



Cornell University
Office of
Research Integrity and Assurance
Institutional Biosafety Committee

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Institutional Biosafety Committee **Annual Report, June 1, 2018-May 31, 2019**

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1. *Charge to the IBC*

Cornell University's 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's Ithaca campuses (Ithaca, Geneva, Cornell Tech), 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 and 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:

https://researchservices.cornell.edu/sites/default/files/2019-05/IBC_Charge.pdf

2. *Committee Membership*

The committee is Co-Chaired by Professors Colin Parrish and Esther Angert. *Appendix A provides the membership list as of May 31, 2019.* Finding new members is a continuing challenge, and we lack members from some large departments who send us many applications to review. Over the course of the year, the following membership changes occurred:

- The appointments of the following current IBC members were renewed: Julia Felipe, Professor, Clinical Sciences; Bryan Swingle, Assistant Professor, Plant Pathology & Plant-Microbe Biology Section; and Jane Lee, Research Support Specialist III, Biomedical Sciences.
- David Russell, Professor, Microbiology & Immunology and Matthew Willmann, Research Associate Sr., CALS-Plant Transformation Facility were appointed to the IBC through June, 2022. Rhoda Maurer, CALS Greenhouse manager was appointed as an ex-officio non-voting member.
- Gary Whittaker, Professor, Microbiology & Immunology is stepping off the committee June 30, 2019 after 3 terms of excellent service on the Committee.
- Andrew Leed, CALS Greenhouse manager stepped off the committee as he retired from the University.

3. *Active Projects*

The IBC reviews and approves the following categories of projects (detailed explanations of these classifications are 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, **or**
- 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, 2019, there were 298 active MUAs: 294 active MUAs at BSL1 or BSL2 and 4 MUAs at BSL3.

Classification	Type	MUAs Active
Exempt	Section F	31
	Section F with Biohazards	17
Non Exempt	Section D	20
	Section D with Biohazards	124
	Section E	32
	Section E with Biohazards	36
	Biohazards only	34
Biosafety Level 3 practices		4
Active as of May 31, 2019		298

4. *Initiatives managed or supported by the IBC*

- The Association for Biosafety and Biosecurity International sponsored the fifth anniversary of Biosafety Month in October 2018. The theme for the year was “Promoting a Culture of Biosafety and Responsibility.” The IBC participated by sending information focused on practical lab safety habits promoting a culture of biosafety in the lab to all PI’s with an MUA.
- The IBC Chairs received a request from the [U.S. National Authority for the Containment of Poliovirus \(NAC\)](#) at the Centers for Disease Control and Prevention (CDC) to participate in the [National Inventory for Poliovirus Containment](#). The IBC identified Cornell researchers who may test, extract, handle or store biological sample from humans, experimentally infected animals, sewage or environmental waters. These researchers will be contacted by the CDC to complete the inventory survey.

5. *Initiatives managed or supported by ORIA for the IBC*

- The CU-Learn (Learning Management System) has been leveraged to assign training to individuals added to an MUA working with human bloodborne pathogens. The system will automatically send reminders to complete annual training. This allows individuals to have training completed by the time the MUA is approved and decreases administrative time sending reminders.
- ORIA participated in an Administrative Retreat with Cornell Weill to identify areas where burden can be reduced for faculty with research programs at both institutions. Initial areas identified were system differences and different login processes.
- The ORIA website was updated and is now located under the Cornell [Research Services](#) site. The new Cornell Research Services site provides a central resource for information about

managing research at Cornell. Some benefits include a single site address to remember and quick access to important web pages, systems, and tools related to research at Cornell.

6. *MUA (Project) review activities*

During the reporting year June 1, 2018-May 31, 2019, the IBC held 10 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 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 354 MUAs or continuation requests (amendments and annual questionnaires) were reviewed during 2018-19. A breakdown of projects submitted for review during the same periods in 2016-2017 and 2017-2018 is below:

Classification	Type	Number reviewed during 2016-2017	Number reviewed during 2017-2018	Number reviewed during 2018-2019
Exempt	Section F	3	3	4
	Section F with Biohazards	7	7	5
Non-Exempt	Section D	6	1	6
	Section D with Biohazards	28	30	51

	Section E	23	8	9
	Section E with Biohazards	14	8	12
BSL3 Application		1	2	0
BSL3 Amendment		0	0	4
Biohazards only		14	14	20
Annual Reviews		132	152	140
Amendments		98	101	103
Total reviewed		326	326	354
MUAs Terminated		12	0	15

7. *Adverse Events*

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

Adverse Events reported to the NIH-Office of Science Policy (OSP):

- A graduate student was working within a BSL2 laboratory where research with human cell lines was being conducted. In preparation for a flow cytometry experiment, the student was harvesting MDA-MB-231 human cells transfected with a plasmid, iRFP-C1 which encodes a red fluorescent protein. To harvest the cells, growth medium had been removed from the culture and replaced with phosphate buffered saline. To confirm that the cells had started to release from the culture dish, the student lifted the dish above their face to use the overhead lighting to visualize. A small quantity (approximately 500µL) of buffer with cells splashed on the student's forehead and into their right eye.

Under *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Molecules (NIH Guidelines)*, this is a reportable adverse event as personnel deviated from the approved MUA and failed to follow approved containment conditions.

The Biosafety Officer reviewed the incident with the researcher involved and the senior graduate student in the laboratory. The incident was discussed with the Principal Investigator. The Principal Investigator volunteered that laboratory accidents/incidents are regularly reviewed during weekly lab meetings with the entire group. Review of the incident was reported out at the weekly lab meeting. The incident and actions taken were reported out to the IBC at the monthly meeting. The IBC had no further corrective actions in relation to the incident. NIH-OSP reviewed the information provided in the incident report, and concluded that the actions taken in response to the incident were appropriate.

- Two individuals were conducting a high throughput screening assay within a BSL3 lab where research with *Mycobacterium* was being conducted. During the assay, a container with four 96-well plates of macrophages infected with *Mycobacterium tuberculosis* was dropped on the floor. An observation was made that less than 5 mL of liquid had seeped out of the secondary

containment onto the floor. The container and plates were removed from the floor and placed immediately into a Class II Type B2 biosafety cabinet. Absorbent material was placed on top of the spill and saturated with an accelerated hydrogen peroxide disinfectant. The disinfectant was allowed to remain in situ for five minutes. Subsequently the floor was mopped with a freshly prepared solution of 10% bleach.

Both personnel were wearing standard PPE for work with *Mycobacterium tuberculosis*: facility-specific scrubs, socks, polyurethane clogs, safety glasses, hair bonnet, N95 respirator, safety glasses, disposable isolation gown, and double gloves. While still within the room, the researcher who dropped the material saturated her clogs with appropriate disinfectant. With the assistance of the other researcher, she removed her pants and socks and placed them into an autoclave bag. Subsequently the individual left the room to acquire a fresh pair of scrub pants and socks.

After returning wearing fresh PPE, the assay was completed and incident reported to the Biosafety Engineer and Director of Biocontainment Operations at Cornell College of Veterinary Medicine and subsequently the Cornell University Biosafety Officer.

All personnel working with *Mycobacterium tuberculosis* in Cornell University BSL3 laboratories receive BSL3-specific training and agent-specific training. Training for the BSL3 laboratories includes demonstration of proficiency in a BSL3 environment. Before an individual may work unsupervised, they work under the supervision of an experienced authorized individual until the person demonstrates competency. Additionally, researchers are required to participate in an annual refresher training, which reviews basic principles of working in a BSL3 laboratory and significant changes with the previous year

Under NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Molecules (NIH Guidelines), this is a reportable adverse event as personnel deviated from the approved MUA and failed to follow approved containment conditions.

A deviation was noted as the researcher did not evacuate the room and allow aerosols to settle, but rather, dealt with the spill immediately. The Biosafety Officer reviewed the incident with the researcher involved along with the Principal Investigator. During the incident review, the deviation from SOP for spill cleanup was noted and discussed.

The BSL3 laboratory was shut down for annual maintenance and refurbishment. During this period, equipment was moved creating more accessible bench space.

The incident and actions taken were reported out to the IBC at the monthly meeting. The IBC had no further corrective actions in relation to the incident. NIH-OSP reviewed the information provided in the incident report, and concluded that the actions taken in response to the incident were appropriate.

- A greenhouse facility, located on Cornell University property, caught fire with the greenhouses being destroyed. No individuals were present. The greenhouses contained stable transgenic grapevines. No plants were flowering, and all plants and associated material (soil, pots, bamboo stakes, and benches) were destroyed in the fire.

Under NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Molecules (NIH Guidelines), this is a reportable adverse event as transgenic materials could have potentially been released to the environment.

The incident and actions taken were reported out to the IBC at the monthly meeting. The IBC had no further corrective actions in relation to the incident. NIH-OSP reviewed the information provided in the incident report, and concluded that the actions taken in response to the incident were appropriate.

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

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

- The committee discussed the “[Final Joint Association Comments on Proposed Changes to the NIH Guidelines.](#)”

9. *Appendix A: Committee Membership*

Voting Members

Colin Parrish (co-Chair)	Professor, James A Baker Institute for Animal Health
Angert, Esther (co-Chair)	Professor, Microbiology
Felippe, Julia	Professor, Clinical Sciences
Hay, Anthony	Assoc. Professor, Microbiology
Jander, Georg	Adjunct Professor, Plant Biology Section
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
Russell, David	Professor, Microbiology & Immunology
Swingle, Bryan	Asst. Professor, Plant Pathology & Plant-Microbe Biology Section
Wang, Ping	Professor, Entomology
Whittaker, Gary	Professor, Microbiology and Immunology
Willmann, Matthew	Research Associate Sr., CALS Director Plant Transformation Facility

Ex-Officio, Voting Members

Brubaker, Alexis	Biological Safety Officer, Environmental Health & Safety
Jennette, Paul	Biosafety Engineer, CVM Biosafety Program
John Clarke, M.D	Occupational Medicine, Cornell Health Services

Singh, Bhupinder, D.V.M. Veterinarian, CARE

Ex-Officio, Alternate Voting Members

Turse, Josh, PhD.	Associate Biosafety Officer, Environmental Health & Safety
Mangham, Camaron	Biosafety Specialist, Environmental Health & Safety
Bryant Blank, D.V.M.	Clinical Veterinarian, CARE
Ed Koppel, MD	Occupational Medicine, Cornell Health Services

Ex-Officio, Non-Voting Members

Maurer, Rhoda	Manager Tower Road Greenhouses, CALS
Giannelis, Emmanuel	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	6
Applied & Engineering Physics	College of Engineering	6
Baker Institute for Animal Health	College of Veterinary Medicine	8
Biochemistry, Molecular & Cellular Biology	CALS	1
Biological Statistics & Computational Biology	CALS	1
Biological & Env. Engineering	CALS	6
Biomedical Engineering	College of Engineering	16
Biomedical Sciences	College of Veterinary Medicine	15
Boyce Thompson Institute		8
Chemical & Bimolecular Eng.	College of Engineering	5
Chemistry & Chemical Biology	College of Arts & Sciences	10
Civil & Environmental Engineering	Engineering	2
Clinical Sciences	College of Veterinary Medicine	11
Crop & Soil Sciences	CALS	1
Ecology & Evol. Biology	CALS	5
Ecology & Evol. Biology	College of Arts & Sciences	1
Electrical and Computer Engineering	Engineering	1
Entomology	CALS	5
Food Science	CALS	11
Horticultural Sciences	CALS	7
Human Development	CALS	1
Materials Sci. & Engineering	Engineering	2
Mech. And Aero Engineering	Engineering	5
Microbiology	CALS	8
Microbiology & Immunology	College of Veterinary Medicine	18
Molecular Biology & Genetics	College of Arts & Sciences	15
Molecular Biology & Genetics	CALS	16
Molecular Medicine	College of Veterinary Medicine	14
Natural Resources	CALS	1
Neurobiology & Behavior	CALS	6

Neurobiology & Behavior	College of Arts & Sciences	4
Nutritional Sciences	CALS	3
Nutritional Sciences	College of Arts & Sciences	11
NYS Animal Health Diagnostic Lab	College of Veterinary Medicine	0
Physics	College of Arts & Sciences	2
Plant Biology	CALS	14
Plant Biology	College of Arts and Sciences	1
Plant Breeding & Genetics	CALS	4
Plant Pathology & Plant-Microbe Biology	CALS	20
Plant Transformation Facility	CALS	1
Pop. Medicine & Diag. Science	College of Veterinary Medicine	15
Psychology	College of Arts & Sciences	2
Quality Milk Production Svc.	College of Veterinary Medicine	1
Weill Inst. for Cell & Molecular Biology	Research Centers	4

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, 2019, are as follows. This information is provided on the MUAs by researchers:

- 278 laboratories operating at BL1
- 370 laboratories operating at BL2
- 114 BL2-P level greenhouses/growth chambers
- 4 facilities operating at BL3
- 1 facility operating at ABSL3