



Institutional Biosafety Committee Annual Report, 2012-2013

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

- July 1, 2012 –Craig Altier, Assoc. Prof., Department of Population Medicine and Diagnostic Sciences, was appointed Chair of the IBC
 - New Voting Members with terms beginning in July 2012:
 - Randall Renshaw, PhD, Population Medicine and Diagnostic Sciences, Animal Health Diagnostic Center
 - Professor Helene Marquis, Microbiology and Immunology
 - Professor Marc Fuchs, Plant Pathology
 - Professor Douglas Knipple, Entomology
 - Ms. Alexis Brubaker, Associate Biosafety Officer, voting alternate for the Biosafety Officer

2. Project Review Activities

The IBC reviews and approves the following categories of projects:

- Projects with r/sNA use:
 - Exempt from the NIH guidelines (Class F)
 - Non- Exempt, subject to NIH guidelines (classified as Class D or E)
- Projects with Biohazardous Materials

Detailed explanation of these classifications is provided in Appendix A.

During the reporting year July 1, 2012-June 30, 2013, the IBC held thirteen duly convened meetings to review new Memoranda of Understanding and Agreements (MUA), amendments to approved MUAs and applications for renewal of approved MUAs.

- **Active Projects registered with the IBC:**
There were 254 active projects as of June 30, 2013.

Classification	Type	MUAs Active
Exempt	Class F	47
	Class F with Biohazards	33
Non Exempt	Class D	9
	Class D with Biohazards	68
	Class E	50
	Class E with Biohazards	18
	Biohazards only	26
Biosafety Level 3		3
Active as of June 30, 2013		254

- **Projects reviewed during 2012-2013**
 - 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.
 - 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).
 - 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.

- Annual questionnaires and MUA amendments: These applications are reviewed by the Chair of the IBC or Biosafety Officer and the IBC administrator. Amendments with personnel and facility changes 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 336 MUAs or continuation requests (amendments and annual questionnaires) were reviewed during 2012-13. A breakdown of projects submitted for review during the same timeframes in 2011-2012 and 2012-2013 is below:

Classification	Type	Number reviewed during 2011-12	Number reviewed during 2012-13*
Exempt	Class F	6	5
	Class F with Biohazards	7	21
Non-Exempt	Class D	1	6
	Class D with Biohazards	19	33
	Class E	8	33
	Class E with Biohazards	5	12
BSL3 Application			1
BSL3 Amendment		2	2
Biohazards only		10	11
Annual Questionnaires		188	123
Amendments		62	89
Total reviewed		308	336
MUAs Terminated		42	102**

* 22 new MUAs were submitted

** 95 MUAs were terminated when the PI filed a new 3 year renewal

***7 MUA's were terminated as PIs left the university or stated that they no longer were using r/sNA or biohazards in their research

3. MUAs by Department

The IBC receives MUAs from individuals conducting research at the Ithaca campus, 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, 2012 through June 30, 2013, is available as Appendix B of this document.

4. Laboratory spaces and facilities by Biosafety Level

The number of laboratories (rooms) known to be conducting research at Biosafety levels BL1, BL2 or BL3, as of June 30, 2013, are as follows. This information is provided on the MUAs by researchers:

- 333 laboratories operating at BL1
- 241 laboratories operating at BL 2
- 115 BL2-P level greenhouses/growth chambers
- 52 BL1-N animal care rooms
- 49 BL2-N animal care rooms
- 3 laboratories operating at BL 3
- 1 laboratory operating at ABSL3

5. Significant topics and policies discussed by the IBC

- On March 5, 2013 the *NIH Guidelines for Research Involving Recombinant DNA Molecules* became the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* thus adding the review of work with synthetic nucleic acids to the IBC's purview. Cornell policies, procedure, guidance and application materials were revised to reflect this change and information distributed to researchers to educate and inform them of how the change may impact their applications to the IBC or the conduct of their research.
- IBC approved the use of one's own blood:
 - in NS3320 with specific safety practices and required training for the TAs;
 - in validation of laboratory assays with specific safety practices and required training for individuals working with the samples.
- A new policy for the conduct of Convened IBC Meetings
- A new policy regarding IBC meeting minutes, including redaction
- An Updated Charge to the IBC, which was approved by the Dean of Faculty
- Clarification of requirements for IBC review and required information about the use of plant pathogens in the IBC application. An IBC Subcommittee was formed to discuss and present a recommendation to the IBC for changes. The IBC accepted the recommendations made by the subcommittee. The resulting changes will be incorporated in the revised online MUA application.

6. Site Visit by the Office of Biotechnology Activities (OBA) - NIH

On May 8, 2013, Dr. Kathryn Harris, Senior Outreach Officer from OBA conducted a site visit to review Cornell's IBC oversight program. A number of materials and documentation were sent to the OBA in advance of the visit; such as biosafety manuals and procedures, waste disposal and exposure responses procedures, IBC meeting minutes and other documents related to the management of the Biosafety program, etc. The site visit included interviews with three researchers, members of the IBC, the Biosafety officer and responsible officials at Cornell. Various stakeholders from the University were engaged in the preparation and were present at the Opening and Closing meetings of the site visit. We received a formal letter from OBA on July 3, 2103, with the following high level observations, findings and recommendations, and are in the process of conducting an assessment of the program to determine the appropriate steps to take; including implementing some required changes as well as preparing a response to OBA.

Commendations:

- Robust membership which includes experts from a wide array of fields, active member participation, frequent renewal of the membership, recognition of IBC members as providing an important service to the institution. Training for committee members meets the requirements of the NIH Guidelines.
- Efficient, effective and comprehensive review and approval process for applications submitted to the IBC; good process for periodic reviews of on-going research.
- Biosafety and IBC staff viewed by researchers as accessible, efficient and attentive to the researchers' needs.
- Documentation, policies and procedures were for the most part appropriate.

Findings and recommendations:

- Certain policies that are currently in place need to specifically and more clearly reference the NIH Guidelines for the use of r/sNA materials. Even though the IBC reviews all guidance/procedural and other documents used in the biosafety program, OBA stated that formal approval of such documents by the IBC must be specifically documented.
- OBA determined that the IBC policy on redaction of information from the meeting minutes may not include the redaction of PI names.
- OBA determined that the IBC must provide further training materials specifically directed at the contents of the NIH guidelines, to the PI's and staff.
- OBA recommended that Cornell consider implementing a more formal program for inspection of facilities that use r/sNA.

7. Adverse Events

- **Adverse Events reported to the NIH:** 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:
 - Needle stick injury – An individual incurred possible exposure to recombinant attenuated strain of *Listeria monocytogenes* while giving an injection to a mouse. The skin barrier was scraped. The individual immediately cleaned the site with sporel solution followed by soap and water. The individual showed no signs of inflammation and experienced no side effects. The biosafety officer was contacted who investigated the incident and retrained the individual in safe practices while handling of animal, hand placement, disposal of sharps, injection of animals and first aid.
 - Needle stick injury – An individual stuck their finger with a needle while they were injecting a mouse with *Listeria monocytogenes* genetically modified strain (GP) peptide, and the animal began to come out of anesthesia and moved. The individual immediately doffed their gloves and washed the site with soap and water. The incident was reported to EH&S and Gannett Occupational Medicine was consulted. The individual was counseled on the risk factors associated with exposure to *Listeria*. The individual will be supervised when injecting mice and will undergo refresher training to recognize when an animal may be coming out of anesthesia. Additional PPE was also recommended.
 - Needlestick injury- While manipulating unfixed brain tissue from deceased patients in Malawi, a researcher suffered a needlestick injury from a 23g needle that he was using to remove the blocks of frozen tissue from the cryovial. The researcher suspended work, removed his gloves and washed the injury with soap and water. His injury was evaluated by Occupational Medicine personnel at Gannett Health Services in accordance with standard protocol and received medical consultation. At this time there is no outstanding health issue of concern. The Biosafety Officer has met with the individual and discussed alternative methods of removing the materials and safe practices in general. IBC staff also worked with the PI to address documentation issues related to the use of unfixed tissue in his MUA.

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

- **Centrifuge incident** – While a researcher was working with protozoan *Blastocystis*, the tubes containing the agent broke within the centrifuge. The Biosafety response team entered the room approx. 45 minutes after

the incident to allow settling of any large aerosols. The rotor was taken to a biosafety cabinet for cleaning and the bowl of the centrifuge was cleaned and decontaminated. It was determined that the root cause was user error and lack of awareness. Specifically, the tubes being used were not appropriate for the conditions of the centrifuge. The individual was trained appropriately. Occupational medicine instructed the individual to contact Gannett Health Services immediately if gastrointestinal symptoms are experienced.

- **Autoclave Incident – BSL3 lab** – An autoclave used in a PI's BSL3 laboratory was repaired by an outside technician who also reduced the time of the heat cycle and did not reset it to the original settings after completion of the repair work. This change was not noticed by the members of the lab or the BSL3 oversight team. Subsequently when a lab staff member removed a bag of waste from the autoclave, a corner of the bag opened. At that time the individual realized that the autoclave cycle had been shortened and was not appropriate for the agent being used. The possible exposure was reported and the BSL3 program team investigated the incident and the events that led to it and the potential for exposure to the agent from the insufficient autoclaving. Their assessment was that there was no potential risk due to the fact that the inner bags which contained the more concentrated waste had remained sealed. However this incident raised questions about the processes associated with equipment repair, reporting and monitoring. The incident was reviewed by the IBC and it was determined that root cause that needed to be addressed was lack of clear roles and responsibilities and standard operating procedures for scheduling and maintenance of equipment within the BSL3 facility. The BSL3 program team is implementing corrective actions to address this root cause.

8. Biosafety Lab Visits Reported to IBC

The Biosafety team conducted lab visits to the following labs, based on an assessment of risk of the agent used, the nature of work being done, the experience and knowledge of the PI and the research team and history of safe practices with the use of biohazardous materials:

- Dr. Mao- Weill Institute for Cell and Molecular Biology – Non-exempt work, added biohazardous agent Lp02 strain of *Legionella*, work will be conducted at BSL2. The BSO did Biosafety awareness training with the lab and use of Biosafety Cabinet.
- Dr. Mohammed – Population Medicine and Diagnostics – new work with Biohazards. PI will be using *Campylobacter*, *E. coli* and *Salmonella*. Work will be done at BSL2. No issues discovered.
- Dr. Xu-Applied and Engineering Physics – PI is adding new imaging techniques using rodents with human cancer cells transplanted in the brain. Work will be done at

BSL2. Biosafety and CARE Vet provided training and observed the initial procedures.

- Dr. Ke - Molecular Biology and Genetics -PI is using ricin toxin chain A. Work will be done at BSL1. No adverse issues were discovered.
- Dr. Garcia-Garcia –Molecular Biology and Genetics - BSO followed up with PI after meeting concerning the bio-waste stream from the lab. All was being done correctly. Work is being done at BSL2.
- Dr. Qi – Nutritional Sciences –new work with biohazard. PI will be using *Listeria monocytogenes*. Work will be done at BSL2. Lab received agent specific training from a lab with much experience using the agent. BSO observed individuals for proficiency in assays preformed using the agent.
- Dr. Luo –Biological and Environmental Engineering - PI is receiving samples that could potentially have human health concerns. BSO reviewed the lab and the processes that would be used and found the processes and containment to be appropriate for the samples. Work will be done at BSL2.
- Dr. DeLisa – Chemical and Biomolecular Engineering - PI is adding use of human cell lines in his research. The BSO did a lab review, discussing use of Biosafety cabinet, personnel protective equipment (PPE), disinfectant and signage needed for these agents. The BSO also did Biosafety awareness training with the lab per the PI request.
- Dr. Lucks – Chemical and Biomolecular Engineering- PI is adding use of influenza and cucumber virus in his research program. The BSO did a lab review and discussed transportation of samples, PPE and HASP signage. The PI already has an isolated room and biosafety cabinet in place. Work will be done at BSL2.
- Dr. Bonassar- Biomedical Engineering - PI is adding use of human cell lines to his research. BSO did a site review and the lab and cell culture room were appropriate for the work and training requirements had been completed. Work will be done at BSL2.
- Dr. Thalacker-Mercer- Nutritional Science- New PI using human tissue and blood in her research program. The BSO preformed a lab review, discussed pulverization process, PPE needed, and appropriate disinfectants. The work will be done at BSL2.
- Dr. Levine- Molecular Medicine - PI is using human cell lines. BSO preformed a lab review, signage was updated. (PI shares lab with Dr. Nowak) Work will be done at BSL2.
- Dr. Nowak - Molecular Medicine - PI is using human cell lines. BSO preformed a lab review, signage was updated. (PI shares lab with Dr. Levine) Work will be done at BSL2.

- Dr. Peters- Microbiology- PI is adding use of *A. baumannii*. BSO preformed a site review, observed work practices, disinfectant and disposal. Only the PI will be working with the agent and it is in infectious form for a very short period of time. PI will have general health surveillance training as it is recognized this is a very serious pathogen. Work will be done at BSL2.
- Dr. Beer- Plant Pathology - PI is adding use of *B. cepacia* and *B. gladioli* which potentially have human health concerns. The BSO reviewed the lab set up and safety practices including handling of sharps, PPE and updating HASP signage. Work will be done at BSL2.
- Dr. Bogdanove –Plant Pathology - The Biosafety team announced the completion and successful approval of a Select Agent Program for the use of a regulated plant pathogen in the PI's research.

9. IBC review metrics

- See Appendices D and E

10. Administrative updates:

- **Updated the IBC application to include synthetic nucleic acids per changes to the NIH guidelines (effective March 5, 2013)**
 - All ongoing and proposed experiments that will be newly subject to these amended *NIH Guidelines* will need to be registered by the Principal Investigator with the IBC by the effective date listed above.
- **Update and redesign of the IBC online application**
 - Explored development of a new IBC system with enhanced functionality. Initially the project was focused on engaging an outside vendor to develop a new application. However more recently, as new concerns about the vendor's ability to deliver a quality product on time, became apparent, we are no longer exploring that option. The current focus is to implement significant improvements to the current online application system itself, to meet the IBC and researcher needs. Expected delivery of the completed enhancements is June 2014.
- **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.

11. Ongoing Education and Training for IBC members and Biosafety team:

- The BSL3 program team practiced man-down drills with emergency response teams and Bangs ambulance crew as well as emergency training with CU Police
- G. Whittaker attended an influenza meeting at T. Sinai and shared with the IBC, information on the research involving influenza and work in ferrets and the discussion on whether to allow publication to the work. The draft report for policy oversight for Dual Use was shared at this time as well.
- Committee discussed the Final Action under the NIH Guidelines addressing the safety concerns for research with synthetic nucleic acids. This document adds new language to regulate synthetic DNA, which will fall under the same category as recombinant DNA.
- Committee was briefed on the changes to the NIH guidelines incorporating review of recombinant and synthetic nucleic acid molecules.
- The following journal article was discussed: Reuter, J.D., Fang, X., Ly, C., Suter, K., and Gibbs, D. 2012. Assessment of Hazard Risk Associated with the Intravenous Use of Viral Vectors in Rodents, Comparative Medicine, Vol. 62, No. 5

12. Appendix A: Classification definitions from the NIH Guidelines 2013

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.

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 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

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

Department	College	# of MUAs
Animal Science	CALS	8
Applied & Engineering Physics	College of Engineering	3
Baker Institute for Animal Health	College of Veterinary Medicine	8
Biochemistry, Molecular and Cellular Biology	CALS	1
Biological Statistics and Computational Biology	CALS	1
Biological & Env. Engineering	CALS	6
Biomedical Engineering	College of Engineering	10
Biomedical Sciences	College of Veterinary Medicine	11
Boyce Thompson Institute		6
Chemical & Biomolecular Eng.	College of Engineering	4
Chemistry & Chemical Biology	College of Arts & Sciences	9
Clinical Sciences	College of Veterinary Medicine	6
Crop & Soil Sciences	CALS	2
Ecology & Evol. Biology	College of Arts & Sciences	4
Electrical and Computer Engineering	Engineering	2
Entomology	CALS	7
Food Science	CALS	5
Horticultural Sciences	CALS	7
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	16
Molecular Medicine	College of Veterinary Medicine	10
Natural Resources	CALS	1
Neurobiology & Behavior	College of Arts & Sciences	6
Nutritional Sciences	CALS	5
Nutritional Sciences	Human Ecology	12
Physics	College of Arts & Sciences	3
Plant Biology	CALS	4
Plant Biology	Arts and Sciences	10
Plant Breeding & Genetics	CALS	7
Plant Pathology	CALS	20
Pop. Medicine & Diag. Science	College of Veterinary Medicine	11
Quality Milk Production Svc.	College of Veterinary Medicine	1
Vet Administration	College of Veterinary Medicine	1

14. Appendix C. Committee membership: (July 1, 2012 to June 30, 2013)

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
Fuchs, Marc mf13@cornell.edu Plant Pathology	Assoc. Professor Plant Pathology Barton Lab Geneva, NY 14456	315-787-2487
Jennette, Paul jpj22@cornell.edu Biosafety Engineer	Biosafety Engineer CVM Biosafety Program S2-060 Schurman Hall	253-4227
Knipple, Doug dck2@cornell.edu Entomologist	Assoc. Professor Entomology Kennedy Hall, Box 15 Geneva, NY 14456	315-787-2363
Marquis, Helene Hm722cornell.edu Microbiologist	Assoc. Professor Microbiology and Immunology VMC, Room C5-159]	253-3273
Michaels, Christy cmichae1@dryden.k12.ny.us Non-affiliated member	Biology Teacher	749-2776
Moseley Moore, Cathy cathy.moseley@lcsd.k12.ny.us Non-affiliated member	Enrichment Teacher	533-4652
Mutschler-Chu, Martha mam13@cornell.edu Plant Breeding	Professor Plant Breeding and Genetics 303 Bradfield Hall	255-1660
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
Renshaw, Randy rwr3@cornell.edu Virology	Research Associate Population Medicine and Diagnostic Sciences Diagnostics Lab, Room A3-120	253-4019
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

Alexis Brubaker ab2324@cornell.edu Alternate for voting Assoc. Biosafety Officer	Associate Biosafety Officer East Hill Office Building Suite 210	254-8475
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
Hsiao, Vivian vh14@cornell.edu	Nurse Practitioner Gannett Health Services	p. 255-6960
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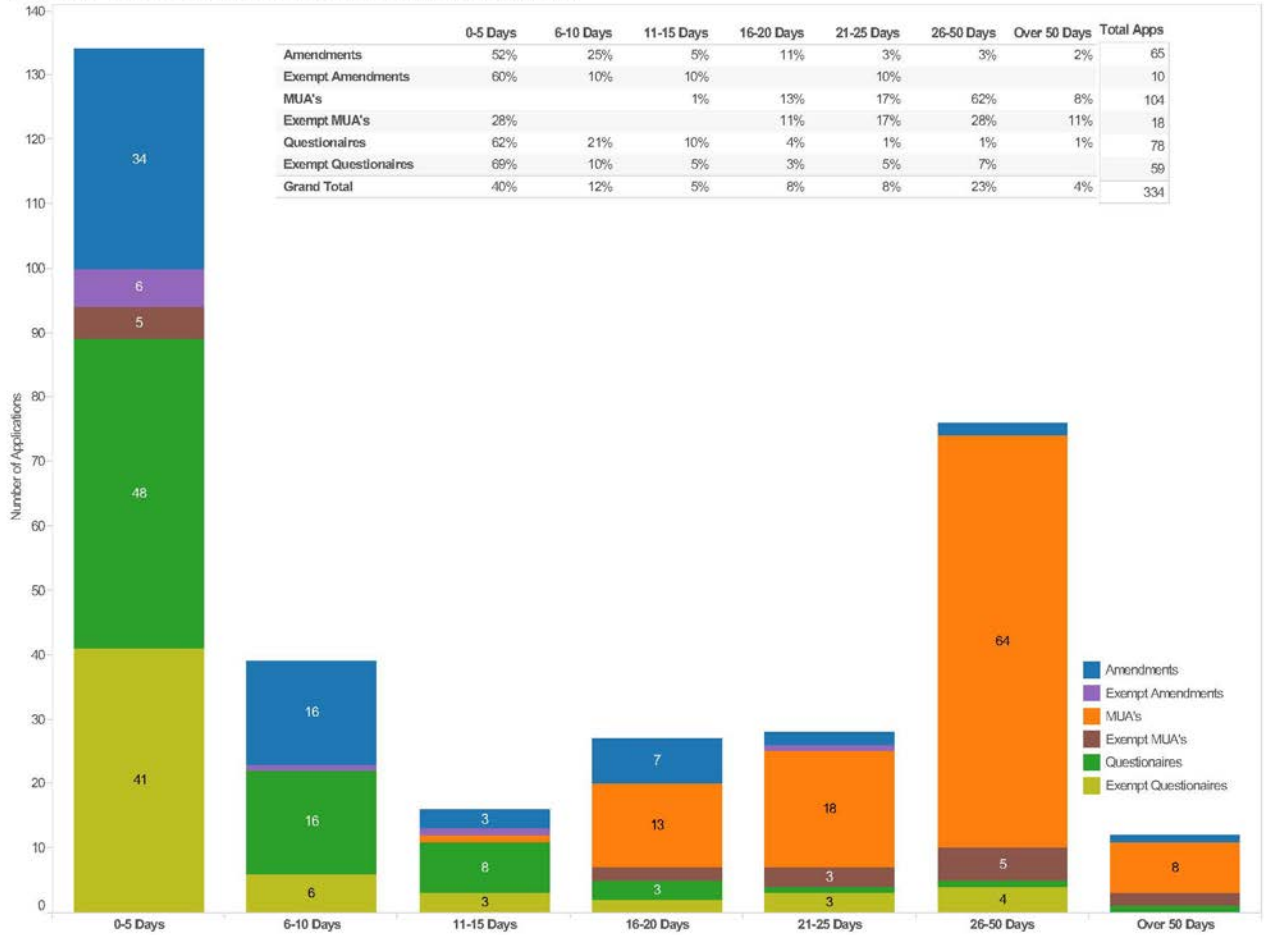
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16. Appendix D: Approved Applications by Processing Time

July 2012 - June 2013 Approved Applications by Processing Time



17. Appendix E: 2013 IBC Metrics

IBC 2013 Metrics

