

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: <u>oria@cornell.edu</u> www.oria.cornell.edu

# Institutional Biosafety Committee Annual Report, 2015-2016

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# 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: <u>http://www.ibc.cornell.edu/documents/IBC\_Charge.pdf</u>

# 2. Committee Membership

The committee is Co-Chaired by Professors Colin Parrish and Keith Perry. The current committee membership list is found in *Appendix A*. Over the course of the year the following membership changes occurred:

- Joshua Turse and Penny Holeman, Biosafety professionals from the Office of Environmental Health and Safety, were newly appointed as voting alternate to the Biosafety Officer.
- Dr. Edward Koppel, a physician and Occupational Medicine professional from Gannett Health Services, was appointed as *ex-officio* voting, to replace Dr. Relford Patterson who left Cornell in March.
- The appointments of the following current IBC members were renewed: Professor Esther Angert, Professor Bryan Swingle, Professor Gary Whittaker and Professor David Wilson.
- Professor Andrea Quaroni, left the committee after nine years of serving as a voting member.

## 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:

As of May 31, 2016, there were a total of 274 active MUAs: 270 active MUA's at BSL1 and BSL2 and 4 MUA's at BSL3.

Classification	Туре	<b>MUAs Active</b>
Exempt	Class F	43
	Class F with Biohazards	31
Non Exempt	Class D	13
	Class D with Biohazards	85
	Class E	33
	Class E with Biohazards	28
	Biohazards only	37
Biosafety Level 3 practices		4
Active as of May 31, 2016		274

# 4. Update on IBC System Implemented in November 2014

As we reported in the previous Annual report to the Senate, the IBC switched to a new MUA management system in Q4 2014. Over much of the past year, the information from the previous MUA system was being converted to the new system to ensure completeness and integrity of the information and to maintain continuity in the process. To facilitate this conversion, the IBC Administrator has completed one on one meetings with 192 MUA holders to ensure that information migrated to the converted MUA accurately reflects the work that was approved by the IBC. As of this update, all non –exempt projects have been updated in the new system. Work will continue with 39 holders of exempt MUA's to complete the conversion, with the goal of completing this work by end of calendar year 2016.

The system is fully functioning for registration of new MUA's, approvals, Amendments, Annual Questionnaires and 3 year renewals. Researcher feedback on improvements in the system, including overall organization, new and improved features, and usability, have been positive, and we continue to work with the IT organization to address bugs and minor enhancements deemed necessary for usability and compliance.

## 5. Significant events managed by the IBC

# • U.S. Government Policy for Oversight of Life Sciences Dual Use Research Concern (DURC) issued on September 24, 2014, effective date September 24, 2015:

Cornell IBC implemented a new policy on DURC in September 2015, in response to the regulatory requirement for institutions accepting government funds Please note that although a policy is in place, no research using such DURC agents is currently occurring or planned in the near future, for the Cornell Ithaca based campuses.

The full policy can be accessed at: http://www.ibc.cornell.edu/documents/Dual\_Use\_Research\_of\_Concern\_Policy.pdf

#### • Release of transgenic Diamond back moths

The IBC reviewed and approved an MUA requesting approval to release transgenic diamond back moths in a field trial. The PI also had an approved USDA-APHIS –BRS permit required for such research. As a pilot program the PI proceeded with a caged release of the moths in the field. The Biosafety officer and the IBC worked with the PI on determining and implementing best practices and secondary containment and the trials were able to take place. The IBC continues to work with the PI in attempting to move this research forward.

#### • Exposure Control Plan (ECP) required under OSHA Blood borne pathogen standards

All research using blood borne pathogens or other potentially infectious agents are required to maintain an exposure control plan (ECP). To decrease burden, EH&S Biosafety developed an ECP to cover all research activities working with human materials at the University. This document used in conjunction with the specifics of the Memorandum of Understanding and Agreement (MUA) reviewed and approved by the IBC will meet the OSHA requirements. This decreases burden on the PI as they will not be required to annually update the ECP.

## 6. MUA (Project) review activities

During the reporting year July 1, 2015-May 31, 2016, the IBC held 11 duly convened meetings to review new Memoranda of Understanding and Agreements (MUA), amendments to approved MUAs and applications for renewal of approved MUAs.

- <u>Review of Exempt projects:</u> 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.
- <u>Review of Non Exempt MUAs and MUAs with Biohazards:</u> 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).
- <u>Review of Biosafety Level 3 (BSL3) Application:</u> 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.

• <u>Annual questionnaires and MUA amendments:</u> 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 279 MUAs or continuation requests (amendments and annual questionnaires) were reviewed during 2015-16. A breakdown of projects submitted for review during the same timeframes in 2013-2014 and 2014-2015 is below:

Classification	Туре	Number reviewed during 2013-2014	Number reviewed during 2014-2015	Number reviewed during 2015-2016
Exempt	Class F	3	5	4
	Class F with Biohazards	10	2	9
Non-Exempt	Class D	2	1	6
	Class D with Biohazards	14	13	45
	Class E	11	0	6
	Class E with Biohazards	4	2	12
BSL3 Application		1	2	0
BSL3 Amendment		2	0	3
Biohazards only		11	16	12
Annual Reviews		171	69	101
Amendments		60	66	81
Total reviewed		289	176*	279
MUAs Terminated		47	11	16**

\*Note that total number reviewed in 2014-15 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. The number of reviews in 2015-16 are back to expected normal levels. \*\* 3 MUAs were terminated when the PI filed a new 3 year renewal, 9 left the institution and 4 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.

#### Adverse Events reported to the NIH:

#### I. Accidental Release of recombinant Schizosaccharomyces pombe

On September 1, 2015 during a routing lab visit it was discovered that dry waste containing cultures of recombinant *Schizosaccharomyces pombe* was being disposed of in the regular trash stream without prior deactivation. The liquid waste was being inactivated appropriately.

The PI was informed that all liquid and solid waste must be inactivated prior to disposal. The PI immediately implemented this practice, incorporated this in the lab Standard Operating Procedures, reviewed the waste disposal guidelines, and Appendix G-II-A of the NIH guidelines. The IBC office has distributed copies of the waste disposal guidelines during personnel visits and posted them on the IBC website to remind the research community of the university waste disposal guidelines for recombinant materials. ORIA reported the incident to the National Institutes of Health Office of Biotechnology Activities (NIH-OBA) on September 9, 2015.

On September 17, 2015 confirmation from the NIH OBA was received stating that the actions taken were appropriate and no further action was required.

#### II. Accidental release of waste bags drosophila cultures at the Tompkins County Recycling Center

On January 6, 2016 Cornell University Facilities Services R5 Operations contacted EH&S Biosafety that 2 bags containing culture tubes of drosophila had entered the recycling stream at Tompkins County Recycling Center in Ithaca. There were no identifying marks that gave enough information to trace the origin of the tubes or to determine if the materials contained in the bags were transgenic. The bags were then properly disposed of at the Cornell Veterinary Medicine Waste Management plant.

The IBC Administrator contacted NIH OBA on January 12, 2016 to describe the incident and to seek advice. As Cornell conducts research with transgenic drosophila, and it was not possible to determine if the discarded materials contained transgenic flies, the NIH instructed Cornell to file an incident report.

The IBC sent letter to all individuals holding a MUA to review the Cornell University recycling policy and College waste stream policies.

NIH-OBA responded on January 29, 2016 that the correct action were appropriate and no further information was required.

## 8. Lab Visits by EH&S Biosafety

Date	Department	Principal	Corrective actions	Discussion points

		Investigator		
2016.01.14	COE Chemical & Biological Engineering	C Alabi	n/a	Signage Housekeeping Emergency response Facilities issue Biosafety cabinet use Aerosol reduction
2016.02.01	CHE Human Ecology	A Anderson	n/a	Biosafety cabinet operations
2016.02.23	COE Chemical & Biological Engineering	M DeLisa	n/a	Labeling Aerosol reduction PPE selection Disinfection practices Biohazard disposal
2016.03.16	COE Cornell Center for Materials Research	L Bonassar	Update MUA to include new material BBP training	Labeling Spill reduction Waste management
2016.04.29	CALS Microbiology	A Hay	n/a	Biosafety cabinet use Housekeeping Biohazard disposal Personal protective equipment use Disinfection practices
2016.05.19	CAS Biomedical Engineering	W Zipfel	n/a	Biosafety cabinet operations Aerosol reduction Sharps handling
2016.05.23	CALS Food Science	M Mukai	n/a	Biosafety cabinet operations Sharps handling
2016.05.31	CALS Microbiology	S Winans	Lab coat availability Biohazardous waste management	Housekeeping Personal protective equipment use Biosafety cabinet use

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

All new members of the IBC were provided an orientation on the NIH guidelines, risk assessment of use of biohazardous materials.

# 10. 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
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
Edward Koppel, M.D	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
Turse, Josh, PhD.	Associate Biosafety Officer, Environmental Health & Safety
Hsiao, Vivian, PhD.	Nurse Practitioner Supervisor, Gannett Health Services
Pavek, Todd, D.V.M.	Clinical Veterinarian, CARE

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

Leed, Andrew	Manager Tower Road Greenhouses, CALS
Buhrman, Robert A. Ph.D.	Senior Vice Provost for Research- Institutional Official

# 11. 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 review 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

Department	College	# of MUAs
Animal Science	CALS	5
Applied & Engineering Physics	College of Engineering	4
Baker Institute for Animal	College of Veterinary Medicine	8
Health		0
Biochemistry, Molecular and	CALS	1
Cellular Biology		
Biological Statistics and	CALS	1
Computational Biology		
Biological & Env. Engineering	CALS	7
Biomedical Engineering	College of Engineering	15
Biomedical Sciences	College of Veterinary Medicine	17
Boyce Thompson Institute		7
Chemical & Bimolecular Eng.	College of Engineering	5
Chemistry & Chemical Biology	College of Arts & Sciences	10
Clinical Sciences	College of Veterinary Medicine	9
Crop & Soil Sciences	CALS	1
Ecology & Evol. Biology	CALS	4
Ecology & Evol. Biology	College of Arts & Sciences	1
Electrical and Computer	Engineering	2
Engineering		
Entomology	CALS	7
Food Science	CALS	7
Horticultural Sciences	CALS	7
Human Development	CALS	1
Materials Sci. & Engineering	Engineering	1
Mech. And Aero Engineering	Engineering	5
Microbiology	CALS	10
Microbiology & Immunology	College of Veterinary Medicine	14
Molecular Biology & Genetics	College of Arts & Sciences	15
Molecular Biology & Genetics	CALS	15
Molecular Medicine	College of Veterinary Medicine	13
Natural Resources	CALS	1
Neurobiology & Behavior	CALS	5
Neurobiology & Behavior	College of Arts & Sciences	3
Nutritional Sciences	CALS	4
Nutritional Sciences	Human Ecology	12
NYS Animal Health Diagnostic Lab	College of Veterinary Medicine	1
Physics	College of Arts & Sciences	3
Plant Biology	CALS	8
Plant Biology	College of Arts and Sciences	5
Plant Breeding & Genetics	CALS	4
Plant Pathology	CALS	18
Plant Transformation Facility	CALS	1
Pop. Medicine & Diag. Science	College of Veterinary Medicine	12

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

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Psychology	College of Arts & Sciences	2
Quality Milk Production Svc.	College of Veterinary Medicine	1
Weill Institute for Cell and	Research Centers	3
Molecular Biology		

## 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 May 31, 2016, are as follows. This information is provided on the MUAs by researchers:

- 281 laboratories operating at BL1
- 291 laboratories operating at BL2
- 131 BL2-P level greenhouses/growth chambers
- 62 BL1-N animal care rooms
- 83 BL2-N animal care rooms
- 3 facilities operating at BL3
- 1 facility operating at ABSL3