Requirements for Institutional Biosafety Committees under the NIH Guidelines



National Institutes of Health Office of Biotechnology Activities Institutional Biosafety Committees The cornerstone of oversi

The cornerstone of oversight for research involving recombinant and synthetic nucleic acid molecules at the local level







Levels of Oversight

FEDERAL

LOCAL & NONFEDERAL

• HHS:

- □ OHRP □ NIH:
 - OBA
 - IC Program Staff
- USDA
- EPA
- FDA

- Institutions:
 - IBCs
 - IACUCs
 - IRBs
- Investigators
- Private Sponsors



Institutional Biosafety Committees

 Established under the NIH Guidelines specifically for the review of research involving recombinant or synthetic nucleic acid molecules



Institutional Biosafety Committees

- IBCs are typically assigned additional review responsibilities
 - Select agents and toxins
 - Blood borne pathogens
 - Xenotransplantation
 - Stem cell research
 - "Dual Use" research
 - Nanotechnology



 Broader purview is a matter of institutional discretion

- Membership
 - At least five individuals
 - Appropriate recombinant and synthetic nucleic acid expertise collectively
 - Plant and animal experts, biosafety officer as appropriate
 - At least two members not affiliated with the institution



- Expertise
 - Expertise in assessment of risk to environment and public health
 - Knowledge of institutional commitments and policies, applicable law, professional standards, community attitudes, and environment
 - Biological safety and physical containment
 - Laboratory technical staff (recommended)

- Biological Safety Officer (BSO)
 - A BSO must be appointed and be a member of the IBC if the institution conducts recombinant or synthetic nucleic acid research at:
 - Large scale (>10 L)
 - High containment (BL-3 or BL-4

The BSO's duties include:

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



- 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 should be individuals who "represent community attitudes"

Staffing the IBC

- Not prescribed in the NIH Guidelines
 - IBC Administrator
 - Biological Safety Officer
 - Compliance Officer
 - Environmental Health and Safety Professionals
 - 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





Number of IBCs registered with OBA



IBC Registration Trends

Year



Growing Significance of IBCs

- Research involving recombinant and synthetic nucleic acid molecules has grown in volume and complexity
 - NIH budget more than doubled from 1998 (\$13.7 billion) to present (\$31.3 billion requested for 2014)
 - Expanding programs of research into
 - Biodefense
 - Emerging infectious disease research
 - New technological capabilities
 - Genome synthesis (e.g. polio)
 - Reverse engineering of non-contemporaneous pathogens (e.g., 1918 influenza)
 - Novel approaches to human gene therapy

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 is consistent with the NIH Guidelines
 - Indicates institutional point of contact
 - Provides census of the field: where
 research subject to the NIH Guidelines
 is being conducted

Registering an IBC

- IBC RMS Online registration tool
 - Facilitates submission of IBC registrations and annual updates to OBA
 - Allows for easy verification of annual report due dates
 - Provides "tickler" e-mails for overdue updates
 - Permits identification of IBCs with current registrations

IBC Registration Management System (RMS)

National Institutes of Health Office of Biotechnology Activities Institutional Biosafety Committee Registration Management System

Welcome to the Institutional Biosafety Committee Registration Management System (*IBC-RMS*). This system supports online submission of IBC registrations and annual registration updates to the NIH Office of Biotechnology Activities (OBA).

All visitors to this page may also access information on IBC compliance and **view a list of IBCs that are currently registered with OBA.**

You may use this system to:

- Submit a new IBC registration
- Update an existing IBC registration

We invite you to **request access** and begin a convenient way to keep your IBC's registration up-to-date.



Related Information

- IBCs Registered with OBA
- Frequently Asked Questions on Incident Reporting
- Other Information on IBC Compliance
- NIH Guidelines

Support

- Tutorial
- Contact Us
- Browser Requirements

U.S. Department of Health and Human Services | NIH | USA.gov - Government Made Easy | Privacy Notice | Site Map

IBC Responsibilities

- In a nutshell, what must IBCs review?
 - Research involving recombinant or synthetic nucleic acid molecules for conformity with the *NIH Guidelines*
 - Potential risk to environment and public health
 - Containment levels per NIH Guidelines
 - Adequacy of facilities, SOPs, PI and lab personnel training
 - Institutional and investigator compliance; e.g., adverse event reports

IBC Responsibilities

- In basic and preclinical research, IBCs have authority to:
 - Lower containment levels for certain experiments in which nucleic acid from Risk Group 2-4 is cloned in nonpathogenic 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

IBC Responsibilities

- For human gene transfer research, IBCs must also ensure:
 - No participant enrolled in a trial until RAC review, IBC and IRB approval has been obtained
 - Issues raised by the RAC in public review are considered
 - Final IBC approval occurs only <u>after</u> RAC review
 - PI compliance with surveillance, data reporting, and adverse event reporting



IBCs and Exempt Research

- Should IBCs determine what research is exempt?
 Should the PI?
 - A matter of institutional policy
 - IBC may wish to designate the chair, a member, or the BSO to conduct an initial review to confirm what is exempt and what requires full IBC review
 - NIH OBA can help with determinations

IBCs and Other Institutional Research Oversight Committees



IBC Coordination with Other Institutional Oversight Committees

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

IBCs and IACUCs – Oversight of Animal Research

- Joint purview, and ideally collaborative review, over certain types of research
 - Transgenic or cloned animals
 - Use of recombinant or synthetic nucleic acid molecules in animals
 - Pre-clinical studies and data assessment for human gene transfer protocols

IBC and IACUC Review of Animal Research Subject to the *NIH Guidelines*

IBC Review	IACUC Review
Risks to human health	Animal welfare
 Transfer of genetically altered material, viral vectors etc. 	 Pain and distress from adverse phenotypes (behavioral
 Risks to the environment Escape and establishment in the wild 	anatomical and physiological abnormalities)
 Interbreeding with wild stock Consumption by other animals 	 Risks to other animals in the facility from the inadvertent spread of vectors

IBCs and IRBs – Oversight of Juna Gene Transfer Research IRB Review IBC Review • Conducts risk/benefit assessment relative to individual research participants (physical, • Research for conformity with the NIH Guidelines

psychological, social harms)

Selection of subjects and the

Data monitoring provisions to

ensure the safety of subjects

privacy and confidentiality of data

Injuries or any other unanticipated

Provisions to protect subject

Compliance with regulations

problems

informed consent process

- Potential risk to environment and public health (risks to close contacts, health care workers, and the community, as well as to individual research participants)
- Containment levels per NIH Guidelines
- Adequacy of facilities, SOPs, PI and other personnel training
- Institutional and investigator compliance (e.g., adverse event reports)
- Reviews trial design, biosafety and containment, and compliance with *NIH Guidelines*

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

- Policy and professional development conferences for IBC members and staff
- Training courses and presentations at key professional and scientific meetings

IBC resources on OBA's web site

- NIH Guidelines and Federal Register notices
- Reports of safety symposia
- "Latest news" items on meetings, policy guidance, resources, compliance notices, etc.
- FAQs
- Training materials: slide presentations, brochures, posters, and videos



Questions?

