Cornell University
Office of
Research Integrity and Assurance
Institutional Biosafety Committee

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Institutional Biosafety Committee
Annual Report, 2010-2011

Contents

1. Project Review Activities

The IBC reviews and approves the following categories of projects:

- Projects with rDNA use:
    - Exempt from the NIH guidelines (Class F)
    - Non-Exempt Projects (classified as Class D or E)
- Projects with Biohazardous Materials

Detailed explanation of the classification is provided in Appendix A.

During the fiscal year 2010-2011 the IBC held eight duly convened meetings to review new Memoranda of Understanding and Agreements (MUA), amendments to approved MUAs and applications for renewal of approved MUAs. The meetings scheduled for August, January, March and June were cancelled because there were insufficient items on the agenda requiring the committee to convene.

The numbers of projects by classification are provided below:

a. Active Research Projects registered with the IBC:
There were 228 active research projects as of July 30, 2011.

Classification	Type	MUAs Active
Exempt	Class F	48
	Class F with Biohazards	21
Non Exempt	Class D	11
	Class D with Biohazards	52
	Class E	53
	Class E with Biohazards	22
	Biohazards only	18
Biosafety Level 3		3
Total Active as of July 30, 2011		**228**

b. Research projects reviewed during 2010-11

i. Review of Exempt projects: 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.
ii. Review of Non Exempt MUAs and MUAs with Biohazards: 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).
iii. 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, Bioengineer, 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.
iv. Annual questionnaires and MUA amendments are reviewed by the IBC Chair or Biosafety Officer and the IBC administrator. Amendments with personnel and facility changes are approved administratively.

A total of 354 MUA's or continuation forms (amendments and annual questionnaires) were reviewed during 2010-11. The following table indicates the breakdown of projects submitted for review.

Classification	Type	Number reviewed during 2010-11
Exempt	Class F	3
	Class F with Biohazards	9
Non-Exempt	Class D	5
	Class D with Biohazards	6
	Class E	21
	Class E with Biohazards	1
BSL3		2
Biohazards only		8
Annual Questionnaires		182
Amendments		60
MUAs Terminated		57
Total reviewed		354

2. MUAs by Department

The IBC receives protocols from researchers at all Ithaca campus colleges, the Geneva Agricultural Experiment Station, the Baker Institute for Animal Health, the Boyce Thompson Institute for Plant Research and the USDA, ARS laboratories. A breakdown of MUAs submitted by college or unit during 2010-2011, is available as Appendix B of this document.

3. Laboratory spaces and facilities by Biosafety Level:

According to the information provided on the MUAs by researchers, the following laboratories (rooms) are known to be conducting research at Biosafety levels BL1, BL2 or BL3. The breakdown according to Biosafety level is as follows:

- 311 laboratories operating at BL1
- 198 laboratories operating at BL 2
- 136 BL2-P level greenhouses/growth chambers
- 47 BL1-N
- 62 BL2-N animal care facilities
- 3 laboratories operating at BL 3

4. **Important Issues discussed by the IBC:**

- **Summary Approval timeline metrics are as follows:**
    - 23 MUA's were reviewed in a typical review cycle taking an average of 43 days to approval
    - 11 MUA's were reviewed in an atypical review cycle as a monthly meeting was skipped due to insufficient items on the agenda. These MUAs required an average of 53 days to approval.
    - 6 MUA's required several rounds of revisions by the PI and therefore took 161 days to approval.

- **Discussions on Review of use of rDNA and biohazardous materials in the teaching lab**
    - The IBC discussed whether or not the review of teaching activities involving the use of biohazardous materials and rDNA, should continue to be reviewed by the IBC. The current application form and process are not designed for teaching activities; therefore some thought needs to go into how to ensure safety of personnel from using these materials, while maintaining a streamlined process for review and approval of these activities. This topic will be discussed further with EH&S and seek institutional input.

- **Tour of Biosafety Level 3 (BSL3) Facility:**
    - September 2010 the IBC toured the East Campus Research Facility BSL3 facility. The facility was still undergoing minor repairs and testing. Final approval of the facility by the IBC is pending completion of the remaining steps.

- **Proposed Changes to the Electronic Form – eMUA**
    - To provide a better decision making tool for PI's in determining if their work is exempt under NIH guidelines
        - The Committee revised questions to help direct self-classification and approved the changes.
        - It is expected that these changes will be implemented in late 2011.

- **Select Agent Program**

    - The Committee was informed by the Biosafety Officer that as of July 8, 2011 Cornell University does not have a Select Agent Program.

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

    - Exposure of eye to listeria culture stock.
    - Possible exposure to West Nile Virus due to dropping a culture plate outside the biosafety cabinet.

- **Biosafety Lab Visits Reported to IBC** – the Biosafety Officer conducted lab visits to the following: new faculty member's labs or labs that were adding new work to their IBC MUA's.

    - Dr. Matthew Delisa - Chemical and Biomolecular Engineering – Exempt work with E. coli K12 as the host strain.
    - Dr. Daniel Buckley - Crop and Soil Science – Exempt work with E. coli K12 and with biohazard Enteropathogenic E. coli at BSL2.
    - Dr. Ruth Ley – Microbiology – Exempt work with E. coli K12 and work with human fecal samples at BSl2
    - Dr. Gerald Duhamel - Biomedical Sciences – Nonexempt rDNA working with multiple risk group 2 bacteria at BSL2.
    - Dr. Xiling Shen - Electrical and Computer Engineering – Exempt work with E. coli K12 and nonexempt work with risk group 2 bacteria and human cell lines at BSL2.
    - Dr. Claudia Fischbach – Nonexempt rDNA work with Lentiviral vectors and biohazardous work with human cell lines at BSL2.

5. **Administrative updates:**

- **Enhancements to the current electronic form:**

    - Implemented Electronic signatures for the PI and Lab contact at time of approval of the questionnaire and amendments
    - Added private comment boxes for the reviewers
    - Added automatic notification to the Chair of the Subcommittee when all members' reviews are in.

- **Re-design of the MUA form:**

  - The IBC continues to collect information and consider the best approach for the new application to collect the information necessary but decrease duplication for the PIs concerning animal use information already collected by the IACUC. We will continue to address the revision of the MUA to meet the evolving needs of the IBC and the institution's need to better coordinate compliance related information across multiple compliance functions such as the IRB and the IACUC.

6. Committee Education:

- The following documents from NIH were discussed at the committee meetings Federal Register Vol. 76, No. 12 Discussed changes to Appendix C-VII. Generation of BL1 Transgenic Rodents via Breeding

- The Biosafety Officer brought the journal article Fatal Laboratory –Acquired Infection with an Attenuated *Yersinsi pestis* Strain – Chicago, Illinois, 2009 Morbidity and Mortality Weekly Report, Vol.60, No. 7, Feb. 25, 2011

- Discussed – Federal Register, Vol., No. 130: Executive Order on Optimizing the Security of Biological Select Agents and Toxins in the United States

7. Committee membership: Appendix C

- No new members were appointed during FY 2010-2011.
- Cathy Moseley Moore was reappointed as a community member for a second term.
- Stephan Menne resigned from the committee as he has left the institution.
- Rosemary Loria resigned from the committee as she has left the institution.

We are currently seeking new committee members with special need in the disciplines of virology, and plant pathology. We also feel that the expertise of a faculty member from Biomedical Engineering would be a huge asset to the committee.

8. Appendix A: Classification definitions from the NIH Guidelines 2011

Exempt Experiments

Section III-F.

The following recombinant DNA molecules are exempt from the *NIH Guidelines* and registration with the Institutional Biosafety Committee is not 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 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.

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 DNA; (ii) the nature of the inserted DNA 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

9. Appendix B: Number of Active MUAs by Unit/Department

Department	College	# MUA
Animal Science	CALS	6
Applied & Engineering Physics	College of Engineering	2
Baker Institute for Animal Health	College of Veterinary Medicine	7
Biochemistry, Molecular and Cellular Biology		1
Biological Statistics and Computational Biology	CALS	1
Biological & Env. Engineering	CALS	6
Biomedical Engineering	College of Engineering	8
Biomedical Sciences	College of Veterinary Medicine	12
Boyce Thompson Institute		10
Chemical & Bimolecular Eng.	College of Engineering	5
Chemistry & Chemical Biology	College of Arts & Sciences	6
Civil & Environmental Eng.	College of Engineering	1
Clinical Sciences	College of Veterinary Medicine	6
Crop & Soil Sciences	CALS	2
Ecology & Evol. Biology	College of Arts & Sciences	3
Electrical and Computer Engineering	Engineering	2
Entomology	CALS	7
Food Science	CALS	4
Horticultural Sciences	CALS	8
Mech. And Aero Engineering	Engineering	2
Microbiology	CALS	9
Microbiology & Immunology	College of Veterinary Medicine	15
Molecular Biology & Genetics	College of Arts & Sciences	18
Molecular Biology & Genetics	CALS	14
Molecular Medicine	College of Veterinary Medicine	7
Natural Resources	CALS	1
Neurobiology & Behavior	College of Arts & Sciences	5
Nutritional Sciences	CALS	2
Nutritional Sciences	Human Ecology	8
Physics	College of Arts & Sciences	3
Plant Biology	CALS	3
Plant Biology	Arts and Sciences	11
Plant Breeding & Genetics	CALS	8
Plant Pathology	CALS	18
Pop. Medicine & Diag. Science	College of Veterinary Medicine	7
Quality Milk Production Svc.	College of Veterinary Medicine	1
Vet Administration	College of Veterinary Medicine	1
Weill Institute for Cell and Molecular Biology	VPR	1

10. Appendix C. Committee membership:

Craig Altier ca223@cornell.edu **Microbiology**	Assoc. Professor Population Medicine and Diagnostic Sciences D2 031 Vet College	253-3926	2012
Scott Butler sdb9@cornell.edu **Lab Research member**	Research Support Specialist II Biomedical Sciences Vet Research Tower, Room T9-007	253-3733	2013
Cantone, Frank A. fac2@cornell.edu **Biosafety Officer**	Biological Safety Officer 395 Pine Tree Road, Suite 210	254-4888	
Jennette, Paul jpj22@cornell.edu **Biosafety Engineer**	Biosafety Engineer CVM Biosafety Program S2-060 Schurman Hall	253-4227	2012
Michaels, Christy cmichae1@dryden.k12.ny.us **Non-affiliated member**	Biology Teacher	749-2776 844-8694 (work)	2012
Moseley Moore, Cathy cathy.moseley@lcsd.k12.ny.us **Non-affiliated member**	Enrichment Teacher	533.4652 x 3286	2014
Mutschler-Chu, Martha mam13@cornell.edu **Plant Breeding**	Professor Plant Breeding and Genetics 303 Bradfield Hall	255-1660	2013
Parker, John jsp7@cornell.edu **Virology**	Assoc. Professor, Baker Institute Animal Health College of Vet. Medicine	256-5626	2012
Perry, Keith klp3@cornell.edu **Plant Pathology**	Assoc. Professor Plant Pathology 210 Bradfield Hall	254-8243 255-9744	2012
Quaroni, Andrea aq10@cornell.edu **Physiology**	Professor Biomedical Sci T8 008 A Vet Research Tower	253-3463	2013
Soderlund, David dms6@cornell.edu **Chair, Entomology**	Professor and Chair Department of Entomology Director, Northeast Regional IR-4 Program NYSAES, Cornell University	315-787-2364	2012

Whittaker, Gary grw7@cornell.edu **Virology**	Professor VM Microbio & Immun C4 127 Vet Med Center	253-4019	2013
Wilson, David dbw3@cornell.edu **Biochemistry** **Molecular Biology**	Professor Molecular Biology and Genetics 458 Biotechnology	255-5706	2013

These positions will be permanently represented on the Committee:

Ex-Officio, Voting Members

Todd Pavek, D.V.M. tjp46@cornell.edu Alternate for voting **Veterinarian**	Clinical Veterinarian Vet Research Tower Room 1-010	253-3058
Bhupinder Singh, D.V.M. bs256@cornell.edu **Veterinarian**	Veterinarian Vet Research Tower Room T1010M	253-4193
Relford Patterson, M.D. rep86@cornell.edu **Occupational Medicine Physician**	Director of Occupational Medicine 110 Ho Plaza Ithaca, NY 14850	255-5155

Ex-Officio, Non-Voting Members

Leed, Andrew arl6@cornell.edu **Greenhouse Manager**	Manager Tower Road Greenhouses Kenneth Post Greenhouse	p. 254-7266 f. 255-4457
Hsiao, Vivian vh14@cornell.edu	Nurse Practitioner Gannett Health Services	p. 255-6960
Buhrman, Robert A. Ph.D. rab8@cornell.edu	Senior Vice Provost for Research 222 Day Hall	p.255-3732 f. 255-7200
Fry, William, Ph.D wef1@cornell.edu	Dean of Faculty Prof. of Plant Pathology 315 Day Hall	p. 255-4843
Long, Cathy cel3@cornell.edu	Associate Vice President of Research 222 Day Hall	p.255-2946
Verma, Amita av234@cornell.edu	Interim Director ORIA 395 Pine Tree Road, Suite 320	p. 255-2214 f. 255-0758