# Institutional Biosafety Committees and the NIH OBA Site Visit Program





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# Growing Significance of IBCs Recombinant DNA research has grown in volume and complexity NIH budget has more than doubled from 1998 (\$13.7 billion) to present (\$28.6 billion); comparable growth in recombinant DNA research Expanding programs of research into Biodefense strategies Emerging infectious diseases New technological capabilities Genome synthesis (e.g. polio) Reverse engineering of non-contemporaneous pathogens (e.g., 1918 influenza) Novel approaches to human gene transfer



### IBCs and Public Support of Research

- Public trust is critical to continued scientific support and progress
- IBCs are an increasingly critical linchpin to public trust in recombinant DNA research – and by extension, support of the research enterprise broadly
- We must ensure that IBCs are equipped to fulfill their responsibilities so that public safety and trust are preserved



# OBA Guidance, Training, and Resources Conferences for IBCs Policy conference Professional development conference Training courses ASGT, ABSA, ACRP, PRIM&R Exhibits and presentations at key professional and scientific meetings AAMC, ABSA, ACLAM, ARENA, ASGT, MSMR, NBAC, PhRMA, PRIM&R, etc.





# OBA Guidance, Training, and Resources

- NIH Guidelines and Federal Register notices
- Minutes and video of RAC meetings
- Reports of safety symposia
- "Latest news" items on meetings, policy guidance, resources, compliance notices, etc.
- GeMCRIS
- IBC Web page
  - FAQs
  - Training materials: Slide Presentations and Video of Professional Development Workshops







# Site Visit Program Methodology

- Pre-visit
  - Notification letter
  - Questions regarding program
  - Request for documentation



# Site Visit Program Methodology

- Post-visit
  - Report from OBA
    - Desitive characteristics and practices
    - Considerations for possible change or improvement
    - Possible deficiencies or practices not in keeping with the NIH Guidelines
  - □ Follow up as required

# Site Visit Program Diversity of Institutions

### Institutional

### Туре

- Academic
  - Public
  - Private
- Commercial
- Research institute

Research

### Characteristics

- In vitro
- Human gene transfer
- Animal
- Plant
- Biosafety level 1-4

### Site Visit Program Positive Practices



### IBC procedure manual or SOPs

- Comprehensive SOPs help ensure that IBCs and others with biosafety responsibilities fulfill their duties consistently and correctly
- SOPs can also facilitate successful training by articulating clear performance expectations

### Site Visit Program Positive Practices

- Senior institutional official on IBC
  - Helps ensure institutional support

### IBC conflict of interest policy

 Promotes attention to this topic and consistent approaches to dealing with it

### Public access to IBC meetings

 Transparency encourages public trust and support

## Site Visit Program Positive Practices



- Coordination between IBC, IACUC, IRB
  - Helps ensure that all recombinant DNA protocols are reviewed by the IBC
- Coordination with Grants and Contracts Office
  - Helps provide an additional checkpoint for compliance with the NIH Guidelines



# Site Visit Program Compliance Challenges

- Robust training for IBC members, research staff, and support staff (e.g., animal care):
  - Utilize slides on OBA's Web site
  - Take advantage of "IBC Basics" and other external training opportunities
  - Develop in-house programs that build on these resources
  - Devote explicit attention to recombinant DNA
  - Document attendance

### Site Visit Program Compliance Challenges

- Approval of all projects subject to Sections III-A through III-E of the NIH Guidelines at a <u>convened meeting</u> of a quorum of the IBC
  - See OBA guidance on meetings (http://www4.od.nih.gov/oba/IBC/IBCindexpg.htm)

### Site Visit Program Compliance Challenges

- Periodic review of recombinant DNA research
  - Have the IBC determine when project registrations should be renewed
  - Conduct rigorous laboratory inspections:
    - Documentation
    - Frequency
    - Qualification of inspector
    - Inspection standards

### Site Visit Program Compliance Challenges

- Awareness of incident reporting requirements:
  - Incorporate incident reporting into training programs
    - Report within <u>30 days</u> to NIH OBA any significant problems, violations of the NIH Guidelines, or any significant researchrelated accidents and illnesses
    - Report <u>immediately</u> to NIH OBA certain incidents described in Appendix G-II





# What if Your Institution is Contacted for a Site Visit?

- Don't panic!
- Prepare
  - Pull together necessary documentation
  - Conduct an introspective examination of your IBC program









BC Management System - Institutions - Microsoft Internet Explorer	
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National Institutes of Health Office of Biotechnology Activities	ttee tem m 1.0
Welcome to the Institutional Biosafety Committee Registration Management System (BC, RMS). This system was designed to facilitate the submission of IBC updates to the Office of Biotechnology Activities, National Institutes of Health and to enhance the ability of IBC: Ordenee with the NH Guidelinees for Recombinant DNA Molecules (NH Guidelinees). Users can:       Name IBC:	I take Res Fraining sword Usiness civil, and shall be This or use of
② Done	Local intranet







# New Educational Materials from OBA

### Major Action FAQs

- Section III-A-1: The deliberate transfer of a drug resistance trait to microorganisms that are not known to acquire the trait naturally, if such acquisition could compromise the use of the drug to control disease agents in humans, veterinary medicine, or agriculture, will be reviewed by RAC
  - Experiments considered as *Major Actions* under the *NIH Guidelines* <u>cannot be initiated</u> without submission of relevant information on the proposed experiment to the Office of Biotechnology Activities, the publication of the proposal in the *Federal Register* for 15 days of comment, review by RAC, and <u>specific approval by NIH</u>.



