Cornell University
Office of
Research Integrity and Assurance
Institutional Biosafety Committee

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Institutional Biosafety Committee
Annual Report, 2011-2012

Contents

1. Change to Committee Membership – (Membership list in Appendix C)

- June 30, 2012 - David Soderlund, Department of Entomology, stepped down after serving two terms as Chair of the IBC
- John Parker, James A. Baker Institute of Animal Health, stepped down after serving two terms
- July 1, 2012 –Craig Altier, Assoc. Prof., Department of Population Medicine and Diagnostic Sciences, was appointed Chair of the IBC
    - New members starting July 2012:
        - Randall Renshaw, PhD, Department of Population Medicine and Diagnostic Sciences
        - Prof. Helene Marquis, Microbiology and Immunology
        - Prof. Marc Fuchs, Plant Pathology
        - Prof. Douglas Knipple, Entomology
        - Alexis Brubaker, Associate Biosafety Officer, voting alternate for Biosafety Officer

2. 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 2011-2012 the IBC held eleven duly convened meetings to review new Memoranda of Understanding and Agreements (MUA), amendments to approved MUAs and applications for renewal of approved MUAs.

The meeting scheduled for March was cancelled due to insufficient items.

The numbers of projects by classification are provided below:

a. Active Projects registered with the IBC:
There were 239 active projects as of June 30, 2012.

Classification	Type	MUAs Active
Exempt	Class F	53
	Class F with Biohazards	21
Non Exempt	Class D	10
	Class D with Biohazards	61
	Class E	48
	Class E with Biohazards	23
	Biohazards only	21
Biosafety Level 3		2
Active as of June 30, 2012		**239**

b. Projects reviewed during 2011-12

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, Biosafety Engineer, 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. Amendments that are adding a new line of research or work that requires more scrutiny are reviewed at full committee.

A total of 352 MUA's or continuation forms (amendments and annual questionnaires) were reviewed during 2011-12. Breakdown of projects submitted for review during the same timeframes in 2010-2011 and 2011-2012 is below:

Classification	Type	Number reviewed during 2010-11	Number reviewed during 2011-12
Exempt	Class F	3	6
	Class F with Biohazards	9	7
Non-Exempt	Class D	5	1
	Class D with Biohazards	6	19
	Class E	21	8
	Class E with Biohazards	1	5
BSL3 Amendment		0	2
Biohazards only		8	10
Annual Questionnaires		182	188
Amendments		60	62
MUAs Terminated		57	42
Total reviewed		352	350

3. MUAs by Department

The IBC receives MUAs from individuals 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 July 1, 2011 through June 30, 2012, is available as Appendix B of this document.

4. Laboratory spaces and facilities by Biosafety Level:

According to the information provided on the MUAs by researchers, the following laboratories (rooms) as of July 1, 2012 are known to be conducting research at Biosafety levels BL1, BL2 or BL3. The breakdown according to Biosafety level is as follows:

- 312 laboratories operating at BL1
- 241 laboratories operating at BL 2
- 140 BL2-P level greenhouses/growth chambers
- 56 BL1-N animal care rooms
- 63 BL2-N animal care rooms
- 3 laboratories operating at BL 3
- 1 laboratory operating at ABSL3

5. Important Issues discussed or approved by the IBC:

- **Biosafety Level 3 (BSL3) Facility Updates:**
  - The IBC approved the certification of the East Campus Research Facility ABSL3 facility in October 2011
  - The IBC toured the NYS Diagnostic Lab BSL3 facility in May 2012.
  - The IBC approved the certification of the BSL3 facility in the NYS Diagnostic Lab and the Veterinary Medical Center, in June 2012.
- **Biosafety Level 3 (BSL3) Actions and updates:**
  - BSL-3 Program Policy Review –Since the conception of the BSL3 program document there has been need for an update to the policies and procedures outlined in the document. A Steering Committee representing all stake holders involved in the administration and management of the BSL3 program at Cornell, was formed to review and update the BSL3 program document. The IBC approved the revised BSL-3 Program Policy in April 2012.
- **Select Agent Program:**
  - The committee was informed at the April 2012 meeting that the research program of a new faculty member at Cornell involves a plant Select Agent**.** EH&S began the process of setting up a Select Agent program and shared the draft Select Agent Program to solicit feedback from the IBC.

- **Vaccinia Virus Policy:**

  - In August 2011 a new faculty member at Cornell proposed use of non-highly attenuated strain of Vaccinia Virus, a research tool used in a variety of biomedical applications. The research included both laboratory and animal experiments. Researchers who engage in activities with non-highly attenuated strains of the virus are at increased risk for laboratory acquired infections, serious complications, and transmission to close personal contacts. The risks of infection are much more serious for individuals who are immune-compromised. Because of these risks, the IBC agreed with the Center for Disease Control Advisory Committee on Immunization Practices (ACIP) recommendation that all medically eligible individuals who work with the virus be immunized. An upper level committee of university administrators worked together to review initial information on Vaccinia virus, the vaccination available and risks to individuals provided by the IBC. A joint recommendation was taken back to the Institutional Biosafety Committee.

  - Consequently, in February 2012 the Cornell University Institutional Biosafety Committee (IBC) approved a policy for individuals working with non-highly attenuated vaccinia viruses and recombinant vaccinia viruses derived from these strains. This policy provides background information about vaccinia virus and affected personnel and provides the administrative, medical counseling and vaccination, and biosafety procedures requirements for working with vaccinia virus.
  - IBC approved the policy February 2012 and it can be viewed at http://www.ibc.cornell.edu/documents/Vaccinia_virus_v1.9_approved.pdf

- **Animal Biosafety Procedure Documents approved by the IBC**

- **Reportable Adverse Events**: The following incidents were reported to the IBC and their outcomes, prevention and follow-up were discussed. All incidents were handled according to applicable Cornell policy and regulatory requirements and reported to the NIH- OBA:

  - **Loss of Containment** –On August 25, 2011 four juvenile transgenic plants were mistakenly moved from the greenhouse to an isolated open air roof top. The plants were immediately returned to the greenhouse when the breach was identified. As the plants were juvenile and non-flowering the risk of cross pollination to the environment was negligible. The PI held refresher training with students and staff emphasizing the NIH regulations for containment of transgenic plants.

  - **Loss of Containment** – On August 25, 2011 a flask containing recombinant E.coli cells in Luria-Bertaini broth fell off a shaker bath during a lab experiment. The Biosafety Officer investigated and worked with the facility on clean-up. The shaker bath was inspected and the springs were replaced prior to putting the shaker bath back into use.

- **Needle stick** – On March 19, 2012 a Post Doc was injecting a mouse with recombinant materials and nicked the cuticle on his finger. The syringe was empty when the incident occurred. At the time of injury the individual cleaned the area with hot water and soap, applied antibiotic ointment and covered with a band aid. No signs of inflammation were found and the individual suffered no side effects or symptoms related to the injury. The student reported the incident immediately through the university reporting system. It was not noticed, until after the 30 day reporting period, that the materials were recombinant. The incident was then immediately reported to NIH-OBA

  It was determined that this incident was an accident and not caused by lack of training or inability to follow proper procedures. The post-doc was following standard operating procedures that had been reviewed and approved by EH&S Biosafety and had prior experience successfully performing these procedures. The PI and the post-doc had determined that in order to avoid any further accidents, the procedure should be done more slowly. EH&S concurred with the assessment. EH&S followed up with a refresher training with the lab, reviewing sharps safety, rodent handling techniques and anesthesia and review of first aid reporting.

- **Biosafety Adverse Events and exposures:** The following incident was reported at full committee meeting, and the outcome, prevention and follow-up was discussed. The incident was handled according to applicable Cornell policies and regulatory requirements.

  - Possible exposure - On August 9, 2011 an individual incurred a possible exposure to Salmonella typhi due to Pasteur pipette breaking and contaminated glass came in contact with bare skin. The skin barrier was not broken and the individuals proceeded to wash the area with alcohol followed by soap and water. The Biosafety Officer consulted with Gannett Health Services, Occupational Medicine department. It was concluded that the risk of exposure to *S. typhi* was minimal. The bacterium is normally transmitted via ingestion and no evidence could be found for induction of disease through dermal contact. The Biosafety Officer immediately contacted the individual to inform her that medical evaluation was not indicated. However, the individual was requested to monitor their arm for redness, swelling, or irritation, and to contact a health care provider if any of the symptoms should appear.

    The biosafety officer followed up with the lab and the following items were agreed upon:

    - Investigate the use of alternative materials (e.g., plastic pipette tips) for aspiration.
    - Individuals engaging in activities with Salmonella typhi must wear appropriate personal protective equipment such as disposable gloves and a lab coat or disposable sleeves.
    - Reinforce emergency response procedures for exposures.

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

- Dr. Susan Daniel- Chemical and Biomolecular Engineering – Nonexempt work using recombinant inserts form influenza virus at BSL2.
- Dr. Ruth Ley – Microbiology – Nonexempt work rDNA work and work with human fecal samples at BSL2.

- **Proposed Changes to the Electronic Form – eMUA**

  - A sub-committee was formed to look at the redundancy in questions between the IBC MUA and the IACUC protocol.
    - Progress has been made in identifying questions but implementing changes has been put on hold as the IBC electronic system is being re-evaluated.
- **IBC Charge:**
  - Discussions are ongoing of the need to update the charge to more correctly align with the current administrative organizational structure, to further clarify committee roles and to update with changes in regulation.

6. IBC review metrics by classification:

- **Summary Approval timeline metrics are as follows:** the committee continues to work on maintaining and improving the timeline to review and approval applications.

Class	# of MUA's reviewed	Total Days ORIA	Total Days with PI	Total Days Subcommittee	Total Days until subcommittee complete from First Submit	Total days to approval
BIO only	10	2	20	37	59	61
F	6	4	1	29	34	34
F with BIO	7	2	12	32	46	60
E	8	4	1	29	33	42
E with BIO	5	4	5	21	30	50
D	1	10	0	11	21	42
D with BIO	19	3	5	33	41	51

7. Administrative updates:

- **Update and redesign of the IBC website:**
  - Released April 2012
- **Enhancements to the electronic form:**
  - Personnel updates on continuing reviews are now in the same format as the MUA, increased ease of adding personnel and provides for more accurate reporting.
- **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.
- **Discussions on review of use of rDNA and biohazardous materials in teaching labs:**
  - ORIA is following up with teaching labs across campus and will bring findings back to the IBC.
- **Vice Provost of Research Professor Robert Buhrman attended the October 2012 IBC meeting.**

8. Committee Education: the following documents or topics were discussed

- **Select Agents – Proposed Changes to Title 42, part 73**
- **NIH – Notice of Final Action: Federal Register Vol. 76, No. 196** – Update of Appendix B of NIH Guidelines to specify the Risk group classification for several common attenuated strains of bacteria and viruses that are frequently used in rDNA research.
- **CDC – Notice of Proposed Rulemaking: Federal Register Vol. 76, No. 199** – to revise the regulation covering the importation of etiological agents and the hosts and vectors of human disease.
- **Controversy regarding H5N1 influenza**
  - Level of oversight of the research
  - Publishing
  - Dual-use
- **Report on Research Compliance, 2012, Vol. 9, No. 2**
  - Article on Dual-Use Oversight plan

9. 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

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

Department	College	# MUA
Animal Science	CALS	7
Applied & Engineering Physics	College of Engineering	2
Baker Institute for Animal Health	College of Veterinary Medicine	7
Biochemistry, Molecular and Cellular Biology	CALS	1
Biological Statistics and Computational Biology	CALS	1
Biological & Env. Engineering	CALS	6
Biomedical Engineering	College of Engineering	9
Biomedical Sciences	College of Veterinary Medicine	13
Boyce Thompson Institute		7
Chemical & Bimolecular Eng.	College of Engineering	7
Chemistry & Chemical Biology	College of Arts & Sciences	6
Clinical Sciences	College of Veterinary Medicine	6
Crop & Soil Sciences	CALS	1
Ecology & Evol. Biology	College of Arts & Sciences	3
Electrical and Computer Engineering	Engineering	2
Entomology	CALS	7
Food Science	CALS	5
Horticultural Sciences	CALS	5
Mech. And Aero Engineering	Engineering	4
Microbiology	CALS	9
Microbiology & Immunology	College of Veterinary Medicine	13
Molecular Biology & Genetics	College of Arts & Sciences	16
Molecular Biology & Genetics	CALS	14
Molecular Medicine	College of Veterinary Medicine	8
Natural Resources	CALS	1
Neurobiology & Behavior	College of Arts & Sciences	5
Nutritional Sciences	CALS	4
Nutritional Sciences	Human Ecology	11
Physics	College of Arts & Sciences	3
Plant Biology	CALS	4
Plant Biology	Arts and Sciences	12
Plant Breeding & Genetics	CALS	8
Plant Pathology	CALS	18
Pop. Medicine & Diag. Science	College of Veterinary Medicine	9
Quality Milk Production Svc.	College of Veterinary Medicine	1
Vet Administration	College of Veterinary Medicine	1

11. Appendix C. Committee membership: (July 1, 2011 to June 30, 2012)

Craig Altier ca223@cornell.edu **Microbiology**	Assoc. Professor Population Medicine and Diagnostic Sciences D2 031 Vet College	253-3926
Scott Butler sdb9@cornell.edu **Lab Research member**	Research Support Specialist II Biomedical Sciences Vet Research Tower, Room T9-007	253-3733
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
Michaels, Christy cmichae1@dryden.k12.ny.us **Non-affiliated member**	Biology Teacher	749-2776 844-8694 (work)
Moseley Moore, Cathy cathy.moseley@lcsd.k12.ny.us **Non-affiliated member**	Enrichment Teacher	533.4652 x 3286
Mutschler-Chu, Martha mam13@cornell.edu **Plant Breeding**	Professor Plant Breeding and Genetics 303 Bradfield Hall	255-1660
Parker, John jsp7@cornell.edu **Virology**	Assoc. Professor, Baker Institute Animal Health College of Vet. Medicine	256-5626
Perry, Keith klp3@cornell.edu **Plant Pathology**	Assoc. Professor Plant Pathology 210 Bradfield Hall	254-8243 255-9744
Quaroni, Andrea aq10@cornell.edu **Physiology**	Professor Biomedical Sci T8 008 A Vet Research Tower	253-3463
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
Whittaker, Gary grw7@cornell.edu **Virology**	Professor VM Microbio & Immun C4 127 Vet Med Center	253-4019

Wilson, David dbw3@cornell.edu **Biochemistry** **Molecular Biology**	Professor Molecular Biology and Genetics 458 Biotechnology	255-5706

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