Effective Institutional Biosafety Committees

An Academic Example

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University of Maryland
June 25, 2009

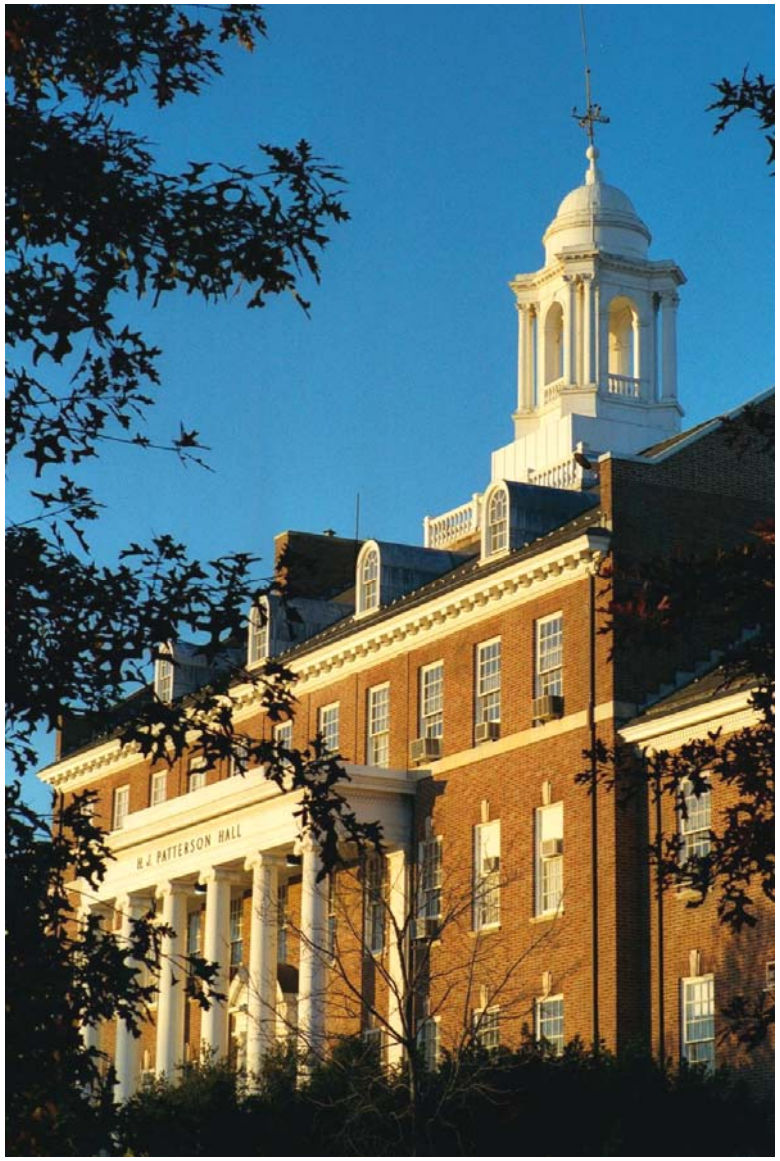
What we'll cover

- Introduction
- IBC procedures
- Administrative procedures / biosafety program
- Lessons learned
- The future

University of Maryland, College Park

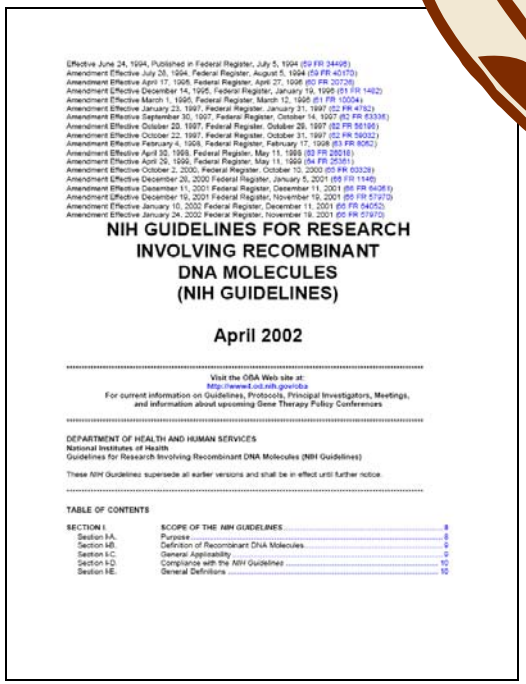
Introduction

- Research University
- No medical school
- No human gene transfer
- Large scale rDNA research
- BSL3 laboratories
- 2 BSOs



UM rDNA oversight program

- IBC
- BSO administrative procedures
- NIH Guidelines



NIH GUIDELINES FOR RESEARCH INVOLVING RECOMBINANT DNA MOLECULES (NIH GUIDELINES)

April 2002

Visit the OBA Web site at:
http://www4.od.nih.gov/oba
For current information on Guidelines, Protocols, Principal Investigators, Meetings, and information about upcoming Gene Therapy Policy Conferences

DEPARTMENT OF HEALTH AND HUMAN SERVICES
National Institutes of Health
Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines)

These NIH Guidelines supersede all earlier versions and shall be in effect until further notice.

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UM IBC stats

- Established in 1995
- 14 members
  - 12 voting; 2 non-voting
- Meets monthly
- 3-year term (may be reappointed)
- Annual report to OBA

IBC procedures

- Scope
- Membership
- Strategies for recruitment / retention
- Charter
- Minutes
- Review process
- Training IBC members
- Promoting institutional support

Scope

- rDNA
- Non-recombinant infectious agents
- Select agents / toxins
- Synthetic nucleic acids will be added

IBC membership

- 4 rDNA experts (bacteriology/ virology / molecular biology)
- Animal expert
- Plant expert
- Biosafety experts (2)
- Laboratory technical staff representative

IBC membership

- AVP for Research
- Director of University Health Center
- 3 non-affiliated members
  - City Manager of College Park (retired)
  - Mayor of University Park (retired)
  - Director of Public Services, College Park

Strategies for membership

- Establish good relationship with researchers
- Counts towards tenure for junior faculty
- Lunch, or at least dessert

IBC Charter

- Introduction
- Responsibilities
  - Identifies research that will be reviewed
- Membership
- Management
  - Quorum
  - Conflict of interest
  - Response to FOIA

IBC minutes

- Written by BSO / ABSO
- Date / time
- Lists members present, absent, guests
- Protocol title, PI name, agents, recombinant methodology, section of Guidelines
- Containment level discussion
- Vote or not, approved or not
- Circulate to committee for comments
- Vote to accept at next meeting

Review process - rDNA

- All rDNA experiments registered
- BSO reviews all registrations
- BSO approves exempt (Section III-F)
- Full IBC review of all experiments requiring IBC review and approval (Sections III-A, III-B, III-C III-D, III-E).

Review process: Not recombinant

- Non-recombinant infectious agents
  - BSO reviews RG2 agents, with input from IBC chair as needed (usually goes to committee)
  - IBC reviews and approves all RG3 level agents
- Select agents – IBC review and approval

Training IBC members

- OBA visit
- IBC basics course
- Occasional short (5-10 min.) training sessions during meetings

Promoting institutional support

- Associate Vice President for Research on committee
- OBA site visit

Administrative procedures / biosafety program

- Biosafety program staffing
- Research registration form
- Strategies for capturing research
- Training PIs / researchers

Staffing structure

- Vice President for Administrative Affairs
- Department of Environmental Safety
- Biosafety Officer
- Assistant Biosafety Officer
- Part time Biosafety Assistant

UNIVERSITY OF MARYLAND **ENVIRONMENTAL S@FETY** Division of Administrative Affairs

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Research Registration Form

Please answer all the questions below to generate the Research Registration Form. The Institutional Biosafety Committee meets monthly on the first Thursday of the month. Registrations must be submitted by the 20th to be considered at the following month's meeting.

Does the project you are registering involve:

1. **Recombinant DNA Research?**
   ○ Yes ◉ No
2. **Infectious agents?**
   ○ Yes ◉ No
3. **Human blood, cell culture, or unfixed tissue?**
   ○ Yes ◉ No
4. **Non-human primate blood, primary cell culture or unfixed tissue?**
   ○ Yes ◉ No

Begin

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Maintained by Department of Environmental Safety

Direct questions and comments to safetyv@umd.edu

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Does the project you are registering involve:

1. **Recombinant DNA Research?**
   - (●) Yes ( ) No

   A. rDNA in prokaryotic hosts:
      ( ) Yes (●) No
   B. rDNA in lower eukaryotes (e.g, yeast):
      ( ) Yes (●) No
   C. rDNA in cell culture:
      ( ) Yes (●) No
   D. Transgenic animals:
      ( ) Yes (●) No
   E. rDNA in animals:
      ( ) Yes (●) No
   F. rDNA in whole plants:
      ( ) Yes (●) No
   G. rDNA in insects:
      ( ) Yes (●) No

2. **Infectious agents?**
   - ( ) Yes (●) No

3. **Human blood, cell culture, or unfixed tissue?**
   - ( ) Yes (●) No

4. **Non-human primate blood, primary cell culture or unfixed tissue?**
   - ( ) Yes (●) No

Begin

Research Registration Form

(Required information is designated in black)

1. **Principal Investigator (PI):**
   First Name:
   Last Name:
2. **College:** Agriculture and Natural Resources Other:
3. **Department:**
4. **Phone Number:**
5. **Email:**
6. **Project Title:**
7. **Other Personnel working on Project:**
8. **Lab Building:** 9999 - Other Building Not Listed
9. **Lab Room Number:**
10. **Department Chair Name*:**
11. **Department Chair Email Address*:**
    * The Department Chair information is used to contact your Chair so he/she can approve this registration.

12. **Recombinant DNA in prokaryotic hosts**
    a. **E. coli K12 as host:** ○ Yes ◉ No
    b. **Other prokaryotes as host:** ○ Yes ◉ No
       If yes, what Species:
    c. **Gene(s) encoded by inserted DNA:**
    d. **Source (species) of inserted DNA:**
    e. **Vectors:**
    f. **Will inserted gene(s) be expressed:** ○ Yes ◉ No
    g. **If yes, what are the gene product effects (toxicity, physiological activity, oncogenic potential, or ability to alter cell cycle):**
    h. **Do experiments involve large scale (>10 liters in one container) culture of organisms containing rDNA:** ○ Yes ◉ No
    i. **rDNA research involving biological toxin gene:** ○ Yes ◉ No
       If yes, the Name of toxin:
    j. **rDNA research involving transfer of drug resistance gene:** ○ Yes ◉ No
       - **If J is yes, the Name of drug resistance gene:**
       - **If J is yes, is the host a human or animal pathogen:** ○ Yes ◉ No
       - **If J is yes, is the antibiotic a first-line or second-line treatment against the disease:** ○ Yes ◉ No
       - **If J is yes, is the antibiotic used to treat the disease in a specific patient population (pregnancy):** ○ Yes ◉ No
       - **If J is yes, is the antibiotic used to treat the disease in other countries:** ○ Yes ◉ No
       - **If J is yes, does the microorganism acquire the drug resistance naturally:** ○ Yes ◉ No

18. **Overview.** Please attach a brief overview of the proposed research in layman's terms.

19. **Risk Assessment and control.** Please attach a brief protocol-specific risk assessment. Include consideration of parent and recombinant agent pathogenicity, virulence, infectious dose, route of transmission, host range, and stability, as well as the likelihood of exposure and consequences of exposure. How will identified risks be controlled (e.g. PPE, work practices, etc.)?

20. **Post-exposure procedures.** Please describe post-exposure procedures that will be followed in the event of an accidental exposure.

21. **Section of NIH Guidelines:**
22. **Containment:** BL1

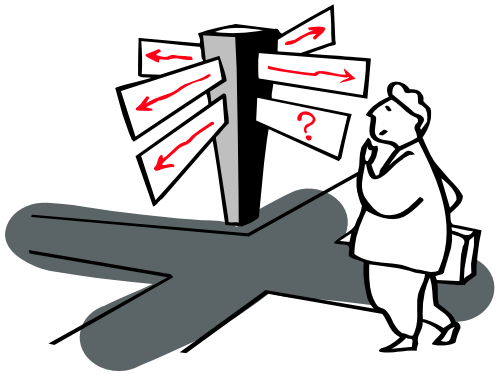
- By submitting this form, I acknowledge my responsibility for the conduct of this research in accordance with section IV-B-7 of the NIH Guidelines for Research Involving Recombinant DNA Molecules.
- By submitting this form, I acknowledge responsibility for the safe conduct of work with this organism(s) at Biosafety Level BL1 (indicate appropriate level) and have informed all personnel who may be at risk of potential exposure to the organism of the appropriate procedures for this work.

Submit

Capturing rDNA research

- Review grant applications
- Review MTAs
- Membership on IACUC
- Discussions during lab audits

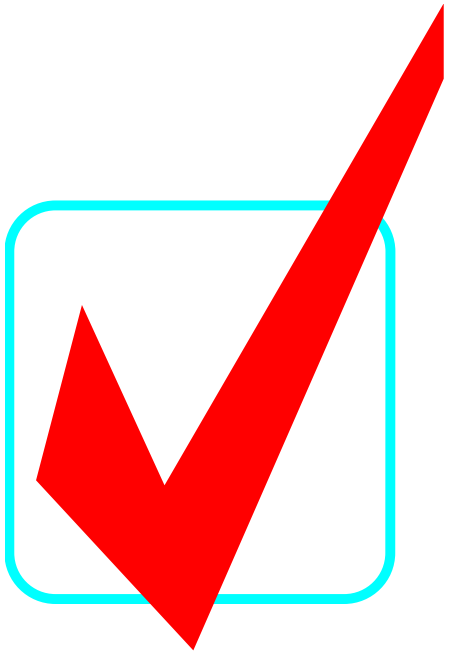
Training researchers



- NIH Guidelines training during lab audits
- Guide to the NIH Guidelines (www.des.umd.edu/biosafety/rdna/nih.html)
- Web page, new researcher training, COs
- IBC approval letters
- Online rDNA/infectious agents registration

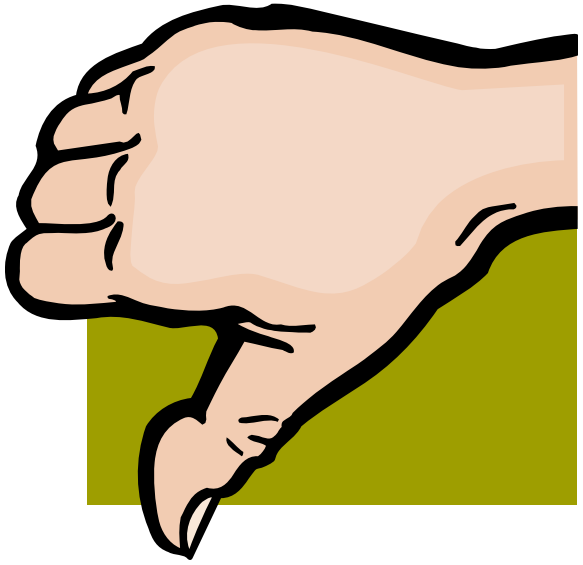
Lessons learned: What works

- Lunch
- Good committee members
- Great community members
- Online registration form
- Electronic approval letters
- Well-planned meetings
- Balancing transparency and security



Lessons learned: What doesn't work

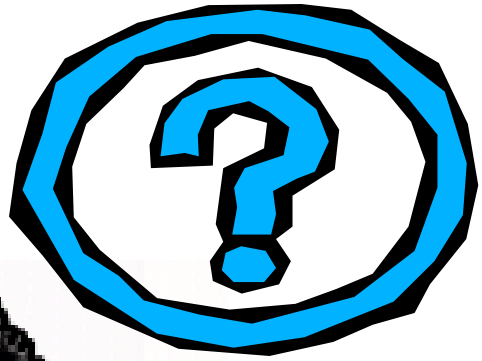
- Some rDNA research still slips through the cracks – e.g., preliminary data
- Some PIs still resistant
- Finding time for adequate training for IBC

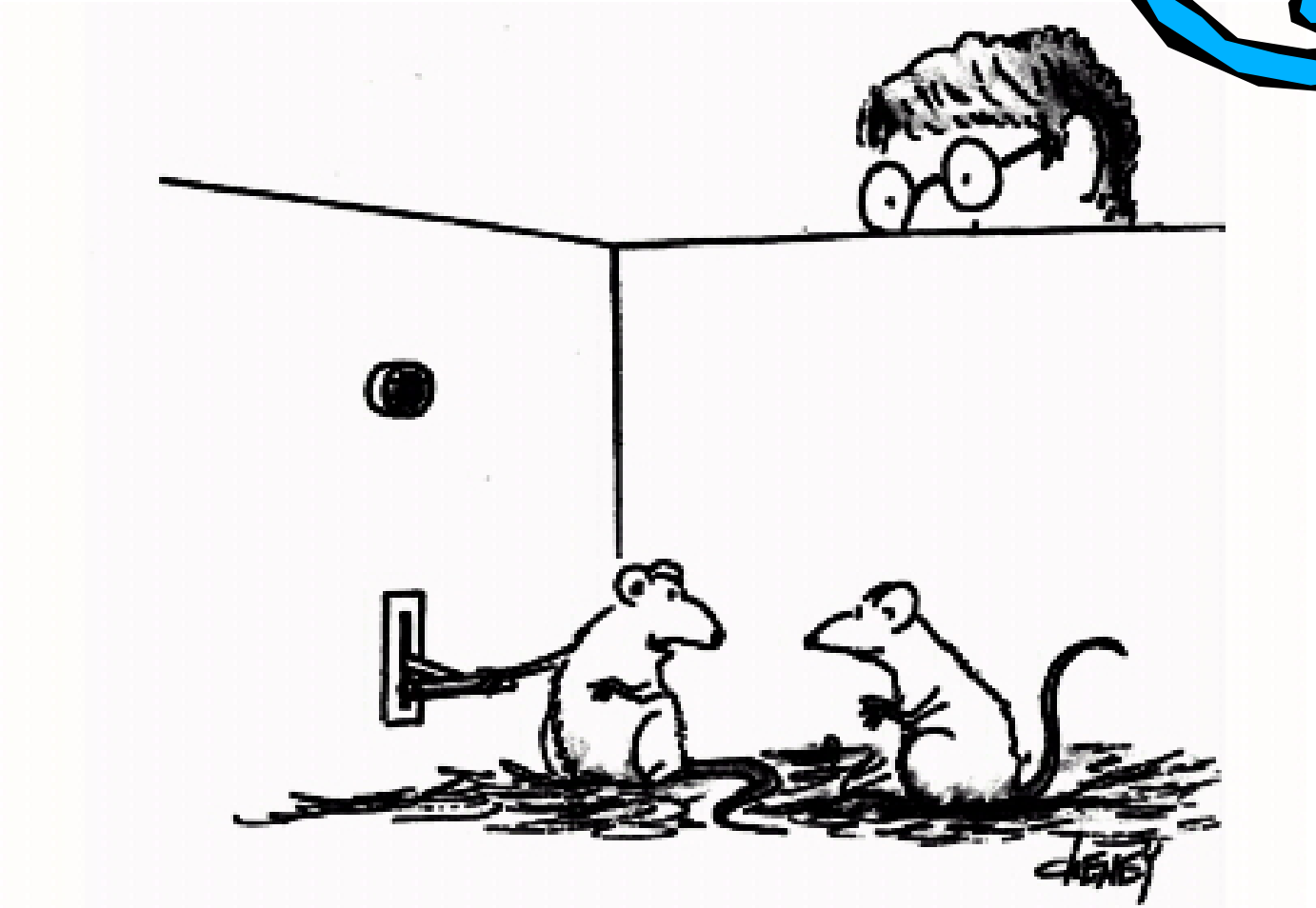


What does the future hold?

- More work for the IBC
- More BSL3 labs = more BSL3 protocols for IBC review
- Addition of synthetic nucleic acids to NIH Guidelines
- Local review of dual use research of concern?

Questions?





It's a rather interesting phenomenon. Every time I press this lever, that post-graduate student breathes a sigh of relief.