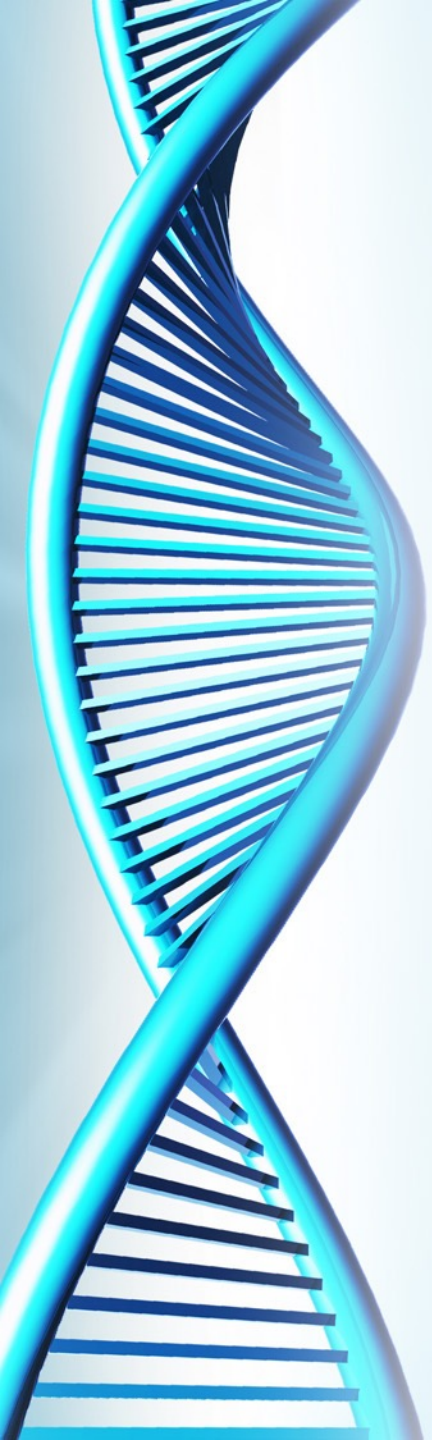


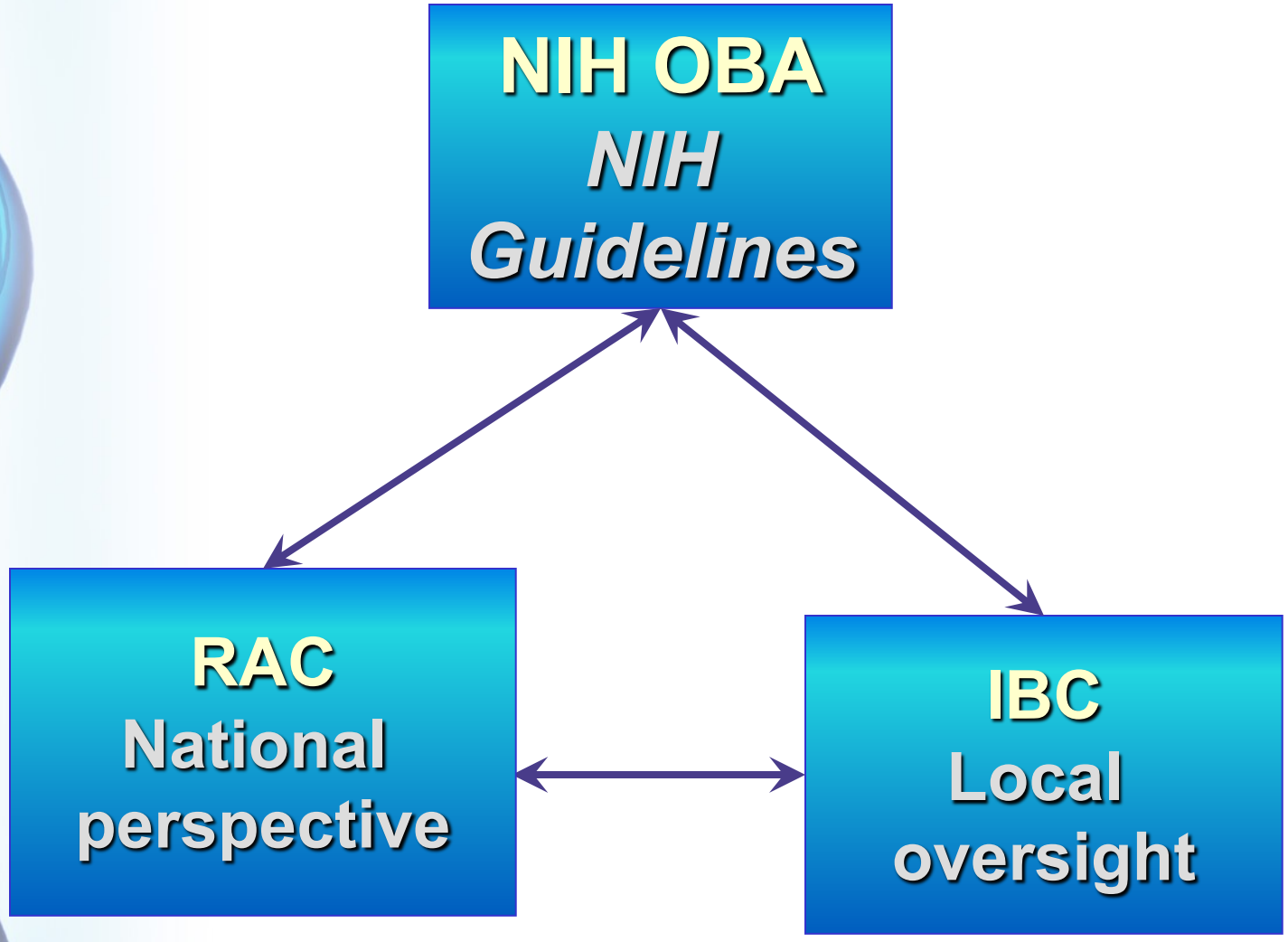
# Requirements for Institutional Biosafety Committees under the *NIH Guidelines*

National Institutes of Health
Office of Biotechnology Activities

# Institutional Biosafety Committees

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

# IBCs and NIH - Partners in Oversight



# Levels of 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 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

# Assembling an IBC

- **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**

# Assembling an IBC

- **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)**

# Assembling an IBC

- **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**

# Assembling an IBC

- **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 the IBC 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 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

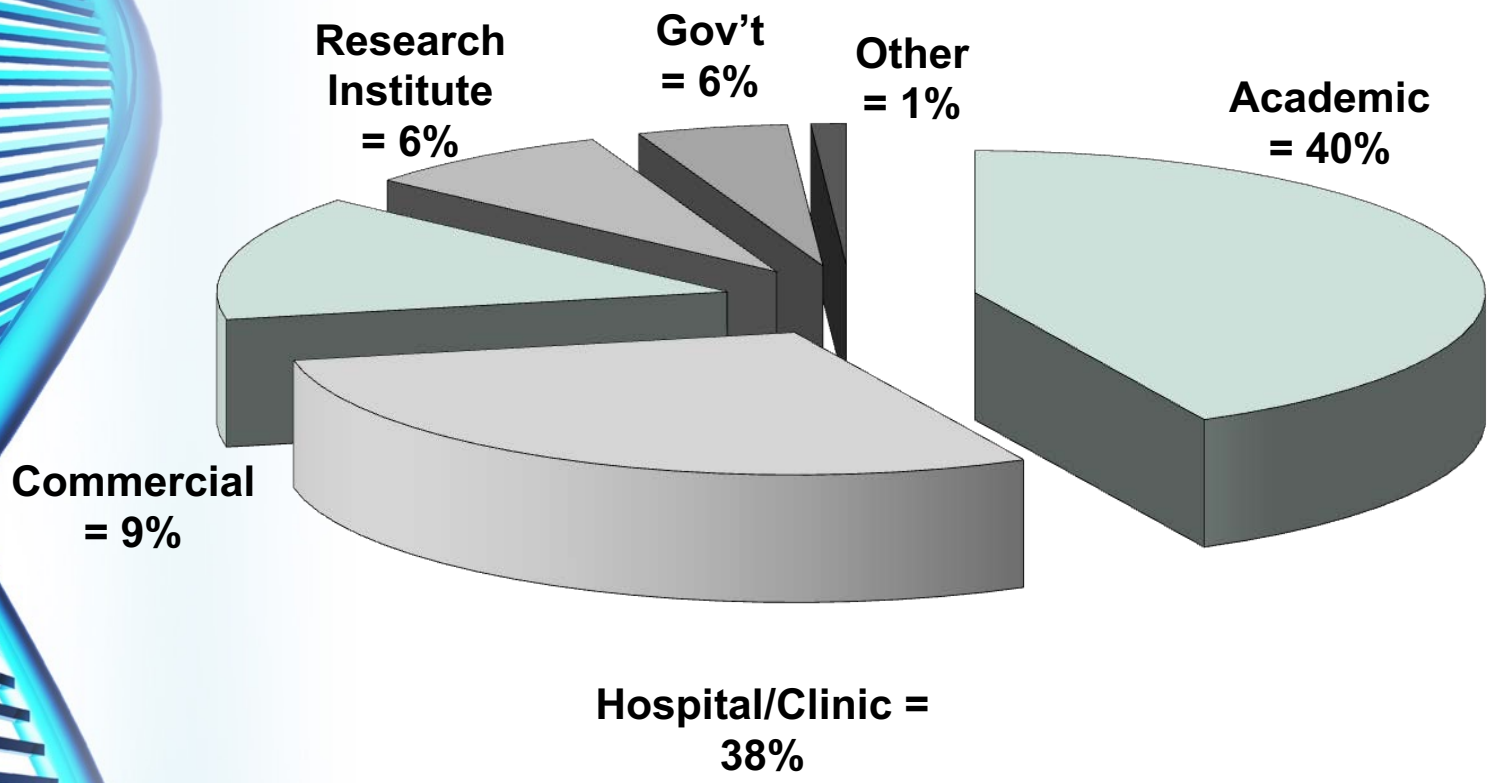
# *Ad hoc* Consultants

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

# Registering an IBC

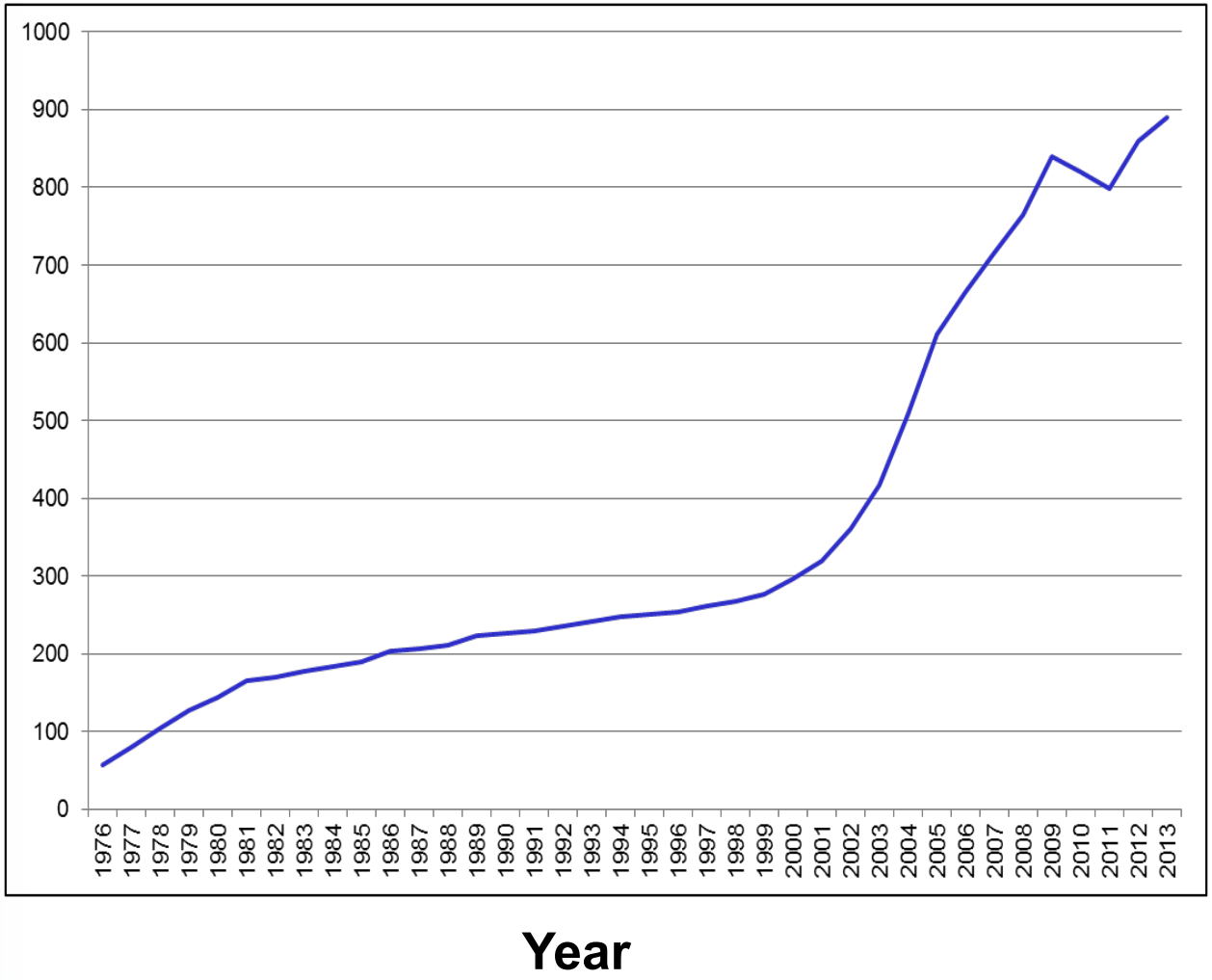
- Register the IBC with OBA and file annual membership updates
  - A roster of IBC members
    - Clearly indicate chair, contact person, and special expertise as appropriate (BSO, animal, plant, human gene transfer)
  - Biographical sketches of all members

# IBCs Registered with NIH OBA




March 2014 = 863

# IBC Registration Trends



# 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

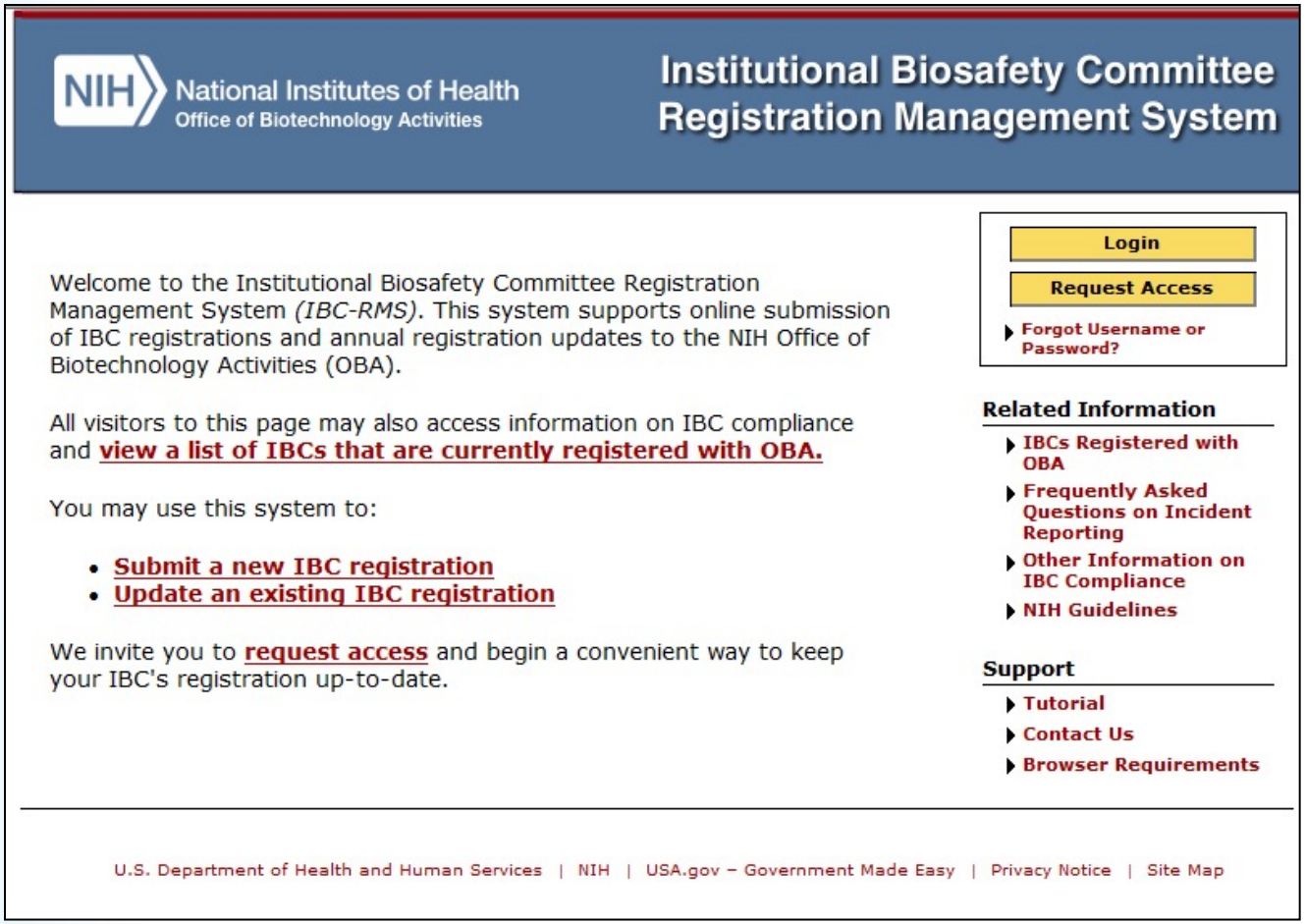
# Registering an IBC

- **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)



# 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 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**

# 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 after RAC review**
  - **PI compliance with surveillance, data reporting, and adverse event reporting**

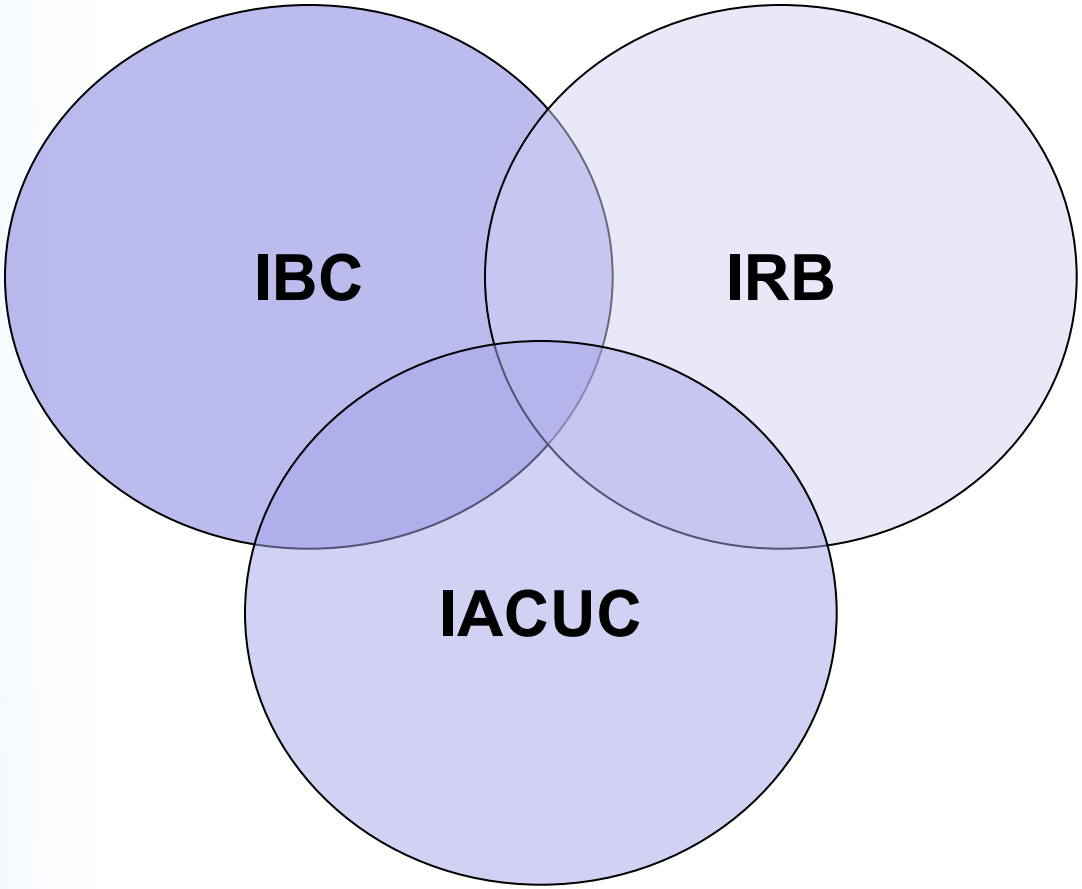
# IBCs and Exempt Research

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

# IBCs and IRBs – Oversight of Human Gene Transfer Research

| IRB Review | IBC Review |
|---|---|
| ▪ Conducts risk/benefit assessment relative to individual research participants (physical, psychological, social harms)<br>▪ Selection of subjects and the informed consent process<br>▪ Data monitoring provisions to ensure the safety of subjects<br>▪ Provisions to protect subject privacy and confidentiality of data<br>▪ Injuries or any other unanticipated problems<br>▪ Compliance with regulations | ▪ Research for conformity with the *NIH Guidelines*<br>▪ Potential risk to environment and public health (risks to close contacts, health care workers, and the community, as well as to individual research participants)<br>▪ Containment levels per *NIH Guidelines*<br>▪ Adequacy of facilities, SOPs, PI and other personnel training<br>▪ Institutional and investigator compliance (e.g., adverse event reports)<br>▪ 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?