AN OVERVIEW OF THE INSTITUTIONAL BIOSAFETY COMMITTEE

Tracy Henry, Research Compliance Supervisor
Office of the Vice President for Research
IBC Charge

- Review all research and teaching activities involving potentially hazardous biological agents, including:
  - Recombinant DNA and Artificial Gene Transfer (i.e., human gene transfer, transgenic animals, cloning)
  - Infectious Agents (i.e., bacteria, viruses, fungi)
  - Biologically Derived Toxins (i.e., botulinum toxin, ricin)
Purpose of IBC Review

- The IBC is concerned with ensuring the protection of:
  - Research Laboratory Personnel
  - The Environment
  - Public Health
Regulatory Framework

### NIH Guidelines

- Institutions receiving NIH funds are required to adhere to the NIH Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines) October 2011

### Regents Policy

- Regents Policy requires researchers using infectious agents and biological toxins to adhere to safety guidelines described in the Biosafety in Microbiological and Biomedical Laboratories (BMBL)
IBC Responsibilities

- Review rDNA research for conformity with NIH Guidelines (expanded to include infectious agents and biotoxins at UMN)
- Evaluate potential risks to public health and environment
  - Containment levels per NIH Guidelines
  - Adequacy of facilities, SOPs, P.I. and lab personnel training
  - Investigator and institutional compliance
IBC Responsibilities continued…

- For human gene transfer research, the IBC must additionally ensure that:
  - No subject is enrolled until RAC review, IBC and IRB approval obtained
  - Issues raised by RAC in public review are considered
  - Final IBC approval occurs only after RAC review
  - There is compliance with surveillance, data reporting, and adverse event reporting

- The RAC is the Recombinant DNA Advisory Committee (located within NIH-OBA).
- The RAC focuses on facilitating public discussion of novel, or especially important scientific, safety or ethical considerations involved with recombinant DNA research.
- Human gene transfer trials conducted at, or sponsored by, institutions receiving NIH funding for recombinant DNA research must be registered with NIH-OBA and be reviewed by the RAC.
P.I. Responsibilities

- Obtain IBC approval for any research and teaching activities involving rDNA, infectious agents, and/or biologically-derived toxins

- Adhere to requirements set forth in the Regents Policy, U of MN Biological Safety Manual, and the NIH Guidelines

- Request IBC approval for any modifications to an approved protocol, prior to initiation

- Report any research related incidents (including accidental spills)
Communicating with the IBC

- The committee conducts business in an electronic format. All correspondence to the IBC should be submitted electronically to ibc@umn.edu from the P.I.’s U of MN e-mail account.

- Always download the current version of IBC forms from the IBC website: www.research.umn.edu/ibc/forms.html

- Official documents from the IBC will be sent via e-mail to the P.I. and designated correspondents.
IBC Process

☐ The P.I. is required to:

☐ Complete and submit the appropriate application form

☐ attach applicable supporting documentation

☐ The IBC staff will pre-review all submissions for completeness
The IBC works closely with:
- IACUC and IRB to coordinate review of research involving animals and human subjects
- DEHS and OHS to communicate requirements for laboratory inspections and occupational medicine

The IBC meets monthly to review research protocols involving potentially hazardous biological agents, and including:
- Humans
- Animals
- Plants
- In vitro experiments
IBC Process continued…

- The committee determines safety procedures and the level of physical containment (BSL1 – BSL3) necessary to:
  - Prevent release of recombinant organisms or potentially hazardous biological agents into the environment
  - Protect laboratory staff and researchers

- Funding will not be released if required committee approvals are missing:
  - The IRB and IACUC are notified of IBC approval when necessary
Typical Timeline for IBC Review Process

- Within 7-10 business days after an item is reviewed at an IBC meeting, the P.I. and designated correspondents will receive an electronic letter that outlines the committee’s decisions.

- The majority of applications are approved with stipulations.

- Applications lacking sufficient detail may be deferred. Responses to deferral will require another review at a convened IBC meeting.

The IBC recommends that researchers begin the application process at least 2-3 months in advance of the anticipated start date.
IBC Contact Information

Questions for the Biological Safety Officer (BSO):

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Questions?