Biosafety and the Culture of Compliance at U-M

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Regulatory and Compliance Oversight
Biosafety compliance at U-M is a partnership between the U-M Office of Research (UMOR) and Occupational Safety and Environmental Health (OSEH):

- The U-M Institutional Biosafety Committee (IBC) is administered through UMOR and oversees all recombinant DNA research at U-M.

- A BSL3 subcommittee of the IBC and the Responsible Official (in OSEH) review Select Agent research.

- OSEH handles lab inspections, safety training, and oversight of non-recombinant biologics.
Currently:

- 500+ PIs are registered with the U-M Institutional Biosafety Committee (IBC) for recombinant DNA research

- PIs have responsibility for entire research teams, running multiple projects

- 350 of these PIs are approved to conduct Biosafety Level 2 (BSL2) rDNA research

- These projects represent about 16% of the research portfolio of $1.3 billion
October 2012 -- Biologics Oversight Task Force established

- Charged with the responsibility to “evaluate the current U-M oversight functions required to ensure the safe and secure use of potentially hazardous biological agents in research, and to recommend improvements where necessary”

- Co-chaired by AVP Research and AVP Facilities and Operations

- Recommendations submitted February 2013
Task Force observations:

- U-M has a strong set of oversight systems in place for Select Agent and recombinant DNA research.
- The oversight systems at U-M are complex, often creating a maze for researchers to navigate when applying for grants or space to conduct research, and creating potential communication problems between the various oversight bodies.
- The breadth of the activity requiring oversight by various committees or departments is such that a phased effort, with milestones, will be needed to design and implement improvements based on safety or regulatory risks.
U-M’s Biosafety Initiative

Task Force recommendations included:

- Expanding the role of the IBC to oversee not only rDNA and Select Agent research, but also non-recombinant and non-Select Agent research with infectious agents, biological toxins, human blood and body fluids, and potential Dual Use Research of Concern

- Enhancing the overall coordination across IBC, IACUC, IRB, Office of Research and Sponsored Projects (Pre-award), Occupational Safety & Environmental Health, Office of Sponsored Programs (Post-award) and other units as needed
Proposed Biosafety Information Flow, example scenarios

Example scenarios (arrow colors):

**Needle-stick, rDNA, BL2**
- Select Agent approval process
- CDC Select Agent inspection
- Policy development
- Non-compliant PI (IBC, rDNA, in vitro)
U-M’s Biosafety Initiative

Main action items:

- Develop new tools for facilitating and tracking compliance – specifically, expand the electronic IBC application for review of infectious agents, biological toxins, human blood and body fluids, and dual use materials.

- Streamline the oversight structure for Select Agents in research.

- Enhance monitoring and coordination with compliance entities for animal and human research activities when hazardous biological agents are involved in the research.

- Strengthen existing and provide new training programs.

- Enhance the culture of safety by a campus-wide campaign.
Implementation of DURC Policy Requirement

- Develop internal policy and process, includes DURC questions on all IBC applications
- Targeted messaging to raise awareness
- Mandated training prior to submission of proposals
- Embed questions to flag review in:
  - Proposal transmittal form for external and internal awards
  - Material transfer agreements
  - Procurement processing
- Review by subcommittee of IBC
- Risk mitigation plan review
- Approval by VP for Research
Biosafety Stewardship

September 5 – sent “Action Needed” email to the U-M biological research community

October 3 – deadline for voluntary:

- Inventory of infectious agents and biological toxins
- Review of lab biosafety policies and procedures
- Review of training status for lab personnel
- Submission of a short report with the results of the inventory
Biosafety Stewardship Challenges

- Different interpretations of “infectious agents” and “biological toxins”
- Erroneous assumptions that we were only asking about regulated Select Agents and Toxins
- Ambiguity about whether rDNA was to be included
- Uncertainty about whether human cells or body fluids were to be included
Reminder with clarifications sent:

- “Your inventory should include any biological organisms (e.g. viruses or bacteria) stored or used in your lab that would be infectious to humans, animals, or plants.

- As for toxins, we are asking solely about toxins of biological origin, not toxic chemicals. Biological toxins are toxic substances produced by microorganisms, animals, and plants that have the capability of causing harmful effects when inhaled, ingested, injected or absorbed.”
Biosafety Stewardship

What did we gain from this activity?

- Reinforcement at the lab level of good lab practices, including accurate inventory maintenance and the importance of lab safety training for all staff

- Augmentation of central data regarding unregulated biological agents used and stored on campus

Follow-up from this activity?

- Contact key departments to address any inventory gaps

- Reflect back on Biosafety Task Force recommendations
Next Steps

Where does U-M go from here?

- Modifications to our current processes for oversight of research with hazardous materials, including:
  - Revised questions on our proposal transmittal form and MTAs
  - Further integration of our information technology systems
  - Establishment of a new review committee for general lab safety
  - Increased training and monitoring
- Continued efforts to strengthen the safety culture
1. **Articulation** - Communicate the University’s obligation to promote a safe work and educational environment.

2. **Leadership** – Establish the commitment to responsible research and administration at the highest level.

3. **Investment in University Initiatives** – Promote responsibility and values throughout all activities of the institution.

4. **Policy** - Establish or revise formal institutional policies on issues related to research responsibility.

5. **External Initiatives** – Communicate to external constituencies the importance of research responsibility
Top Ten list of recommendations for strengthening the safety culture

6. **Administrative Training** – Ensure that individuals in key administrative roles understand research responsibility issues and are skilled in dispute resolution.

7. **Faculty/Student Training** – Embed safety training and instruction into all research activities.

8. **Compliance** – Monitor compliance with policies governing responsible conduct and administration of research and take corrective actions as needed.

9. **Communication** – Promote communication about research responsibilities throughout the research community.

10. **Sponsor Relationships** – Maintain the confidence of research sponsors that research is conducted and administered responsibly.
Questions and Discussion