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Institutional Biosafety Committee

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## **Institutional Biosafety Committee** **Annual Report, June 1, 2019 - June 30, 2020**

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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), 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/2020-05/IBC\\_Charge.pdf](https://researchservices.cornell.edu/sites/default/files/2020-05/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 June 30, 2020.*** Finding new members who are knowledgeable in the different areas of the IBC's oversight is a continuing challenge, and we lack members from some large departments that 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: Colin Parrish, Professor, Baker Institute for Animal Health; Esther Angert, Professor, Microbiology; Georg Jander, Professor Adjunct, Boyce Thompson Institute; Ping Wang, Professor, Entomology; Christy Michaels, Community Member; Cathy Moseley Moore, Community Member.
- Luis Schang, Professor, Baker Institute for Animal Health was appointed to the IBC through June 2023.
- Julia Felipe, Professor, Clinical Sciences stepped down from the committee as she was appointed as a Provost's Fellow for Public Engagement.
- Joshua Turse, PhD., was promoted to Biosafety Officer.
- Stephanie Mattoon, Biosafety Specialist was appointed the ex. officio, alternate voting member to Dr. Turse.

## 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, which 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 June 30, 2020, there were 314 active MUAs: 307 MUAs at BSL1 or BSL2 and 7 MUAs at BSL3.

Classification	Type	MUAs Active
Exempt	Section F	35
	Section F with Biohazards	11
Non Exempt	Section D	25
	Section D with Biohazards	128
	Section E	34
	Section E with Biohazards	33
	Biohazards only	41
Biosafety Level 3 practices		7
<b>Active as of June 30, 2020</b>		<b>314</b>

**4. *Initiatives managed or supported by the IBC***

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 currently or in the past may have tested, extracted, handled or stored biological samples from humans, experimentally infected animals, sewage or environmental waters. These researchers were contacted by the CDC to complete the inventory survey. The IBC Administrator is continuing to follow up with Cornell researchers. As of 6/16/2020, 27 out of 35 researchers have responded.

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

- Mark Hurwitz, PhD., was named Interim Chief Research Compliance Officer.
- Debra Dwyer was promoted to Senior Institutional Biosafety Committee Administrator
- Michael Betteken, PhD., was appointed Institutional Biosafety Committee Administrator.

- 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. EHS Biosafety updated the training to be web-based for both initial and refresher training, providing easier access to students and researchers.
- The ORIA website is located under the Cornell [Research Services](#) site. The 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, 2019 - June 30, 2020, 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 designee or the Biosafety Officer reviews, confirms the classification of projects that are Exempt from the NIH guidelines and approves the submission. Those 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, who prepare a summary. Those are then discussed by the full committee at a convened meeting, which issues the formal approval. Approvals are granted for a period of three years and are contingent upon the successful completion of annual reviews.
- 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 requiring a more thorough review are reviewed at a regularly scheduled full committee meeting.

A total of 402 MUAs or continuation requests (amendments and annual questionnaires) were reviewed during 2019-20. A breakdown of projects submitted for review during the same periods in 2017-2018 and 2018-2019 is below:

Classification	Type	Number reviewed During 2017- 2018	Number reviewed during 2018-2019	Number reviewed during 2019-2020
Exempt	Section F	3	4	6
	Section F with Biohazards	7	5	3
Non-Exempt	Section D	1	6	15
	Section D with Biohazards	30	51	41
	Section E	8	9	16
	Section E with Biohazards	8	12	14
BSL3 Application		2	0	5
BSL3 Amendment		0	4	3
Biohazards only		14	20	16
Annual Reviews		152	140	138
Amendments		101	103	145
<b>Total reviewed</b>		326	354	402
MUAs Terminated		0	15	8

**COVID-19 related information:** In March 2019, owing to the heightened risk of COVID-19 transmission, the Provost and Vice Provost for Research directed researchers to suspend non-essential laboratory and field research activities. During this time, the IBC continued to review and approve MUAs, annual reviews and amendments so that approvals would be in place when researchers returned to work. The IBC expedited reviews of four BSL3 MUAs and 19 amendments that were deemed essential work by the SARS-CoV-2/COVID-19 Rapid Research Response review. Subject matter experts sitting on the IBC handled these expedited reviews.

## 7. *Adverse Events*

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

- On September 18, 2019 a graduate student researcher from a lab that works with *Mycobacterium tuberculosis* reported that they noticed a leak from a culture vessel containing *M. tuberculosis*. The culture vessel was inside a 37°C incubator routinely used for culture work in a BSL3 facility. The culture vessel used was a disposable T75 tissue culture flask with 40 mL of 7H9 with OADC medium, inoculated with a multiple resistant, genetically modified variant of the *Mycobacterium tuberculosis* Erdman strain. This particular isolate had been selected on streptomycin containing medium, transformed with an integrating plasmid that contained hygromycin resistance and transfected with a mariner transposon carrying kanamycin resistance. The researcher inoculated the culture and placed it on the upper shelf, in the back-left corner of the 37°C incubator. When the researcher retrieved the culture, they noticed that the medium had drained from the culture vessel. They immediately alerted Cornell Biosafety, initiating a spill response. Per Cornell spill response, the researcher cleared the lab, removing outer PPE as they stepped through the doorway, and alerted lab mates in adjacent labs, warning them not to enter the room. Cornell Biosafety contacted all personnel.

Immediate actions: The Cornell Associate Biosafety Officer and a technician from Cornell CVM Biocontainment responded to the leak within 5 minutes of notification. All materials and shelves were removed from the incubator, to an adjacent biosafety cabinet. All materials were treated with Amphyd disinfectant while being removed. No liquid was observed on the shelves, walls, floor, or top of the incubator, though dried residue was found on the upper shelf of the incubator, directly under where the suspect culture vessel was situated. Visual inspection of the culture vessel was unable to determine the cause of the failure.

Deviations: There were no violations/deviations of institutional policy or laboratory SOPs involved in this incident. This incident involved a leak caused by faulty plastic ware.

PPE: All researchers wear a standard set of PPE, consisting of facility-specific scrubs, clogs, gown, N95 or powered air-purifying respirator, and double gloves.

Occupational Medical Requirements: All personnel working with *Mycobacterium tuberculosis* are in a medical surveillance program. Two components of the program are biannual testing Tb response through PPD or similar means and annual respirator fit testing. Injury or Illness and Medical Surveillance: There were no reported injury or illness, and exposure risk is low, particularly since there was no energy imparted to this material and appropriate PPE is used. Since there is low potential exposure, Cornell is working with researchers to determine subsequent medical testing and surveillance.

Equipment Failure: a disposable T75 flask

- The incident occurred in a tissue culture room approved for BSL2 work on Thursday, January 23, 2020, at 11:30 AM. While performing a routine viral-transfection in the biosafety cabinet, the graduate student accidentally pressed the release button of a 1 ml pipet, which was loaded with 4th generation lentivirus carrying the plasmid FUW-tetO-hOKMS (Addgene number 51543). The solution landed on the surface (inside) of the biosafety cabinet, but some of the liquid splashed through the biosafety cabinet opening, landing on the left leg of the graduate student's pants. The lentivirus was in a DMEM solution with 10% FBS. The graduate student was wearing a lab coat, two sets of gloves and denim pants at the time of the incident. However, the coat did not prevent the lentivirus containing-media from soaking through to the level of the user's pants. No one else was present in the room at the time of the incident. Once the incident occurred, the pants were removed and the area of skin that received the splash was washed thoroughly for 15 minutes, with a change of clothes acquired from another student who was not exposed to the room or contaminated clothing. The graduate student promptly contacted Cornell Health and was advised to see a doctor. The Graduate student then went home to get new clothing, contacted Cornell Health, and was given an appointment at 2:30 p.m. with a Cornell Physician. During the medical appointment, the graduate student was prescribed two medications to be taken for the remainder of the week, Truvada and Isentress. The nature of the medication is preventative, to reduce theoretical gene insertion, since no open wounds were located where splash occurred and since HIV risk is negligible with 4th generation lentivirus. The PI contacted the Cornell IBC to report the potential exposure on the day of the incident and filed a Cornell University Injury/Illness/Exposure Report. The student was up to date on their Bloodborne Pathogens Training for Research and Diagnostic Personnel. There were no equipment failures. Cleanup of the affected area of the splash in the biosafety cabinet was handled in accordance to EHS Cornell guidelines, where the area was covered with paper towel and disinfectant.

#### 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 was updated on:

- Animal and Plant Health Inspection Service, USDA: Movement of Certain Genetically Engineered Organisms Proposed rule: proposing to revise our regulations regarding the movement (importation, interstate movement, and environmental release) of certain genetically engineered organisms in response to advances in genetic engineering and our understanding of the plant pest risk posed by them, thereby reducing regulatory burden for developers of organisms that are unlikely to pose plant pest risks. <https://www.federalregister.gov/documents/2019/06/06/2019-11704/movement-of-certain-genetically-engineered-organism>.
- NIH released [FAQs – Interim Laboratory Biosafety Guidance for Research with SARS-CoV-2 and IBC Requirements under the NIH Guidelines](#)



- NIH [Release of Client-Owned Animals After Participation in Research Subject to the NIH Guidelines](#)
- CRISPR Cas9 Genome editing and the ethics associated with it, was offered via a Responsible Conduct of Research symposium on campus. All researchers and graduate students were invited, and the subject matter was of great interest to those holding a Memorandum of Understanding and Agreement with the IBC.

## 9. *Appendix A: Committee Membership*

### **Voting Members**

Colin Parrish (co-Chair)	Professor, James A Baker Institute for Animal Health, Microbiology & Immunology
Angert, Esther (co-Chair)	Professor, Microbiology
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
Schang, Luis	Professor, James A Baker Institute for Animal Health, Microbiology & Immunology
Wang, Ping	Professor, Entomology
Willmann, Matthew	Research Associate Sr., CALS Director Plant Transformation Facility

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

Turse, Joshua	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**

Mattoon, Stephanie	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



Charles Van Loan  
Christine Bellezza

Dean of Faculty  
Interim Director of Office of Research and Integrity

## 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 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*

<b>AGRICULTURE &amp; LIFE SCIENCES</b>	<b>101</b>
Animal Science	6
Biological and Environmental Engineering	6
Biological Statistics & Computational Biology	1
CALS Dean-Administration	1
Crop and Soil Sciences	1
Ecology and Evolutionary Biology (S)	5
Entomology (S)	5
Food Science (S)	12
Horticulture	1
Microbiology	8
Molecular Bio and Genetics (S)	14
Neurobiology & Behavior (S)	4
Nutritional Sciences AG	4
Plant Biology (S)	10
Plant Biology (S) 185	3
Plant Breeding	5
Plant Pathology (S)	15
<b>ARTS AND SCIENCES</b>	<b>42</b>
Chemistry And Chemical Biology	11
Ecology And Evolutionary Biology (E)	2
Molecular Bio and Genetics (E)	16
Neurobiology & Behavior (E)	6
Physics	2
Plant Biology (E)	1
Psychology	4
<b>BOYCE THOMPSON INSTITUTE</b>	<b>10</b>
Boyce Thompson Institute	10
<b>ENGINEERING</b>	<b>41</b>
Applied & Engr Physics	7
Biomedical Engineering	19
Chemical and Biomolecular Engineering	6
Civil & Environmental Engineering	2
Materials Science & Engineering	2
Mechanical & Aerospace Engineering	5
<b>GENEVA</b>	<b>12</b>
Entomology-Geneva	2

Horticultural Sciences-Geneva	5
Plant Pathology-Geneva	5
<b>HUMAN ECOLOGY</b>	<b>10</b>
Human Ecology Administration	1
Nutritional Sciences HE	9
<b>RESEARCH-CENTERS</b>	<b>4</b>
Weill Institute for Cell and Molecular Biology	4
<b>VETERINARY MEDICINE</b>	<b>88</b>
Baker Institute for Animal Health	9
Biomedical Sciences	14
Clinical Sciences	13
Microbiology & Immunology	19
Molecular Medicine	13
Population Medicine & Diagnostic Sciences	18
Quality Milk Production Services	1
Vet Administration	1
<b>VP/RESEARCH</b>	<b>3</b>
Inst for Biotechnology & Life Science Tech (E)	2
Vice Provost for Research	1
<b>Grand Total</b>	<b>311</b>

## 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 June 30, 2020, 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 BSL3
- 1 facility operating at ABSL3