professor, Microbiology |
| Butler, Scott | Research Support Specialist II, Biomedical Sciences |
| Fuchs, Marc | Assoc. Professor, Plant Pathology |
| Hay, Anthony | Assoc. Professor, Microbiology |
| Michaels, Christy | Biology Teacher, Community Member, Non-affiliated |
| Meyers-Wallen, Vicky | Assoc. Professor, James A Baker Institute for Animal Health |
| Moseley Moore, Cathy | Enrichment Teacher, Community Member, Non-affiliated |
| Quaroni, Andrea | Professor, Biomedical Sciences |
| Renshaw, Randall | Research Associate, Population Medicine & Diagnostic Sciences |
| Swingle, Bryan | Assist. Professor, Plant Pathology & Plant-Microbe |
| Whittaker, Gary | Professor, Microbiology and Immunology |
| Wang, Ping | Associate Professor, Entomology |
| Wilson, David | Professor, Molecular Biology & Genetics |

**Ex-Officio, Voting Members**

| | |
|---|---|
| Brubaker, Alexis | Biological Safety Officer, Environmental Health & Safety |
| Jennette, Paul | Biosafety Engineer, CVM Biosafety Program |
| Patterson, Relford, M.D | Director of Occupational Medicine, Gannett Health Services |
| Singh, Bhupinder, D.V.M. | Veterinarian, CARE |

**Ex-Officio, Alternate Voting Members**

| | |
|---|---|
| Holeman, Penny | Associate Biosafety Officer, Environmental Health & Safety |
| Pavek, Todd, D.V.M. | Clinical Veterinarian, CARE |

**Ex-Officio, Non-Voting Members**

| | |
|---|---|
| Leed, Andrew | Manager Tower Road Greenhouses, CALS |
| Hsiao, Vivian | Nurse Practitioner Supervisor, Gannett Health Services |
| Buhrman, Robert A. Ph.D. | Senior Vice Provost for Research |
| Burns, Joseph, Ph.D. | Dean of Faculty |
| Long, Cathy | Associate Vice President of Research |
| Verma, Amita | Director, ORIA |

## 10. *Appendix B: Classification definitions from the NIH Guidelines*

**Exempt Experiments**

**Section III-F.**

Recombinant or synthetic nucleic acid molecules described in Section III-F are exempt from the *NIH Guidelines* but registration with the Institutional Biosafety Committee is still required.

**Non-Exempt Experiments**

**Section III-E. Experiments that Require Institutional Biosafety Committee Notice Simultaneous with Initiation**

Experiments not included in Sections III-A, III-B, III-C, III-D, III-F, and their subsections are considered in Section III-E. All such experiments may be conducted at BL1 containment. For experiments in this category, a registration document (see Section III-D, *Experiments that Require Institutional Biosafety Committee Approval Before Initiation)* shall be dated and signed by the investigator and filed with the local Institutional Biosafety Committee at the time the experiment is initiated. The Institutional Biosafety Committee reviews and approves all such proposals, but Institutional Biosafety Committee review and approval prior to initiation of the experiment is not required (see Section IV-A, *Policy*). For example, experiments in which all components derived from non-pathogenic prokaryotes and non-pathogenic lower eukaryotes fall under Section III-E and may be conducted at BL1 containment.

**III-D. Experiments that Require Institutional Biosafety Committee Approval Before Initiation**

Prior to the initiation of an experiment that falls into this category, the Principal Investigator must submit a registration document to the Institutional Biosafety Committee which contains the following information: (i) the source(s) of nucleic acid; (ii) the nature of the inserted nucleic acid sequences; (iii) the host(s) and vector(s) to be used; (iv) if an attempt will be made to obtain expression of a foreign gene, and if so, indicate the protein that will be produced; and (v) the containment conditions that will be implemented as specified in the *NIH Guidelines*.

For experiments in this category, the registration document shall be dated, signed by the Principal Investigator, and filed with the Institutional Biosafety Committee. The Institutional Biosafety Committee shall review and approve all experiments in this category prior to their initiation. Requests to decrease the level of containment specified for experiments in this category will be considered by NIH

## 11. *Appendix C: Number of Active MUAs by Unit/Department*

| Department | College | # of MUAs |
|---|---|---|
| Animal Science | CALS | 7 |
| Applied & Engineering Physics | College of Engineering | 4 |
| Baker Institute for Animal Health | College of Veterinary Medicine | 9 |
| Biochemistry, Molecular and Cellular Biology | CALS | 1 |
| Biological Statistics and Computational Biology | CALS | 1 |
| Biological & Env. Engineering | CALS | 7 |
| Biomedical Engineering | College of Engineering | 14 |
| Biomedical Sciences | College of Veterinary Medicine | 16 |
| Boyce Thompson Institute | | 7 |
| Chemical & Bimolecular Eng. | College of Engineering | 7 |
| Chemistry & Chemical Biology | College of Arts & Sciences | 10 |
| Clinical Sciences | College of Veterinary Medicine | 8 |
| Crop & Soil Sciences | CALS | 2 |
| Ecology & Evol. Biology | CALS | 4 |
| Electrical and Computer Engineering | Engineering | 3 |
| Entomology | CALS | 7 |
| Food Science | CALS | 6 |
| Horticultural Sciences | CALS | 8 |
| Materials Sci. & Engineering | Engineering | 1 |
| Mech. And Aero Engineering | Engineering | 7 |
| Microbiology | CALS | 9 |
| Microbiology & Immunology | College of Veterinary Medicine | 17 |
| Molecular Biology & Genetics | College of Arts & Sciences | 16 |
| Molecular Biology & Genetics | CALS | 16 |
| Molecular Medicine | College of Veterinary Medicine | 13 |
| Natural Resources | CALS | 1 |
| Neurobiology & Behavior | CALS | 2 |
| Neurobiology & Behavior | College of Arts & Sciences | 6 |
| Nutritional Sciences | CALS | 5 |
| Nutritional Sciences | Human Ecology | 13 |
| NYS Animal Health Diagnostic Lab | College of Veterinary Medicine | 1 |
| Physics | College of Arts & Sciences | 3 |
| Plant Biology | CALS | 6 |
| Plant Biology | Arts and Sciences | 7 |
| Plant Breeding & Genetics | CALS | 6 |
| Plant Pathology | CALS | 17 |
| Pop. Medicine & Diag. Science | College of Veterinary Medicine | 13 |
| Psychology | College of Arts & Sciences | 2 |
| Quality Milk Production Svc. | College of Veterinary Medicine | 2 |

## 12. *Appendix D: Lab Facility Information and Site Visits*

The number of laboratories (rooms) known to be conducting research at Biosafety levels BL1, BL2 or BL3, as of June 30, 2014, are as follows. This information is provided on the MUAs by researchers:

- 297 laboratories operating at BL1
- 284 laboratories operating at BL 2
- 109 BL2-P level greenhouses/growth chambers
- 50 BL1-N animal care rooms
- 48 BL2-N animal care rooms
- 3 facilities operating at BL 3
- 1 facility operating at ABSL3

The Biosafety team conducted lab visits to the following labs, based on an assessment of risk of the agent used, the nature of work being done, the experience and knowledge of the PI and the research team and history of safe practices with the use of biohazardous materials:

- Dr. Luo- Department of Biological and Environmental Engineering: Work is conducted at BSL2. The BSO discussed waste disposal processes with the lab and changes were implemented.
- Dr. Brennan – Department of Biomedical Sciences: Work is conducted at BSL2. BSO discussed best practices when the new PI came aboard.
- Dr. McCleary-Wheeler – Department of Clinical Sciences: BSO discussed waste disposal and signage
- Dr. Zamudio – Department of Ecology and Evolutionary Biology: BSO performed hands on training in Biosafety Cabinet use.
- Dr. VanderVen- Department of Microbiology and Immunology: Work is conducted at BSL2. BSO found PI to have excellent work practices.
- Dr. Warden – Department of Neurobiology and Behavior: BSO observed adeno-associated virus delivery to the rodent brain. BSO provided guidance on waste stream practices.
- Dr. Aye- Department of Chemistry and Chemical Biology: Work is conducted at BSL2. BSO discussed Personal Protective (PPE), best practices for waste stream and use of biosafety cabinet.
- Dr. Danko – Baker Institute for Animal Health: Work is conducted at BSL2. BSO discussed appropriate PPE, hand hygiene and best practices in use of biosafety cabinet.
- Dr. Song- Department of Microbiology and Immunology: Work is conducted at BSL2. BSO discussed various lab procedures and location of the procedures. Additionally signage and waste handling were discussed.

- Dr. Linster- Department of Neurobiology and Behavior: work is conducted at BSL2. BSO observed delivery of adeno-associated virus to the mouse brain and are worked with the PI on developing best practices for the procedures.
- Dr. Cosgrove – Department of Biomedical Engineering: BSO met with new PI to discuss placement of equipment and to answer any safety questions.
- Dr. De Vlaminck - Department of Biomedical Engineering: BSO met with new PI to discuss placement of equipment and to answer safety questions.
- Dr. Tait-Wojno- Department of Microbiology and Immunology: BSO met with new PI to discuss placement of equipment and to answer safety questions.