Requirements for IBCs in the *NIH Guidelines*

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IBCs and NIH - Partners in the Oversight of Recombinant DNA Research

NIH OBA

NIH Guidelines

RAC
National perspective

IBC
Local oversight
IBCs and NIH OBA

- IBCs are the key institutional component of a national system of oversight.
- IBCs are "sentinels" at the local level, identifying new safety and policy issues for NIH OBA and RAC consideration.
Institutional Biosafety Committees

- Established specifically for the review of recombinant DNA research
- Often review other research with biohazardous risks
  - Infectious agents, carcinogens
  - Broader purview is a matter of institutional discretion
Assembling an IBC

- Membership
  - No fewer than 5 individuals
  - Appropriate recombinant DNA expertise collectively
  - Plant and animal experts, biosafety officer as appropriate
  - Expertise in assessment of risk to environment and public health
  - At least two members not affiliated with the institution
Assembling an IBC

- **Additional expertise**
  - Biological safety, and physical containment
  - Knowledge of institutional commitments and policies, applicable law, professional standards, community attitudes, and environment
  - Laboratory technical staff (recommended)
Assembling an IBC

- **Plant Expert**
  - Expertise in plant, plant pathogen or plant pest containment principles when experiments utilizing Appendix P are being conducted
  - Greenhouse Experiments - plants are of a size, number of have growth requirements that preclude the use of laboratory containment conditions (Appendix G)
Assembling an IBC

- Animal Expert
  - Expertise in animal containment principles when experiments utilizing Appendix Q are being conducted
Assembling an IBC

- Biological Safety Officer
  - BSO must be appointed and made a member of the IBC if research is:
    - Large scale (>10 L)
    - BL-3 or BL-4
The BSO’s duties include:

- Periodic inspection of labs
- Reporting to the IBC and institution of any problems, violations, research-related accidents or illnesses
- Developing emergency plans for handling accidental spills and personnel contamination
- Advice on lab security
- Technical advice to PIs and IBCs on research safety procedures
Assembling an IBC

- Non-institutional members - Who are they?
  - Representatives of community interests with respect to health and protection of the environment
  - E.g., officials of state or local public health or environmental authorities, local government bodies, persons with medical, occupational, or environmental expertise
  - They can also be the individuals who “represent community attitudes”
Staffing the IBC

- Not prescribed in the NIH Guidelines
  - IBC Administrator
  - Biological Safety Officer
  - Compliance Officer
  - Manager of Environmental Health and Safety
  - Others
Ad hoc Consultants

- Use when reviewing research outside the expertise of your members.
Registering an IBC

- Register the IBC with OBA and file annual membership updates
  - A roster of IBC members
    - Clearly indicate chair, contact person, and special expertise as appropriate (BSO, animal, plant, human gene transfer)
  - Biographical sketches of all members
Registering an IBC

- **Purpose of registration and annual membership updates**
  - Provides assurance of local review of biosafety risks
  - Allows OBA to see that IBC expertise consistent with the *NIH Guidelines*
  - Indicates institutional point of contact
  - Provides census of the field: where recombinant DNA research being conducted
IBCs Registered with the NIH OBA
March 2005

- Academic = 52%
- Hospital/Clinic = 18%
- Government = 6%
- Other = 1%
- Research Institute = 8%
- Commercial = 15%

Institute = 8%
IBC Responsibilities

In a nutshell, what must IBCs review?

- Recombinant DNA research for conformity with the *NIH Guidelines*
- Potential risk to environment and public health
What do IBCs assess in reviewing recombinant DNA research?

- Containment levels per NIH Guidelines
- Adequacy of facilities, SOPs, PI and lab personnel training
- Institutional and investigator compliance; e.g., adverse event reports
In basic and preclinical research, IBCs have authority to:

- Lower containment levels for certain experiments in which DNA from Risk Group 2-4 is cloned in non-pathogenic organisms
- Set containment levels for experiments involving whole plants and animals
- Review periodically institutional compliance with NIH Guidelines
- Adopt emergency plans covering spills, contamination, other accidents
In human gene transfer research, IBCs must also ensure:

- No participant 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
- Compliance with surveillance, data reporting, and adverse event reporting
IBC Responsibilities

- The IBC may not:
  - Authorize initiation of rDNA experiments not explicitly covered by the *NIH Guidelines* until NIH (with the advice of the RAC when required) establishes the containment requirement.
Do IBCs determine what research is exempt?

Does the PI?

- A matter of institutional policy
- IBC may wish to designate member, chair, or BSO as first line of review to make determinations about what is exempt and what requires full review
- NIH OBA can help with determinations
Current Issues Concerning IBCs

- How should IBCs work with other institutional oversight committees?
- How often should IBCs meet? What constitutes a meeting? Can we use an expedited review process?
- What do we need to record in minutes? How must we provide access to minutes?
IBCs and Other Research Oversight Committees

- IBC
- IRB
- IACUC
How should IBCs work with other institutional oversight committees?

- Not prescribed in the *NIH Guidelines*
- Institutions should determine best way for these committees to interact and share information
IBCs and IACUCs
Animal Research

- Joint purview, and ideally collaborative review, over certain types of research
  - Transgenic or cloned animals
  - Use of recombinant DNA molecules in animals
  - Pre-clinical studies and data assessment for human gene transfer protocols
## IBC and IACUC Review of Animal Research Utilizing Recombinant DNA

<table>
<thead>
<tr>
<th>IBC Review</th>
<th>IACUC Review</th>
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<tbody>
<tr>
<td><strong>Risks to human health</strong></td>
<td><strong>Animal welfare</strong></td>
</tr>
<tr>
<td>– Transfer of genetically altered material, viral vectors etc.</td>
<td>– Pain and distress from adverse phenotypes (behavioral, anatomical and physiological abnormalities)</td>
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<tr>
<td><strong>Risks to the environment</strong></td>
<td></td>
</tr>
<tr>
<td>– Escape and establishment in the wild</td>
<td>– Risks to other animals in the facility from the inadvertent spread of vectors</td>
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<tr>
<td>– Interbreeding with wild stock</td>
<td></td>
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<tr>
<td>– Consumption by other animals</td>
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Animal Research with rDNA: Points to Consider

- Containment procedures (SOP’s)
  - Physical and biological
  - Plans for recapture of escapees
  - Consequences should containment fail
- Procedures for transfer of animals
- Transportation procedures
- Disposal and destruction methods
- Breeding SOP’s
- Occupational biosafety concerns
  - Personal protective equipment
  - Decontamination
# IBC and IRB Review of Research Utilizing Recombinant DNA

<table>
<thead>
<tr>
<th>IRB Review</th>
<th>IBC Review</th>
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<tbody>
<tr>
<td>▪ Possible risks to subjects</td>
<td>▪ Recombinant DNA research for conformity with the <em>NIH Guidelines</em></td>
</tr>
<tr>
<td>▪ Anticipated benefits to subjects and others</td>
<td>▪ Potential risk to environment and public health</td>
</tr>
<tr>
<td>▪ Selection of subjects and the informed consent process</td>
<td>▪ Containment levels per <em>NIH Guidelines</em></td>
</tr>
<tr>
<td>▪ Data monitoring provisions to ensure the safety of subjects</td>
<td>▪ Adequacy of facilities, SOPs, PI and other personnel training</td>
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<tr>
<td>▪ Provisions to protect subject privacy and confidentiality of data</td>
<td>▪ Institutional and investigator compliance (e.g., adverse event reports)</td>
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<tr>
<td>▪ Injuries or any other unanticipated problems</td>
<td></td>
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<td>▪ Compliance with regulations</td>
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### IBCs and IRBs

#### Human Gene Transfer Research

<table>
<thead>
<tr>
<th>IBC</th>
<th>IRB</th>
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<tr>
<td>Approves/disapproves HGT protocols</td>
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</tr>
<tr>
<td>Final approval contingent, in part, on completion of NIH RAC review process</td>
<td>Approval can come before or after RAC review (IRBs do receive information from RAC)</td>
</tr>
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IRB approval necessary before enrollment can begin in HGT trials
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Convening an IBC

- Frequency
  - Periodic per protocol review load
  - Ongoing surveillance (annual review desirable)
Convening an IBC

Section IV-B-2-a-(6) states:

“When possible and consistent with protection of privacy and proprietary interests, the institution is encouraged to open its Institutional Biosafety Committee meetings to the public”

Institution has latitude in determining how to create public awareness of meetings
Convening an IBC

- **Letter of the NIH Guidelines**
  - IBCs are encouraged to open meetings to the public
  - Institution shall make IBC minutes available to the public upon request

- **Intent of the NIH Guidelines**
  - Interactive (face-to-face, video- or teleconferencing)
Email may be appropriate for:
- distribution of protocol materials
- conducting pre-meeting reviews (e.g. exemption determinations)
- polling members about particular matters
Expedited or Designated Reviews

- Concepts in the human subjects regulations (45 CFR 46) and animal welfare act regulations (9 CFR Part 2) respectively

- *Not* concepts in the *NIH Guidelines*

- An initial review process utilizing just the chair or IBC staff person or review by a subcommittee may only be used for:
  - determinations of which research is exempt and which is subject to the *NIH Guidelines*
Current Issues Concerning IBCs

- How should IBCs work with other institutional oversight committees?
- How often should IBCs meet? What constitutes a meeting? Can we use an expedited review process?
- What do we need to record in minutes?
  How must we provide access to minutes?
Access to Minutes

- Section IV-B-2-a-(7) states:
  - Upon request, the institution shall make available to the public all Institutional Biosafety Committee meeting minutes and any documents submitted to or received from funding agencies which the latter are required to make available to the public.

1 Generally, rosters and biosketches
Content of Minutes

- Not prescribed in the NIH Guidelines
- Generally accepted principles exist
  - Robert’s Rules of Order
  - Need to document IBC fulfillment of review and oversight responsibilities
- Avoid extremes
  - Transcripts are probably not necessary
  - Don’t simply state, “We met. We adjourned.”
- Use good judgment and common sense
Access to Minutes

- Redaction

  - Section IV-B-2-a-(6) of the NIH Guidelines acknowledges that the protection of private or proprietary information is a basis for closing meetings to the public.
  
  - Since minutes are records of meetings, it is logical to extend protection of such information to minutes through redaction.
  
  - Redaction must be judicious and consistent.
Access to Minutes

- **Forms of access**
  - Mail, e-mail, Web site (open or password protected)
  - Requiring on-site inspection generally not appropriate
    - can be excessively burdensome on requestor
    - could be considered a deterrent
Access to Minutes

- Special procedures
  - Nothing in the *NIH Guidelines* precludes institutions from applying or complying with specific procedures in releasing minutes
  - State institutions are often subject to state public disclosure laws; Federal facilities are subject to FOIA
  - Following public disclosure laws is not inherently in conflict with the *NIH Guidelines*; reasonable fees to cover costs are acceptable
OBA Guidance

Connect to:

The *NIH Guidelines* emphasize the importance of training and place responsibility on:

- Institutions to train IBC members, BSO, PI, and laboratory staff
- NIH to conduct and support training programs
Institutional Training Programs

- Should provide information on federal requirements
- Should also include information on institutional policies, procedures, and requirements
- Should be tailored to the audience – investigators vs. administrators vs. lab staff
IBCs and NIH OBA

- NIH OBA provides oversight, guidance, and resources for IBCs
  - Staff and information resources available to help ensure IBCs, their institutions, and investigators are compliant with the *NIH Guidelines*
  - Scientific and medical staff available to answer queries
    - Interpretation of NIH Guidelines
    - Containment
    - Exemptions
    - Risk group classification
OBA Outreach and Education

- **Conferences for IBCs**
  - Policy conference (Dec. 2001)
  - Professional development conference (Feb. 2003)

- **Training courses**
  - ASGT, ABSA, ACRP

- **Presentations at key professional and scientific meetings**
  - AAMC, ABSA, ACLAM, ARENA, ASGT, NBAC, PhRMA, PRIM&R, etc.
Electronic communication tools

- Listserv: “OBA_NEWS”
  - Policy notices, meeting announcements, compliance reminders

- Email inbox for queries: oba@od.nih.gov
  - Questions on interpretation of the *NIH Guidelines*, status of protocols, scientific and medical issues
IBC Resources on OBA’s Web Site

- 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
Institutional Biosafety Committees (IBCs) are the cornerstone of institutional oversight of recombinant DNA research. The following information and resources are provided to help IBCs perform this critical role, as well as to inform others about the roles and responsibilities of these important committees.

Frequently Asked Questions (FAQs) of Interest to IBCs

- Key Definitions and Acronyms
- NIH Guidelines for Research Involving Recombinant DNA Molecules
- IBC Roles and Responsibilities
- Committee Membership
- Submissions to the NIH Office of Biotechnology Activities

Meetings & Conferences
IBC Resources – Training Materials

- Professional Development Conferences
  - Slide presentations, reports, and videos
  - “Fundamentals” training sessions:
    - Safety in human gene transfer
    - Ethics of recombinant DNA research
    - Biodefense research and Select Agents
Outreach and Education

- Conduct proactive not-for-cause site visits
  - Educate about IBC requirements
  - Provide on-site advice
  - Identify opportunities for improvement
For Updates on All OBA Initiatives

- Subscribe to OBA_NEWS
  - Email to: listserv@list.nih.gov
  - In body of message:
    - subscribe OBA_NEWS
Contact Information

National Institutes of Health
Office of Biotechnology Activities

6705 Rockledge Drive, Suite 750
Bethesda, Maryland 20892-7985
Phone (301) 496-9838
Fax (301) 496-9839
http://www4.od.nih.gov/oba/
e-mail: oba@od.nih.gov
Morning Session: The Fundamentals

- Introduction to the National Institutes of Health Office of Biotechnology Activities
- Overview of the Current *NIH Guidelines for Research Involving Recombinant DNA Molecules*
- Requirements for IBCs in the *NIH Guidelines*
- Open Forum
- Break
- Role of the Recombinant DNA Advisory Committee and the Protocol Review Process
- Case Studies
BREAK !