Cornell University
Office of
Research Integrity and Assurance
Institutional Biosafety Committee

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Institutional Biosafety Committee
Annual Report, June 1, 2017-May 31, 2018

Contents

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 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 Esther Angert. ***Appendix A provides the membership list as of May 31, 2018.*** Over the course of the year the following membership changes occurred:

- Adjunct Professor Georg Jander, CALS-SIPS- Plant Biology Section was appointed to the committee July 1, 2018, as a voting member.
- Joshua Turse and Camaron Mangham, Associate Biosafety Officer and Biosafety Specialist respectively, from the Office of Environmental Health and Safety, were appointed as voting ex-officio alternate to the Biosafety Officer.
- The appointments of the following current IBC members were renewed: Christy Michaels, Cathy Mosely Moore, non-affiliated community voting members.
- Dr. John Clarke, Occupational Medicine Physician was appointed to the committee as ex-officio voting member and Dr. Ed Koppel's appointment was changed to ex-officio alternate to the Occupational Medicine Physician.
- Marc Fuchs, Professor, Plant Pathology & Plant Microbe Section and Randall Renshaw, Research Associate, Population Medicine & Diagnostic Sciences will be stepping off the committee June 30, 2018.

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, 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, 2018, there were 296 active MUAs: 292 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	20
	Section D with Biohazards	102
	Section E	35
	Section E with Biohazards	35
	Biohazards only	41
Biosafety Level 3 practices		4
Active as of May 31, 2018		**296**

4. *Initiatives managed or supported by the IBC*

- NIH Office of Science Policy announced October 2017 as National Biosafety Month. In concert with National Biosafety Month, the IBC and EHS Biosafety team announced the newly developed Biological Agent Reference Sheet (BARS) developed by the Biosafety team in collaboration with faculty and other subject matter experts. The BARS provide information on the agent, health hazards, laboratory hazards, laboratory handling guidelines, exposure and spill procedures, and containment requirements in a two-page document. The BARS can also be used as a training tool through CULearn. The purpose of these documents is to provide standardized safety practices across campus and help reduce administrative burden for faculty and professional staff, since their use eliminates the need for writing and reviewing separate standard operating procedures.

- Dr. Tony Shelton received an USDA-BRS permit to conduct a mark/release/recapture study of transgenic diamond back moths (genetically modified with a female lethal phenotype) in an open field release. The IBC reviewed the work looking at risk assessment and protocols in place to control the release and follow the life cycle of the moths. The IBC issued approval for this novel research contingent after the PI had demonstrated that he had met the requirements of the USDA–BRS permit.

- The IBC provided risk assessment and support for the establishment of a cell sorting core facility at the Vet School capable of analyzing risk group 2 agents.

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 blood borne pathogens and to 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.

6. *MUA (Project) review activities*

During the reporting year June 1, 2017-May 31, 2018, 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 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 2017-18. A breakdown of projects submitted for review during the same periods in 2015-2016, 2016-2017 and 2017-2018 is below:

Classification	Type	Number reviewed during 2015-2016	Number reviewed during 2016-2017	Number reviewed during 2017-2018
Exempt	Section F	4	3	3
	Section F with Biohazards	9	7	7
Non-Exempt	Section D	6	6	1
	Section D with Biohazards	45	28	30
	Section E	6	23	8
	Section E with Biohazards	12	14	8
BSL3 Application		0	1	2
BSL3 Amendment		3	0	0
Biohazards only		12	14	14
Annual Reviews		101	132	152
Amendments		81	98	101
Total reviewed		279	326	326
MUAs Terminated		16	12	0

7. *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 incidents were handled according to applicable Cornell policies and regulatory requirements.

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

- A transgenic mouse bit a student while he was performing procedures listed in an approved animal use protocol and memorandum of understanding and agreement with the IBC. The student preformed standard first aid by washing the wound with soap and water, reported to his supervisor and filed a Cornell University injury/Illness/Exposure Report. The student was counseled to look for signs of inflammation or swelling or infection and to report any concerns immediately. The supervisor was in contact with the student in the days after the incident and was able to confirm that the wound has healed and there have been no signs of further injury associated with the incident.

  Under *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Molecules* (*NIH Guidelines*), this is a reportable adverse event. There were no deviations from the IBC approved containment level or practices described in the approved Memorandum of Understanding and Agreement but rather the incident occurred due to inherent risk of working with mice.

As follow up the animal room supervisor reviewed the animal handling SOP with the student and observed the student handling mice. The supervisor reported that the student understood the SOP and was proficient in handling the animals safely and in accordance with the SOP. 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 plant that had been transiently infected with a genetically modified, disarmed, Agrobacterium tumefaciens expressing luciferase was moved on an open tray without cover from the greenhouse to a shared core imaging facility, housed within a vivarium.

  This is an adverse event under the *NIH Guidelines* as personnel deviated from the approved MUA and failed to follow approved containment conditions. As follow up the Biosafety Officer and IBC Administrator attended the research lab's weekly group meeting. The conditions of the MUA and the following sections of the *NIH guidelines* Section III-E-2, Appendix G-II and Appendix P-II-B were discussed. The biosafety officer discussed the concerns of open soil being transported through the vivarium, and the need for proper disinfectant as the equipment is shared and used with live mouse experiments. To mitigate risk of possible contamination from soil microbes, the lab agreed that they would use plant cuttings instead of transporting a whole plant. The plant material will be transported in a closed container.

  The incident was reported out to the Cornell IBC. The IBC agreed with the actions taken. Additionally, the shared facility is re-evaluating their SOP's for training users of non-traditional use of the instrumentation. The incident is still under review by NIH-Office of Science Policy.

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 a research article "Adaptive risk management in gene drive experiments: biosafety, biosecurity and ethics" and the need to watch for the possibility of gene drive experiments when reviewing MUA's as they may require additional risk assessment and containment practices.

- The Committee discussed "Construction of an infectious horse poxvirus vaccine from chemically synthesized DNA fragments" in the context of Dual use of research of concern and the biosafety / biosecurity concerns associated.

- Biosafety updated the IBC throughout the year on the changes to Adoption of Final Rule: 6 NYCRR Parts 360-366 and 369, Solid Waste Management sections 360 and 365.

- The committee discussed the USDA Plant Breeding Innovation. "Under biotechnology regulations, USDA does not currently regulate, or have any plans to regulate plants that could otherwise have been developed through traditional breeding techniques as long as

they are developed without the use of a plant pest as the donor or vector and they are not themselves plant pests."

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
Fuchs, Marc	Professor, Plant Pathology & Plant Microbe Section
Felippe, Julia	Assoc. 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
Swingle, Bryan	Assist. Professor, Plant Pathology & Plant Microbe Section
Wang, Ping	Professor, Entomology
Whittaker, Gary	Professor, Microbiology and Immunology

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

Leed, Andrew	Manager Tower Road Greenhouses, CALS
Emmanuel Giannelis	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	7
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	1
Clinical Sciences	College of Veterinary Medicine	11
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	12
Horticultural Sciences	CALS	6
Human Development	CALS	2
Materials Sci. & Engineering	Engineering	1
Mech. And Aero Engineering	Engineering	5
Microbiology	CALS	9
Microbiology & Immunology	College of Veterinary Medicine	19
Molecular Biology & Genetics	College of Arts & Sciences	14
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	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	11
Plant Biology	College of Arts and Sciences	2
Plant Breeding & Genetics	CALS	4
Plant Pathology	CALS	22
Plant Transformation Facility	CALS	1
Pop. Medicine & Diag. Science	College of Veterinary Medicine	13
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, 2018, are as follows. This information is provided on the MUAs by researchers:

- 247 laboratories operating at BL1
- 345 laboratories operating at BL2
- 118 BL2-P level greenhouses/growth chambers
- 64 BL1-N animal care rooms
- 106 BL2-N animal care rooms
- 4 facilities operating at BL3
- 1 facility operating at ABSL3