



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, June 1, 2016-May 31, 2017**

Contents

1. *Charge to the IBC* 1
2. *Committee Membership* 2
3. *Active Projects* 2
4. *Initiatives managed or supported by the IBC* 3
5. *MUA (Project) review activities* 5
6. *Adverse Events* 6
7. *Lab Visits by EH&S Biosafety* 7
8. *Ongoing Education and Training for IBC members and Biosafety team:* 9
9. *Appendix A: Committee Membership* 10
10. *Appendix B: Classification definitions from the NIH Guidelines* 11
11. *Appendix C: Number of Active MUAs by Unit/Department* 12
12. *Appendix D: Lab Facility Information* 13

1. *Charge to the IBC*

Cornell University's (Ithaca and Geneva campuses) Institutional Biosafety Committee (IBC) is responsible for reviewing University research activities that are conducted by faculty, staff, students, 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 review process is initiated by submission of a Memorandum of Understanding Agreement (MUA) to the IBC. 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 comply with all applicable external regulations and University policies. The IBC's objective is also to ensure that such activities meet standards of good biological safety practice emphasizing protection of personnel, the public, and the environment. The IBC assists researchers in meeting their responsibilities; imposes requirements and reviews and approves policies, procedures, programs, and facilities pursuant to the safe use of (r/sNA) or other biological materials.

For a copy of the Charge to the IBC, please see:

http://www.ibc.cornell.edu/documents/IBC_Charge.pdf

2. *Committee Membership*

The committee is Co-Chaired by Professors Colin Parrish and Keith Perry. Professor Esther Angert served as co-chair for Professor Parrish while he was on sabbatic for 6 months, and will be replacing Professor Perry in June when he leaves the committee. ***Appendix A provides the membership list as of May 31, 2017.*** Over the course of the year the following membership changes occurred:

- Alan Bitar, Biosafety professional from the Office of Environmental Health and Safety, was appointed as voting ex-officio alternate to the Biosafety Officer.
- Dr. Bryant Blank, Veterinarian with the Center for Animal Resource and Education, was appointed as *ex-officio* voting alternate to the Attending Veterinarian, to replace Dr. Todd Pavek who left Cornell.
- The appointments of the following current IBC members were renewed: Professor Esther Angert, Professor Bryan Swingle, Professor Gary Whittaker and Professor David Wilson.
- Professor Julia Felipe was appointed to the committee July 1, 2016
- Professor Georg Jander has been nominated to join the committee July 1, 2017
- Professor Keith Perry left the committee after 7 years as a voting member and 4 years as co-chair.
- Professor David Wilson served on the committee for 7 years and sadly passed away this year.

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 ([Section F](#))
- Non- Exempt, subject to NIH guidelines (classified as [Section D](#) or [Section 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, 2017, there were 272 active MUAs: 268 active MUAs at BSL1 and BSL2 and 4 MUAs at BSL3.

Classification	Type	MUAs Active
Exempt	Section F	41
	Section F with Biohazards	18
Non Exempt	Section D	17
	Section D with Biohazards	93
	Section E	28
	Section E with Biohazards	32
	Biohazards only	39
Biosafety Level 3 practices		4
Active as of May 31, 2017		272

4. *Initiatives managed or supported by the IBC*

- Cornell Policy for all transgenic plant work being conducted at BL2-P**

An IBC subcommittee reviewed this policy for pertinence to ongoing work with transgenic plants in greenhouses and growth chambers, and to better document review and approval criteria. The final recommendation to the IBC:

Continue with the requirement that all work with transgenic plants is done at BL2-P containment or higher. If the research meets necessary requirements to be BL1-P+, and there are space issues, the PI can petition the IBC to downgrade their research to BL1-P+.

All work with r/sNA and microbes or viruses associated with plants requires BL2-P containment as specified in the NIH guidelines.

The IBC approved the recommendation.

- Biosafety Month**

NIH Office of Science Policy announced October 2016 as National Biosafety Month.

The IBC and EHS Biosafety Office worked together to send two communications with interactive cases studies concerning biosafety in the lab to the Principle Investigators and Personnel named on all IBC MUAs. Educational materials were also posted on the IBC website.

- **Proof of Concept Study involving use of CRISPR technology in non-human mammalian oocysts.**

The IBC reviewed and approved the use of Clustered Regularly Interspaced Short Palindromic Repeats (CRISPR) technology to effect the phenotype of dogs (a single nucleotide polymorphism) using *in vitro* fertilization techniques in one research program. The PI for the program asserted that genetic material was not transferred to the pups involved in the program and petitioned the IBC to allow adoption of two pups from the experiment. The PI provided data sequences from the target and off-target sites showing (1) no modifications to the gene of interest, and (2) that there was no evidence of the phenotypical characteristic of the gene of interest (straight coat to curly coat). Since the pups were neutered, they would be unable to pass on genetic material.

After review of the data presented and of the *NIH Guidelines for research involving recombinant or synthetic nucleic acid molecules* the committee determined that the pups could be adopted out in accordance with IACUC ACUP 807.

- **Review and Approval of Occupational Medical Exposure Plan for Zika Virus**

This plan, developed by the Cornell Health Occupational Medicine, provides information about transmission risks, including risk to those who are pregnant or plan to become pregnant, counseling for individuals who may be at risk for exposure to the virus, immediate and follow up steps to take in case of exposure, contact information for emergency and medical personnel.

- **Development of Protection, Use and Control Sheets for Biological Materials (BioPUC)**

The Cornell Biosafety team is developing BioPUCs for various pathogenic agents commonly used in Cornell research. The BioPUC is a pathogen safety data sheet, giving agent characteristics (description, route of exposure, host range and shedding, infectious dose, risk group etc.), handling and housing information (lab or animal biosafety level, training requirements, known hazards, requirements for containment levels, engineering controls, personal protective equipment, immunization options etc.), exposure information (incubation period, clinical signs and symptoms, contact information for emergencies etc.) and other helpful information about handling the agents.

These documents are being developed by the EHS Biosafety team, in collaboration with subject matter experts from the IBC and across campus, Occupational Medicine and CARE veterinarians.

When finalized, the BioPUCs will be accessible online for PIs to use them as reference and to link from within their MUA. This will help standardize the handling and containment of these agents as well as decrease the burden for PIs in completing their MUA. The goal is that the BioPUCs will become available for use in this calendar year.

5. MUA (Project) review activities

During the reporting year June 1, 2016-May 31, 2017, the IBC held 12 duly convened meetings to review new MUAs, amendments to approved MUAs and applications for renewal of approved MUAs.

- Review of Exempt projects: One of the Co-Chairs of the IBC or designate or the Biosafety Officer review and approve projects that are Exempt from the NIH guidelines. 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 at least 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 an annual review.
- 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 two 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 classroom 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: Review is by one of the Co-Chairs of the IBC, designated committee member or Biosafety Officer and the IBC administrator. Amendments with only 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 326 MUAs or continuation requests (amendments and annual questionnaires) were reviewed during 2016-17. A breakdown of projects submitted for review during the same periods in 2014-2015, 2015-2016 and 2016-2017 is below:

Classification	Type	Number reviewed during 2014-2015	Number reviewed during 2015-2016	Number reviewed during 2016-2017
Exempt	Section F	5	4	3
	Section F with Biohazards	2	9	7
Non-Exempt	Section D	1	6	6
	Section D with Biohazards	13	45	28
	Section E	0	6	23

	Section E with Biohazards	2	12	14
BSL3 Application		2	0	1
BSL3 Amendment		0	3	0
Biohazards only		16	12	14
Annual Reviews		69	101	132
Amendments		66	81	98
Total reviewed		176*	279	326
MUAs Terminated		11	16	12**

*Note that total number reviewed in 2014-15 is significantly lower than normal, as the expiration dates for all MUAs were extended by six months to allow for migration of the information to the upgraded IBC system. The number of reviews in 2015-16 are back to expected normal levels.

** Terminated MUAs: one PI filed a new 3-year renewal, six left the institution and five are no longer using r/sNA or biohazardous materials in their research.

6. *Adverse Events*

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

- Biosafety Level 3 - During the imaging of macrophage cells infected with live TB, the culture plate well (200 µl) failed resulting in a leak. Risk of exposure was negligible as researchers were in full Personal Protective Equipment, the leak was in containment and appropriate exit procedures were followed.
- Needle stick occurred from a syringe that had contained human epithelial cells. The student was referred to Cornell Health Occupational Medicine.

Adverse Events reported to the NIH:

None

7. *Lab Visits by EH&S Biosafety*

Date	Department	Principal Investigator	Corrective Actions	Discussion Points
2016.07.08	COE - Mechanical & Aerospace Engineering	B. Kirby	None	Sharps handling Hazardous/Infectious materials Waste removal
2016.07.13	CALS Food Science	S. Alcaine	None	New PI Managing workflow with food safe materials and non-food safe materials Autoclave validation
2016.07.18	CAS - Chemistry & Chemical Biology	H. Lin	Update door signage Overflowing biohazard wastes	Multiple injuries Personal protective equipment BBP Training
2016.09.09	CVM - Biomedical Sciences	A. White	None	CRISPR Lentivirus contaminated carcasses Formalin waste Disinfectants
2016.09.16	CALS Food Science	R.H. Liu	Update door signage	Disinfectants Biosafety cabinet procedures
2016.09.19	CALS Plant Pathology	G. Bergstrom	Update door signage	GHS labeling of chemicals PPE Onboarding new students
2016.11.11	CALS Food Science	J. Goddard	None	New PI Sharps PPE MUA Process
2016.12.02	CAS - Neurobiology & Behavior	N. Yapici	None	New PI

2016.12.16	CALS Food Science	S. Nugen	None	New PI Sharps PPE MUA Process
2017.01.05	CALS Food Science	R. Worobo	Update door signage Fire extinguisher needs to be secured	Onboarding, training of new students New equipment – high pressure pasteurization unit
2017.01.13	CALS Food Science	C. Batt	None	Sonication Lab supply purchasing Biosafety
2017.01.25	CVM - Baker Institute for Animal Health	L. Schang	None	Zika PPE Practices Disinfectants BBP training Flu import Moving biologicals
2017.03.02	COE - Biomedical Engineering	I. De Vlaminck	Update door signage	Lab relocation Biosafety cabinets Onboarding new lab members
2017.03.02	COE - Biomedical Engineering	S. Adie	None	Bench coat materials
2017.03.23	Applied & Engineering Physics	H. Craighead	Provide lab coats for personnel	PPE Pass-through personnel
2017.03.29	COE - Biomedical Engineering	M. Shuler	None	Sharps Bunsen burners in BSCs Three dimensional tissue culture
2017.04.07	COE - Biomedical Engineering	C. Fischbach	Waste labeling	PPE Handling of human samples Lab waste management Exposure control plans

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

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

- **Committee was informed of updates and changes to the following regulatory policies**

On January 4, 2017, the U.S. Environmental Protection Agency (EPA), the U.S. Food and Drug Administration (FDA), and the U.S. Department of Agriculture (USDA) released the 2017 Update to the Coordinated Framework for the Regulation of Biotechnology

Document defines:

- Roles and Responsibilities of the Primary Agencies that Regulate the Products of Biotechnology – EPA, FDA and USDA
 - Clarifying Roles and Responsibilities through Case Studies
- Demonstration of the help topic features and review process was given for new members and refresher for continuing members.

9. *Appendix A: Committee Membership*

Voting Members

Colin Parrish (co-Chair)	Professor, James A Baker Institute for Animal Health
Perry, Keith (co-Chair)	Assoc. Professor, Plant Pathology & Plant Microbe Section
Angert, Esther (co-Chair)	Professor, Microbiology
Fuchs, Marc	Assoc. Professor, Plant Pathology & Plant Microbe Section
Felippe, Julia	Assoc. Professor, Clinical Sciences
Hay, Anthony	Assoc. Professor, Microbiology
Lee, Jane	Research Support Specialist III, Biomedical Sciences
Michaels, Christy	Biology Teacher, Community Member, Non-affiliated
Moseley Moore, Cathy	Enrichment Teacher, Community Member, Non-affiliated
Renshaw, Randall	Research Associate, Population Medicine & Diagnostic Sciences
Swingle, Bryan	Assist. Professor, Plant Pathology & Plant Microbe Section
Wang, Ping	Associate Professor, Entomology
Whittaker, Gary	Professor, Microbiology and Immunology
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

Turse, Josh, PhD.	Senior Biosafety Specialist, Environmental Health & Safety
Bitar, Alan	Biosafety Specialist, 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

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 to ensure that they are correctly classified.

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.

Section 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	5
Applied & Engineering Physics	College of Engineering	6
Baker Institute for Animal Health	College of Veterinary Medicine	9
Biochemistry, Molecular & Cellular Biology	CALS	1
Biological Statistics & Computational Biology	CALS	1
Biological & Env. Engineering	CALS	6
Biomedical Engineering	College of Engineering	12
Biomedical Sciences	College of Veterinary Medicine	17
Boyce Thompson Institute		8
Chemical & Biomolecular Eng.	College of Engineering	4
Chemistry & Chemical Biology	College of Arts & Sciences	11
Civil & Environmental Engineering		1
Clinical Sciences	College of Veterinary Medicine	8
Crop & Soil Sciences	CALS	1
Ecology & Evol. Biology	CALS	4
Ecology & Evol. Biology	College of Arts & Sciences	1
Electrical and Computer Engineering	Engineering	1
Entomology	CALS	6
Food Science	CALS	9
Horticultural Sciences	CALS	5
Human Development	CALS	1
Materials Sci. & Engineering	Engineering	1
Mech. And Aero Engineering	Engineering	5
Microbiology	CALS	8
Microbiology & Immunology	College of Veterinary Medicine	16
Molecular Biology & Genetics	College of Arts & Sciences	12
Molecular Biology & Genetics	CALS	13
Molecular Medicine	College of Veterinary Medicine	14
Natural Resources	CALS	1
Neurobiology & Behavior	CALS	6
Neurobiology & Behavior	College of Arts & Sciences	3
Nutritional Sciences	CALS	3
Nutritional Sciences	Human Ecology	9
NYS Animal Health Diagnostic Lab	College of Veterinary Medicine	1
Physics	College of Arts & Sciences	3
Plant Biology	CALS	9
Plant Biology	College of Arts and Sciences	3
Plant Breeding & Genetics	CALS	4
Plant Pathology	CALS	20
Plant Transformation Facility	CALS	1
Pop. Medicine & Diag. Science	College of Veterinary Medicine	11
Psychology	College of Arts & Sciences	2
Quality Milk Production Svc.	College of Veterinary Medicine	1
Weill Institute for Cell & Molecular Biology	Research Centers	3

12. *Appendix D: Lab Facility Information*

The categories and numbers of laboratories (rooms) known to be conducting research at Biosafety levels BL1, BL2 or BL3, as of May 31, 2017, are as follows. This information is provided on the MUAs by researchers:

- 311 laboratories operating at BL1
- 354 laboratories operating at BL2
- 140 BL2-P level greenhouses/growth chambers
- 62 BL1-N animal care rooms
- 103 BL2-N animal care rooms
- 3 facilities operating at BL3
- 1 facility operating at ABSL3