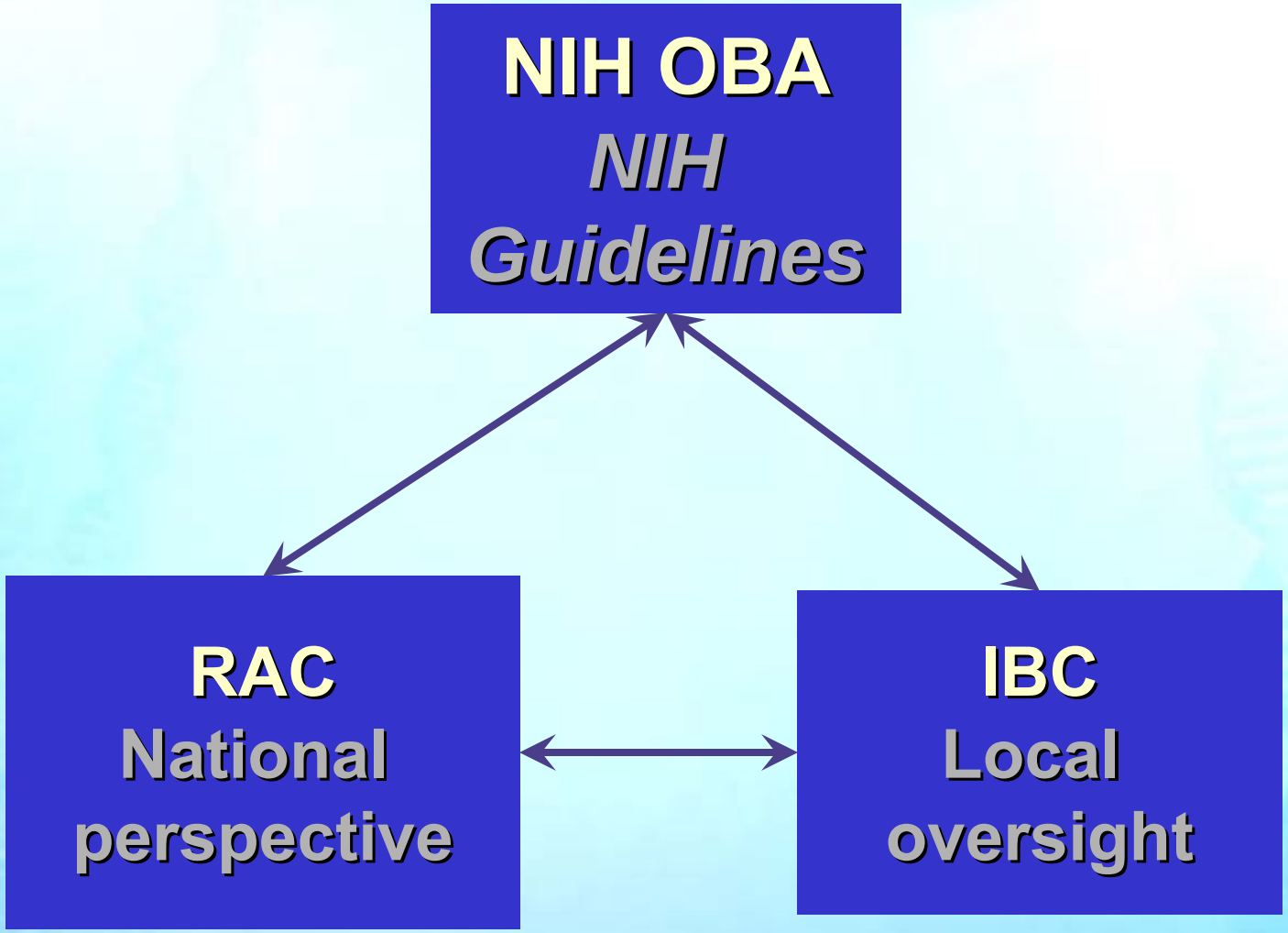
Institutional Biosafety Committees: The Linchpin of Local Oversight

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



Levels of Recombinant DNA Oversight

FEDERAL

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

LOCAL & NONFEDERAL

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

Institutional Biosafety Committees

- Established under the *NIH Guidelines* specifically for the review of recombinant DNA research
- Often review other research with biohazardous risks
  - Infectious agents, Select Agents and carcinogens
  - Broader purview is a matter of institutional discretion

IBC Membership

- No fewer than 5 individuals
- Appropriate recombinant DNA expertise collectively
- Plant and animal experts, biosafety officer as appropriate
- At least two members not affiliated with the institution

IBC Membership

- **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)**

IBC Membership

- **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**

IBC Membership

- **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

IBC Membership

- **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”**

IBC Membership

- **Ad hoc consultants**
  - **May be used when reviewing research outside the expertise of the standing IBC membership**
  - **Often used in human gene transfer research**

IBC Staffing

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

Registering an IBC

- **An institution subject to the *NIH Guidelines* must register an 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

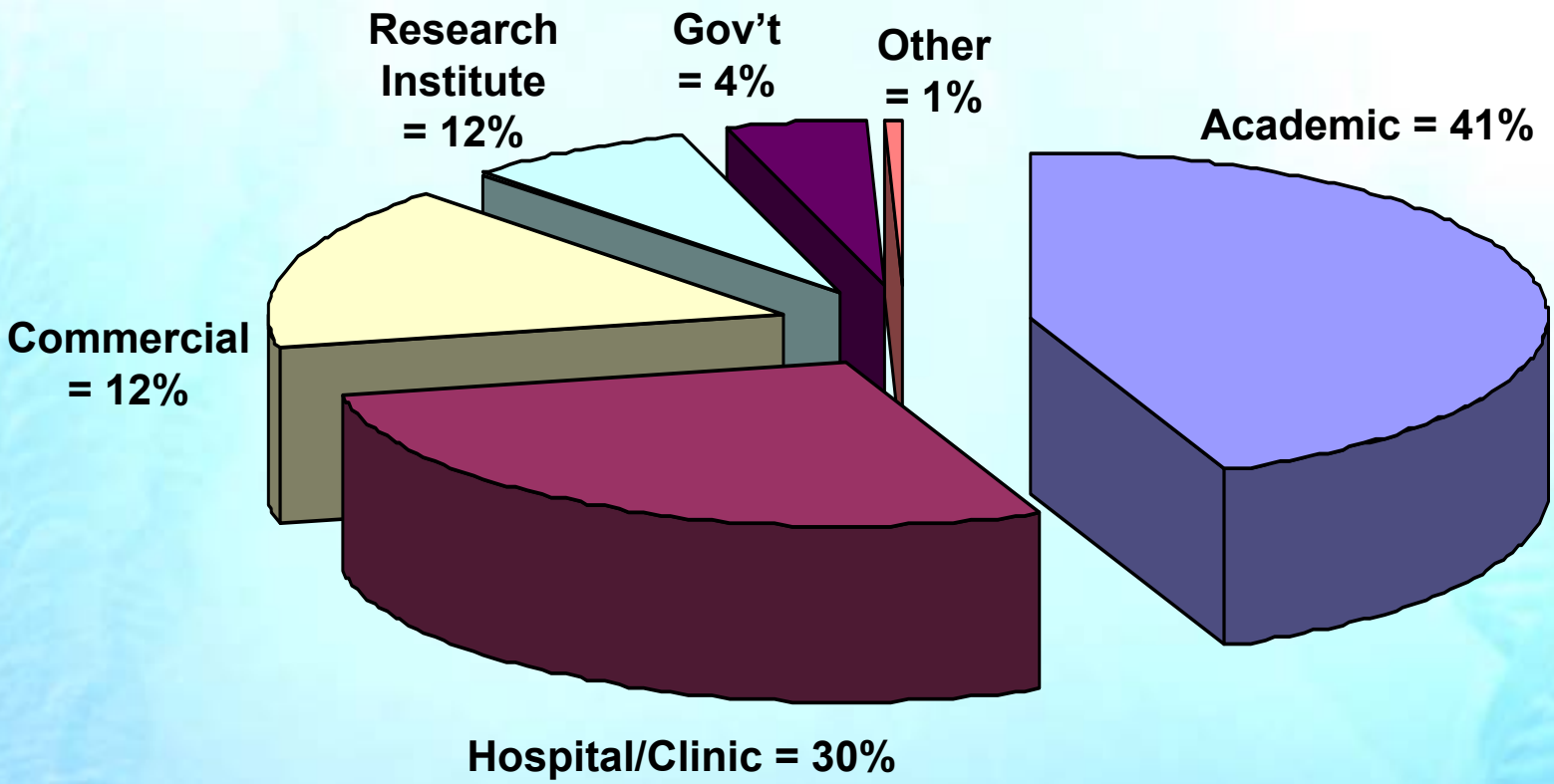
- **In human gene transfer research:**
  - **IBC approval must be obtained from the institution at which recombinant DNA material will be administered to human research participants**
  - **IBC approval for human gene transfer research cannot be granted by the manufacturer of the product being tested**
  - **Clinical trial sites therefore must establish an IBC for the review of gene transfer trials they are conducting and register the IBC with OBA**

Registering an IBC

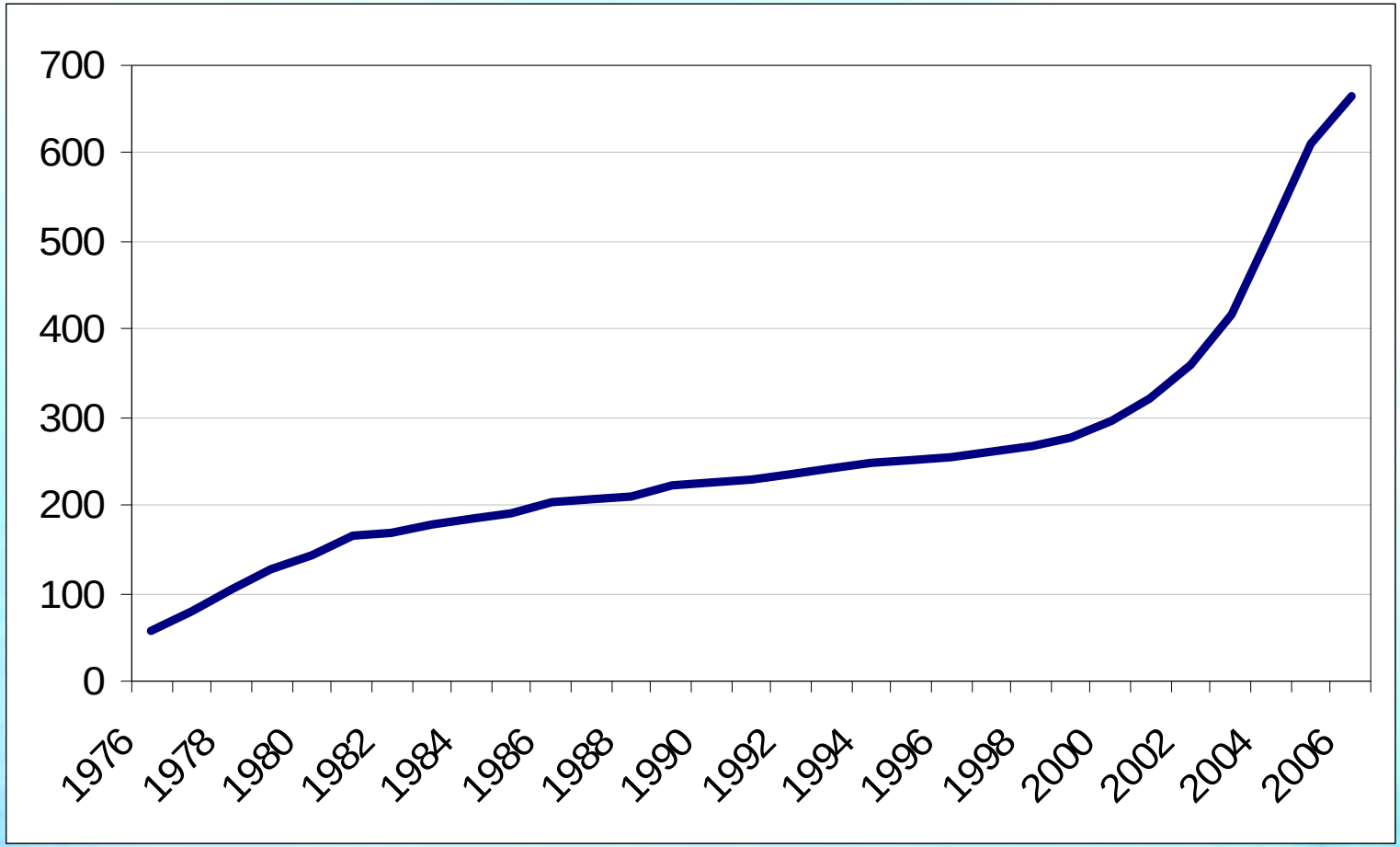
- **Purpose of registration and annual membership updates**
  - **Provides assurance of local review of biosafety risks**
  - **Allows OBA to see that IBC expertise consistent with the *NIH Guidelines***
  - **Indicates institutional point of contact**
  - **Provides census of the field: where recombinant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

IBCs Registered with the NIH OBA
May 2007

N = 699



Growing Significance of IBCs



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**
    - **Containment levels per *NIH Guidelines***
    - **Adequacy of facilities, SOPs, PI and lab personnel training**
    - **Institutional and investigator compliance; e.g., adverse event reports**

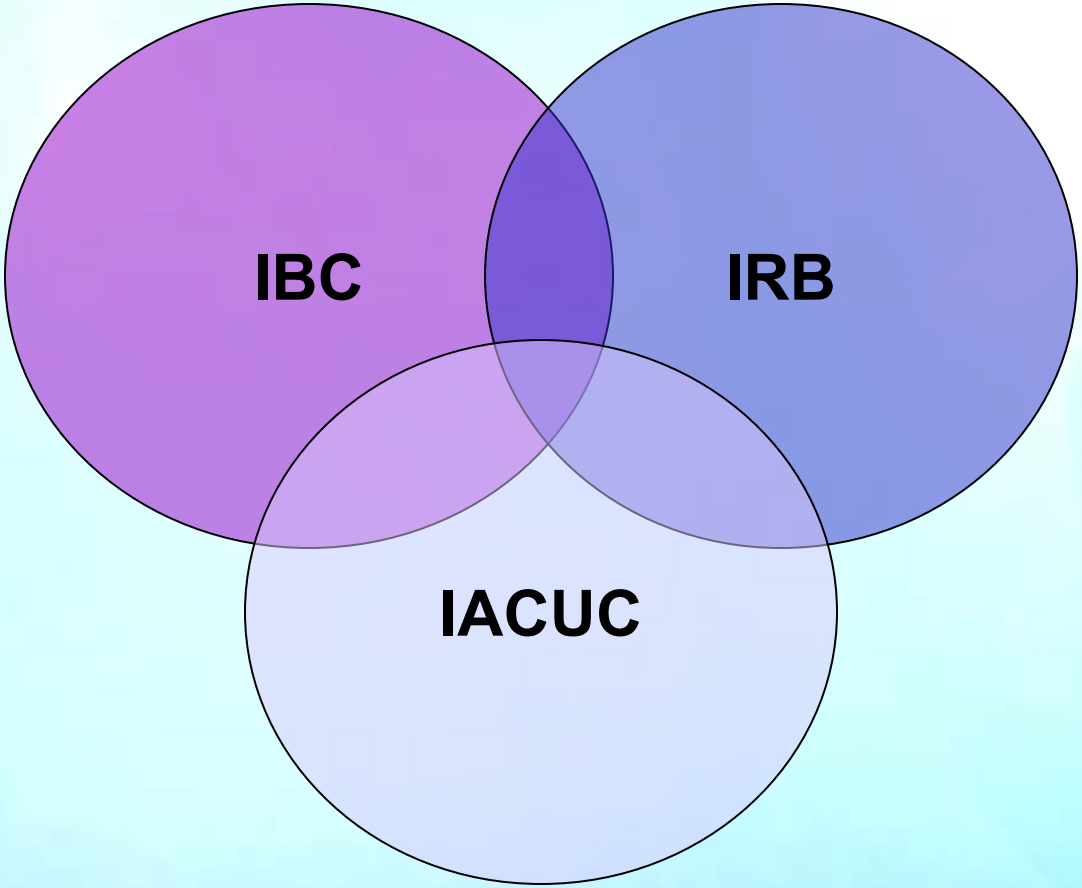
IBC Responsibilities

- **In 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**

IBCs and Exempt Research

- **Who should determine what research is exempt? The PI? The IBC?**
  - **A matter of institutional policy**
  - **NIH OBA can help with determinations**

IBCs and Other Institutional Oversight Committees



IBCs and Other Institutional Oversight Committees

- IBCs work and other institutional oversight committees
  - Not prescribed in the *NIH Guidelines*
  - Institutions should determine best way for these committees to interact and share information

IBC and IACUC Review of Animal Research Utilizing Recombinant DNA

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

IBCs and IRBs
Human Gene Transfer Research

IRB Review	IBC Review
▪ Conducts risk/benefit assessment relative to individual research participants (physical, psychological, social harms) ▪ Selection of subjects and the informed consent process ▪ Data monitoring provisions to ensure the safety of subjects ▪ Provisions to protect subject privacy and confidentiality of data ▪ Injuries or any other unanticipated problems ▪ Compliance with regulations	▪ Recombinant DNA research for conformity with the *NIH Guidelines* ▪ Potential risk to environment and public health (risks to close contacts, HCWs, 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*

The Importance of IBCs and BSOs to Investigators

- **The IBC and BSO can help you to:**
  - **Ensure that you are working with recombinant DNA safely**
  - **Meet all compliance requirements associated with NIH funding for research involving recombinant DNA**
  - **Avoid preventable accidents and incidents that might cause harm or undermine public confidence in your research activities**
  - **Obtain biosafety advice on an ongoing basis**

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

Questions?