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Institutional Biosafety Committee

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Institutional Biosafety Committee
Annual Report, 2009-2010

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1. Project Review Activities

The Institutional Biosafety Committee (IBC) started monthly meetings in August 2009. During the fiscal year 2009-2010 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 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 B.

The details of the number of projects by classification are provided below:

a. Active Research Projects:
There were 231 active research projects as of July 30, 2010.

Classification	Type	MUAs Active during 2009-10
Exempt	Class F	53
	Class F with Biohazards	18
Non Exempt	Class D	12
	Class D with Biohazards	55
	Class E	54
	Class E with Biohazards	19
	Biohazards only	19
Biosafety Level 3		1
Total Active as of July 30, 2010		**231**

b. Research projects reviewed during 2009-10
   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 by 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 336 projects or requests were reviewed during 2009-10. The following table indicates the breakdown of projects submitted for review.

Classification	Type	Number reviewed during 2009-10
Exempt	Class F	8
	Class F with Biohazards	9
Non-Exempt	Class D	9
	Class D with Biohazards	21
	Class E	37
	Class E with Biohazards	14
BSL3		1
Biohazards only		10
Annual Questionnaires		105
Amendments		27
Terminated		95
Total reviewed		336

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 2009-2010, is available as Appendix D 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:

- 323 laboratories operating at BL1
- 171 laboratories operating at BL 2
- 125 BL2-P level greenhouses/growth chambers
- 40 BL1-N
- 49 BL2-N animal care facilities and
- 3 laboratories operating at BL 3

4. Important Issues discussed by the IBC:

- **Addressing the gaps in review of projects involving the use of animals and biohazardous agents:** The IBC and IACUC implemented a series of measures to improve the coordination of the review process for projects that were subject to review by the IACUC and the IBC. A member of the CARE Veterinary staff was appointed as a voting member of the IBC, to add to the expertise on the appropriate use of animals on projects that are submitted to the IBC for review. For protocols under review by the IACUC, the IBC Administrator performs an administrative review of the proposed use of biohazardous materials and ensures that the proposed use has been approved by the IBC in an MUA. Any inconsistencies between the MUA and the pending IACUC protocol are highlighted as recommendations from the AUHSP (animal user health and safety program) Working Group, for the IACUC and the PI. The IACUC adopted a policy that the use of biohazardous agents on an IACUC protocol must be approved by the IBC in an MUA before the protocol can be approved. This overlapping review by the committees has helped to identity and close gaps in the approval requirements set by the committees. We continue to look for ways to reduce duplication of effort by the PI and the compliance committees.

- **Monthly meetings and review schedule:** In consideration of the increasing workload of the MUAs requiring review, the IBC in August 2009, adopted a resolution to increase the frequency of committee meetings from bi-monthly to monthly while continuing to maintain a 2 month review cycle for MUAs. In February 2010, when the IACUC adopted the new policy of requiring prior IBC approval of certain protocols, the IBC recognized the need to speed up the review of MUAs and voted to approve a three month pilot proposal for a monthly review cycle for MUAs requiring full committee review. During the pilot, while the workload for the reviewers remained more or less constant, the review and approval timelines for MUAs were significantly reduced (Detailed results of the pilot are attached in Appendix C.) At the end of the pilot period, the IBC considered the impact on the workload for the reviewers, the quality of the review and the overall impact to the review timeline for MUAs and passed a resolution to adopt the monthly review cycle as standard business practice.

Summary Approval timeline metrics are as follows:

  - Review time bimonthly meetings FY 2009: 97 days
  - Review time bimonthly meetings FY 2010: 105 days (July and August)
  - Monthly meeting with 2 month review cycle: 76 days (Sept- Jan)
  - Monthly meeting with 1 month review cycle: 45 days (Feb – May)

- **Update on Federal reports:** The biosafety officer provided the IBC updates on the following federal initiatives with relevance to the IBC.
  - GAO Oversight of high containment labs
  - Weapons of Mass Destruction Prevention and Preparedness Act of 2009
  - HHS and USDA:Trans-Federal Task Force on Optimizing Biosafety and Biocontainment Oversight

- **Commissioning and Approval of the Biosafety Level 3 (BSL3) Facility:** Independent commissioning agents performed many of the commissioning activities such as ventilation and alarm system checks required for the certification of the facility. Internal testing was performed by the Cornell Bioengineer and Biosafety Officer. The IBC also toured the Research and Diagnostic Annex BSL3 facility. The Bioengineer and Biosafety Officer presented the outcomes of the commissioning activities and their recommendation to the IBC to certify the Research and Diagnostic Annex to operate as a BSL3 facility. The IBC voted to accept their recommendation and approved the facility for BSL3 work on October 8, 2009.

- **Report on Accidental release of transgenic organism:** The IBC received an anonymous report on Ethicspoint in regard to release of transgenic organisms. ORIA led the investigation to establish the facts regarding the allegation. The investigation concluded that there was no release of transgenic materials, but identified gaps in signage on greenhouses where transgenic materials are being used. Temporary signage was immediately put up in the appropriate locations. In parallel, the IBC greenhouse committee developed signage to use in all plant facilities using transgenic materials and made it available to the greenhouse managers and PIs.

- **USDA-APHIS compliance violation involving Xanthomonas oryzae:** A Cornell faculty member had an approved MUA citing the use of Xanthomonas oryzae. While the organism was in the PI's possession it became regulated by the USDA-APHIS as a Select Agent. EH&S took possession of the organism and had it in secure storage but did not destroy it in the allowed timeline decreed by USDA-APHIS. In January, 2010, USDA notified Cornell of the non-compliance and informed Cornell of another Cornell faculty member who held a permit for the organism (not registered with the IBC). The select agents were immediately destroyed upon receiving the non-compliance notification from USDA-APHIS. This incident brought to light an issue with the registration, tracking the acquisition and usage of and reporting for select agents by researchers at Cornell. An institutional process must be developed to close this gap, assign clear responsibilities for the registration, approval and tracking of the usage of select agents at Cornell.

- **USDA noncompliance concerning rDNA field study**. The PI's USDA-APHIS permit stated the distance for the buffer zone of regulated vs. non-regulated grapes in field plots to be 50 meters. Upon inspection of the field plots in June, 2009, APHIS inspectors found the distance to be 50 feet. The permit was amended to allow 50 ft of isolation and no further action was required by USDA-APHIS.

- **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.
  - Needle stick involving Leishmania donavani
  - Needle stick involving Chinese Hamster Ovary Cells. This incident also involved animal use. Needles were found thrown in regular trash in the animal room. The IBC and IACUC responded jointly to the PI with sanctions.
  - Puncture wound caused by breakage of a pipette containing human breast cancer cell lines.

5. Administrative updates:

- **Enhancements to the current electronic form:**
  - Attachments feature – implemented in Spring 2010
  - Electronic signatures for the PI and Lab contact at time of approval of the MUA – implemented in May 2010
  - Minor text changes for clarity of questions
  - Ability to add multiple IACUC protocol numbers to the MUA – implemented in March 2010
  - IBC administrator reporting capability - report to update committee members on the status and workflow of all MUA's assigned – implemented October 2009

- **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
  - FAQs about experiments that are exempt from the NIH guidelines
  - Transgenic Animals and the Use of Recombinant DNA in animals
  - Animal Experiments covered under the NIH Guidelines for Research involving Recombinant DNA Molecules

7. Committee membership:

- The following individuals joined the IBC committee during the year. Training sessions were held for all new members in accordance with internal policy:
  - Dr. Relford Patterson, Occupational Medicine, ex-officio non-voting – changed to ex-officio voting
  - Dr. Bhupinder Singh, ex officio voting
  - David Wilson,Ph.D, Committee member
  - Rosemary Loria, Ph.D, Committee member
  - Martha Mutschler, Ph.D, Committee member

- Scott Butler, Stephan Menne, Keith Perry and John Parker agreed to serve a second term.
- Walter DeJong and SuSheng Gan left the committee at the end of their term.
- Christine Smart stepped down from committee to serve on the CALS Dean search committee.

- Professor David Soderlund was reappointed as the Chair of the IBC in July 2009 for a three year period.

8. Appendix A: Committee membership:

Craig Altier	Associate Professor Population Med and Diagnostic Sci	2012
Scott Butler	Research Support Specialist I Clinical Sciences	2013
Cantone, Frank A.	Biological Safety Officer	ex-officio
Jennette, Paul	Biosafety Engineer CVM Biosafety Program	2012
Loria, Rosemary	Professor Plant Pathology	2013
Menne, Stephan	Asst. Professor Clinical Science	2013
Michaels, Christy **Non-affiliated member**	Biology Teacher	2012
Moseley Moore, Cathy **Non-affiliated member**	Enrichment Teacher	2011
Mutschuler-Chu, Martha	Professor Plant Breeding and Genetic	2013
Parker, John	Asst. Professor, Baker Institute Animal Health	2012
Perry, Keith	Assoc. Professor Plant Pathology	2012
Quaroni, Andrea	Professor Biomedical Sciences	2013
Soderlund, David **Chair**	Professor and Chair Department of Entomology	2012

Whittaker, Gary	Assoc. Professor VM Microbio & Immun	2013
Wilson, David	Professor Molecular Biology and Genetics	2013

These positions will be permanently represented on the Committee:

Ex-Officio, Voting Members

Patterson, Relford M.D.	Director of Occupational Medicine	
Singh, Bhupinder	CARE Veterinarian	
Pavek, Todd	Clinical Veterinarian	Alternate

Ex-Officio, Non-Voting Members

Leed, Andrew	Manager Tower Road Greenhouses
Leitch, Keane	Assoc. Biosafety Officer
Buhrman, Robert A. Ph.D.	Vice Provost for Research
Fry, William, PhD	Dean of Faculty
Long, Cathy	Associate Vice President, Research
Verma, Amita	Interim Director of the Office of Research Integrity and Assurance

9. Appendix B: Classification definitions from the NIH Guidelines 2002

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:

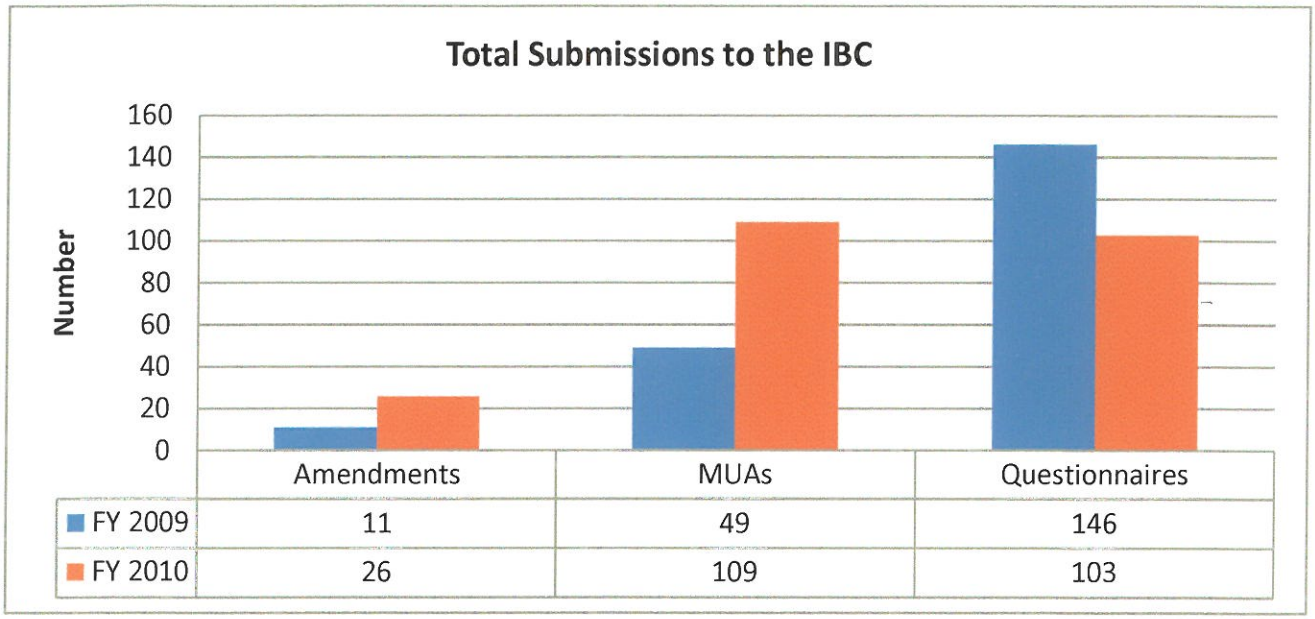
Non-Exempt Experiments

Section III-E. Experiments that Require Institutional Biosafety Committee Notice Simultaneous with Initiation

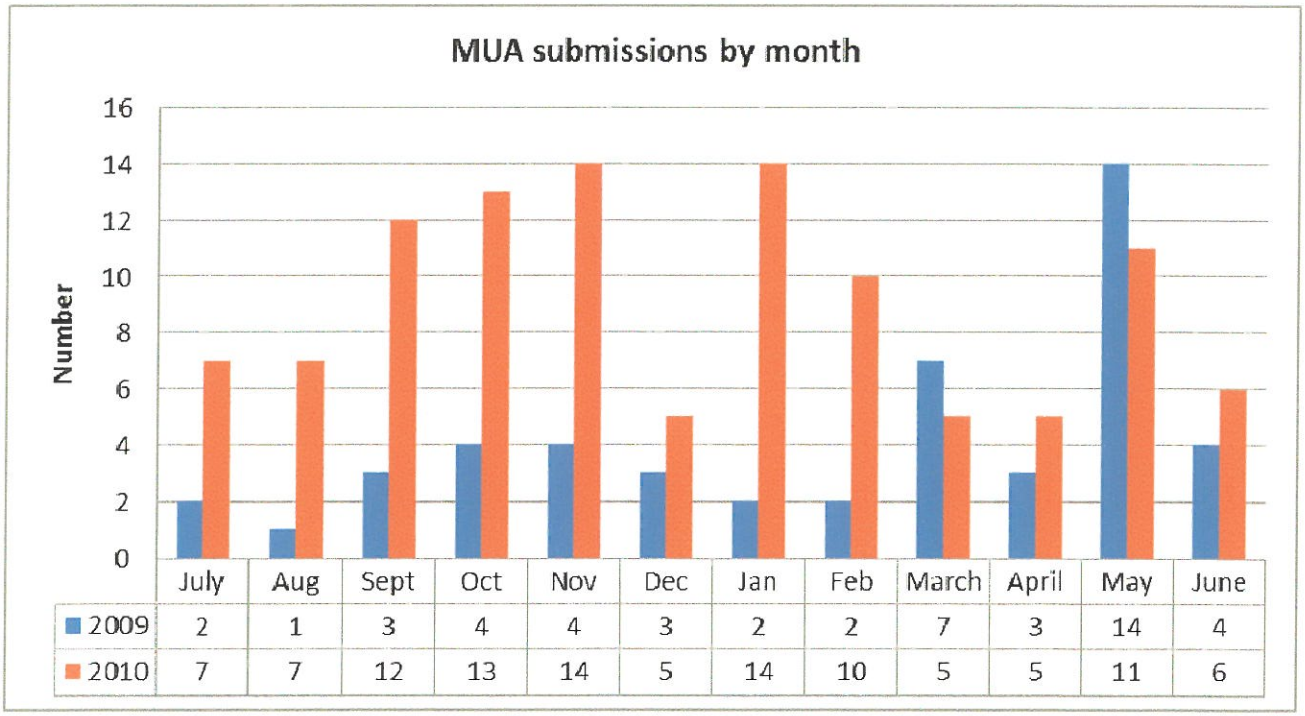
Experiments not included in Sections III-A, III-B, III-C, III-D, III-F, and their subsections are considered in Section III-E. All such experiments may be conducted at BL1 containment. For experiments in this category, a registration document (see Section III-D, *Experiments that Require Institutional 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 C: IBC Metrics



	Amendments	MUAs	Questionnaires
FY 2009	11	49	146
FY 2010	26	109	103



	July	Aug	Sept	Oct	Nov	Dec	Jan	Feb	March	April	May	June
2009	2	1	3	4	4	3	2	2	7	3	14	4
2010	7	7	12	13	14	5	14	10	5	5	11	6

Average Approval timeline FY 2010 Submissions includes submitted MUA data only.

11. Appendix D: Number of Active MUAs by Unit/Department

Department	College	# MUA
Animal Science	CALS	5
Applied & Engineering Physics	College of Engineering	2
Baker Institute for Animal Health	College of Veterinary Medicine	10
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	13
Boyce Thompson Institute		10
Chemical & Biomolecular 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	3
Ecology & Evol. Biology	College of Arts & Sciences	3
Electrical and Computer Engineering	Engineering	1
Entomology	CALS	4
Entomology – Geneva	CALS	5
Food Science	CALS	3
Food Science – Geneva	CALS	1
Horticultural Sciences – Geneva	CALS	4
Horticulture	CALS	4
Mech. And Aero Engineering	Engineering	1
Microbiology	CALS	8
Microbiology & Immunology	College of Veterinary Medicine	16
Molecular Biology & Genetics	College of Arts & Sciences	18
Molecular Biology & Genetics	CALS	15
Molecular Medicine	College of Veterinary Medicine	8
Natural Resources	CALS	1
Neurobiology & Behavior	College of Arts & Sciences	3
Nutritional Sciences	CALS	2
Nutritional Sciences	Human Ecology	7
Physics	College of Arts & Sciences	2
Plant Biology	CALS	4
Plant Biology	Arts and Sciences	13
Plant Breeding & Genetics	CALS	9
Plant Pathology	CALS	17
Plant Pathology – Geneva	CALS	5
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