



**Overview of the Current *NIH*
Guidelines for Research Involving
*Recombinant DNA Molecules***



Kathryn Harris



NIH Guidelines for Research Involving Recombinant DNA Molecules

- A scientifically-responsive document that will continue to evolve
 - Have undergone multiple revisions since 1976
 - Latest version - April 2002

Amendment Effective July 26, 1994, Federal Register, August 5, 1994 (59 FR 40170)
Amendment Effective April 17, 1995, Federal Register, April 27, 1995 (60 FR 20726)
Amendment Effective December 14, 1995, Federal Register, January 19, 1996 (61 FR 1482)
Amendment Effective March 1, 1996, Federal Register, March 12, 1996 (61 FR 10006)
Amendment Effective January 23, 1997, Federal Register, January 31, 1997 (62 FR 4782)
Amendment Effective September 30, 1997, Federal Register, October 14, 1997 (62 FR 5335)
Amendment Effective October 20, 1997, Federal Register, October 29, 1997 (62 FR 5619)
Amendment Effective October 22, 1997, Federal Register, October 31, 1997 (62 FR 5902)
Amendment Effective February 4, 1998, Federal Register, February 17, 1998 (63 FR 3052)
Amendment Effective April 30, 1998, Federal Register, May 11, 1998 (63 FR 2313)
Amendment Effective April 29, 1999, Federal Register, May 11, 1999 (64 FR 2335)
Amendment Effective October 2, 2000, Federal Register, October 10, 2000 (65 FR 6033)
Amendment Effective December 28, 2000, Federal Register, January 5, 2001 (66 FR 1149)
Amendment Effective December 11, 2001, Federal Register, December 11, 2001 (66 FR 5405)
Amendment Effective December 19, 2001, Federal Register, November 19, 2001 (66 FR 5197)
Amendment Effective January 10, 2002, Federal Register, December 11, 2001 (66 FR 5402)
Amendment Effective January 24, 2002, Federal Register, November 19, 2001 (66 FR 5197)

NIH GUIDELINES FOR RESEARCH INVOLVING RECOMBINANT DNA MOLECULES (NIH GUIDELINES)

April 2002

Visit the OBA Web site at:
<http://www4.od.nih.gov/oba>
For current information on Guidelines, Protocols, Principal Investigator Meeting, and information about upcoming Gene Therapy Policy Conference.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
National Institutes of Health
Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines)

These NIH Guidelines supersede all earlier versions and shall be known as the NIH Guidelines.

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<http://www4.od.nih.gov/oba/rac/guidelines/guidelines.html>



Content of the *NIH Guidelines*

- **Section I – Scope**
- **Section II – Safety Considerations**
- **Section III – Types of Experiments Covered**
- **Section IV – Roles and Responsibilities**
- **Appendices**



NIH Guidelines – Section I

- **Scope**
 - **Specifies practices for constructing and handling**
 - **Recombinant DNA molecules**
 - **Organisms and viruses containing recombinant DNA molecules**
 - **Definition**
 - **Constructed outside living cells by joining natural or synthetic DNA segments to DNA molecules that can replicate in a living cell**
 - **Molecules resulting from the replication of those described above**



The *NIH Guidelines* Apply to...

- **Recombinant DNA research that is**
 - **Funded by the NIH**
 - **Performed at or sponsored by an institution that receives any NIH funding for recombinant DNA research**
- **Rationale: For biosafety to be meaningful, it has to be observed by all investigators at an institution**



Are the *NIH Guidelines* Optional?

- **“Guidelines” does not mean “optional”**
- **They are a term and condition of NIH funding for recombinant DNA research**



Are the *NIH Guidelines* optional?

- **What are potential consequences of noncompliance with the *NIH Guidelines*?**
 - **suspension, limitation, or termination of NIH funds for recombinant DNA research at the institution, or**
 - **a requirement for prior NIH approval of any or all recombinant DNA projects at the institution.**



Prescription versus Flexibility

- **Some matters are left to institutional discretion**
- **Flexibility is a two-sided coin**
 - **Accommodates institutional diversity and heterogeneity**
 - **Can create uncertainty about expectations**



NIH Guidelines – Section II

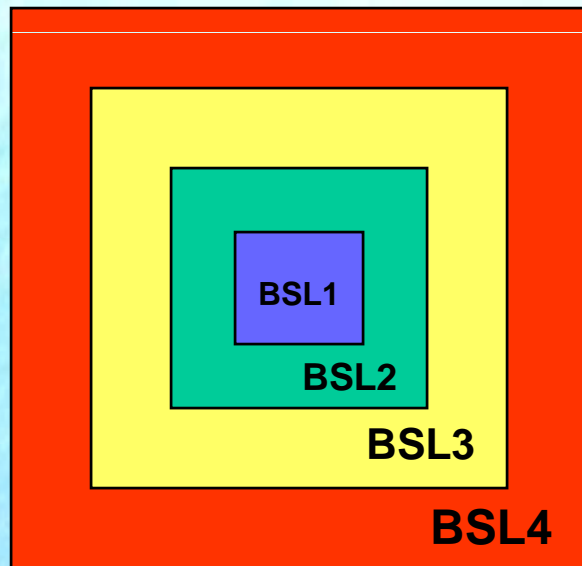
- **Safety Considerations**
 - **Risk assessments: (Appendix B)**

RG 1	RG 2	RG 3	RG 4
Agents that are not associated with disease in healthy adult humans	Agents that are associated with human disease which is rarely serious and for which preventive or therapeutic interventions are <i>often</i> available	Agents that are associated with serious or lethal human disease for which preventive or therapeutic interventions <i>may be</i> available (high individual risk but low community risk)	Agents that are likely to cause serious or lethal human disease for which preventive or therapeutic interventions are <i>not usually</i> available (high individual risk and high community risk)



NIH Guidelines – Section II

■ Safety Considerations



□ Containment

■ Physical (Appendix G)

- Practices
- Equipment/facilities

■ Biological (Appendix I)

- Survival
- Transmission



NIH Guidelines - Section III

Levels of Review

Level of review	Example of recombinant DNA research involving animals	Relevant section(s) of the <i>NIH Guidelines</i>
IBC, RAC review, and NIH Director review and approval	Experiments that compromise the control of disease agents in medicine through deliberate transfer of a drug resistance trait	III-A
IBC approval and NIH review for containment determinations	Experiments conducted with a recombinant DNA modified restricted agent in a whole animal	III-B
IBC and IRB approval and NIH review before research participant enrollment	Not applicable	III-C
IBC approval before initiation	Creating stable germline alterations of an animal's genome, or testing viable rDNA modified microorganisms on whole animals, where BL-2 containment or greater is necessary	III-D
IBC notice at initiation	Creating stable germline alterations of rodents using recombinant DNA when these experiments require only BL-1 containment	III-E
Exempt from the <i>NIH Guidelines</i> . IBC registration not required if experiment not covered by Sections III-A, III-B, or III-C	Purchase or transfer of transgenic rodents	III-F



Key Portions of the *NIH Guidelines* for Animal Research

- **Section III-D-4 Experiments Involving Whole Animals – IBC Approval Before Initiation**
 - **Experiments in which:**
 - the animal's genome has been altered by stable introduction of rDNA into germline, or
 - rDNA modified microorganisms are tested on whole animals
 - BL2 or BL2-N or greater containment



Key Portions of the *NIH Guidelines* for Animal Research

- **Section III-D-5 Experiments Involving Whole Plants – IBC Approval Before Initiation**
 - **Experiments in which:**
 - **Plants genetically engineered by rDNA methods, or**
 - **Plants are used with recombinant DNA-modified insects**
 - **Generally BL2-P through BL4-P, depending on risk**



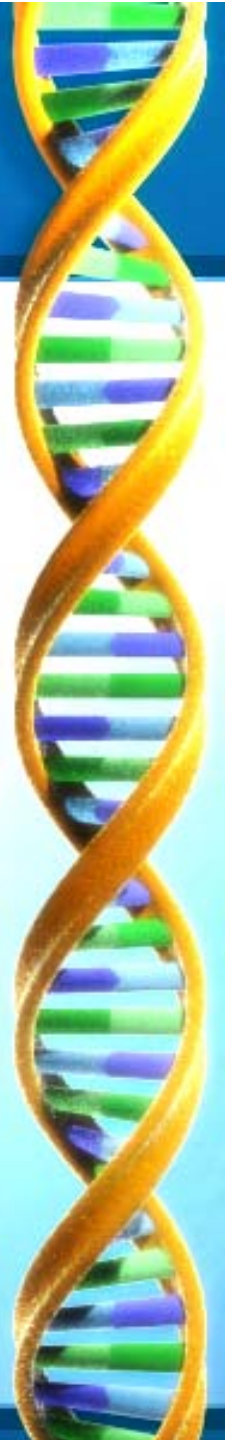
Key Portions of the *NIH Guidelines* for Animal Research

- **Section III-E-3 Experiments Involving the Generation of Transgenic Rodents – IBC Notice at Initiation**
 - **Experiments in which:**
 - **Rodent's genome has been altered by stable introduction of rDNA into germline**
 - **BL1 containment is appropriate**



Key Portions of the *NIH Guidelines* for Animal Research

- **Section III-F (and Appendix C-VI) - Exempt Experiments**
 - The purchase or transfer of rodents for experiments that require BL-1 containment
 - Further manipulations of these animals with recombinant DNA are not necessarily exempt from the *NIH Guidelines*



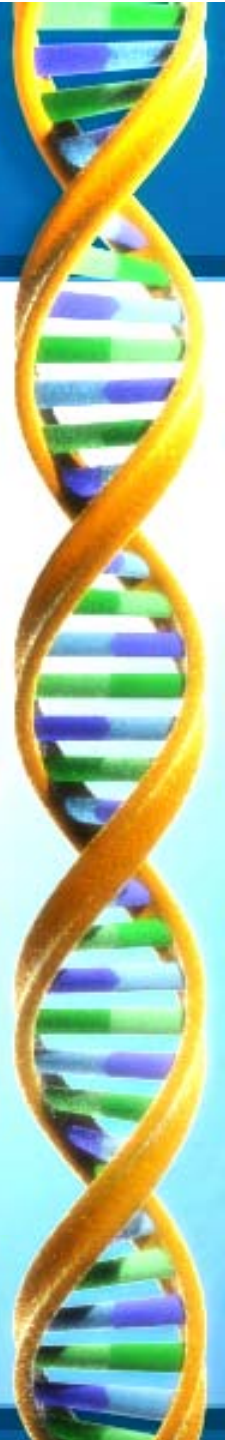
NIH Guidelines – Section IV

- **Roles and Responsibilities**
 - **Institution**
 - **Institutional Biosafety Committee (IBC)**
 - **Biological Safety Officer (BSO)**
 - **Principal Investigator (PI)**
 - **NIH**



Institutional Responsibilities under the *NIH Guidelines*

- **The Institution shall:**
 - **Establish and implement policies for the safe conduct of recombinant DNA research**
 - **Establish an Institutional Biosafety Committee**
 - **Assist and ensure compliance with the *NIH Guidelines* by investigators**
 - **Ensure appropriate training for IBC members and staff, PIs, laboratory staff**
 - **Determine necessity for health surveillance of personnel**
 - **Report any significant problems or violations to OBA within 30 days**



PI Responsibilities under the *NIH Guidelines*

- **The Principal Investigator shall (among other things):**
 - **Initiate or modify no recombinant DNA research which requires IBC approval until approval is granted**
 - **Determine whether experiments are covered under III-E and notify the IBC as appropriate**
 - **Be adequately trained in good microbiological techniques**
 - **Adhere to IBC emergency plans for spills and personnel contamination**
 - **Report any significant problems or violations to OBA within 30 days**



NIH Responsibilities under the *NIH Guidelines*

- **NIH OBA (*on behalf of the NIH Director*)**
 - **Managing the RAC**
 - **Conducting and supporting training of IBCs, BSOs, investigators, laboratory staff**
 - **Convening Scientific Symposia and Gene Therapy Policy Conferences**
 - **Review of:**
 - **Human gene transfer protocols**
 - **Certain basic recombinant DNA experiments**
 - **“Minor actions”**
 - **Changes not requiring approval by the NIH Director**



NIH Responsibilities under the *NIH Guidelines*

- **Basic recombinant DNA experiments reviewed by NIH OBA**
 - **Deliberate transfer of drug resistance trait to microorganisms not known to acquire the trait naturally, if it could compromise disease control**
 - **Cloning of toxin molecules with LD₅₀ <100 ng/Kg bodyweight**
 - **DNA from restricted agents transferred to nonpathogenic prokaryotes or lower eukaryotes**
 - **DNA from nonpathogenic prokaryotes or lower eukaryotes transferred to restricted agents**
 - **Use of infectious or defective restricted poxviruses in presence of helper virus**



NIH Guidelines - Appendices

- **Appendix A – Exemptions: Natural Exchangers**
- **Appendix B – Classification of Etiologic Agents**
- **Appendix C – Exemptions under IIIF**
- **Appendix D – Major Actions**
- **Appendix E – Certified Host-Vector Systems**
- **Appendix F – Biosynthesis of Toxic Molecules**
- **Appendix G – Physical Containment**
- **Appendix H – Shipment**
- **Appendix I – Biological Containment**



Organization of the *NIH Guidelines*

- **Appendix J – Biotechnology Research Subcommittee**
- **Appendix K – Large Scale Physical Containment**
- **Appendix L – Gene Therapy Policy Conferences**
- **Appendix M – Points to Consider in Human Gene Transfer Research**
- **Appendix P – Physical and Biological Containment: Plants**
- **Appendix Q – Physical and Biological Containment: Animals**



Key Portions of the *NIH Guidelines* for Animal Research

- **Appendix G**
 - **Specifies details of containment and confinement for standard laboratory practices**
 - **Defines Biosafety Level 1 through Biosafety Level 4**
 - **Appropriate for animals that are worked with in a laboratory setting**



Key Portions of the *NIH Guidelines* for Animal Research

- **Appendix Q**
 - **Applies when research animals are of a size or have growth requirements that preclude laboratory containment**
 - **For example, cattle, swine, sheep, goats, horses, poultry, etc.**



Key Portions of the *NIH Guidelines* for Animal Research

- **Appendix Q (cont'd)**
 - **Addresses containment and confinement practices in animal facilities (BL1-N to BL4-N)**
 - **Applies to animals:**
 - **In which genome is altered by stable introduction of rDNA; or**
 - **On which rDNA-modified microorganisms are being tested**



Key Portions of the *NIH Guidelines* for Animal Research

- **Primates - Appendix G or Q?**
 - **Depends on the conditions under which the primates are being housed and used in experimentation**
 - **Primates used in high-level, laboratory containment conditions; Appendix G applies**
 - **In other settings, primates may be worked with in settings akin to those described in Appendix Q**
 - **Professional judgment is key - OBA can help!**



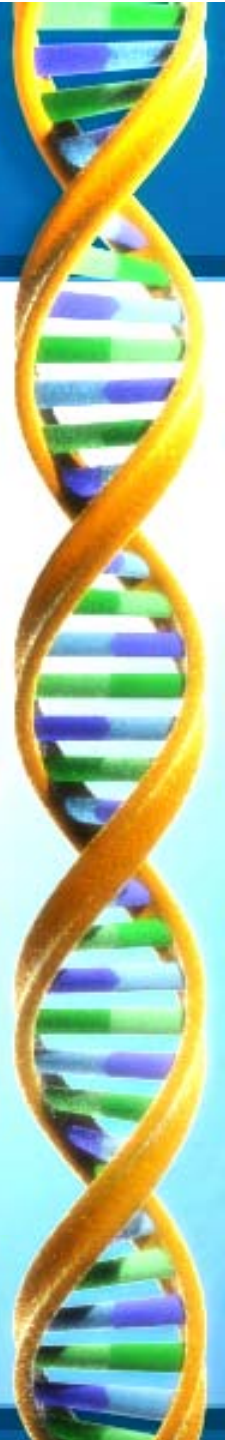
Key Portions of the *NIH Guidelines* for Animal Research

- **Appendix M**
 - Applies to human gene transfer experiments
 - **Includes many considerations related to preclinical studies with animals**
 - **Expedited safety reporting requirements amended to include specifically the reporting of animal data “that suggest a significant risk for human research participants.”**



Good Judgment is Key!

- **“The *NIH Guidelines* will never be complete or final since all conceivable experiments involving recombinant DNA cannot be foreseen. Therefore, it is the responsibility of the institution and those associated with it to adhere to the intent of the *NIH Guidelines* as well as to the specifics.”**
 - ❑ **Good judgment is key**
 - ❑ **OBA can help**



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





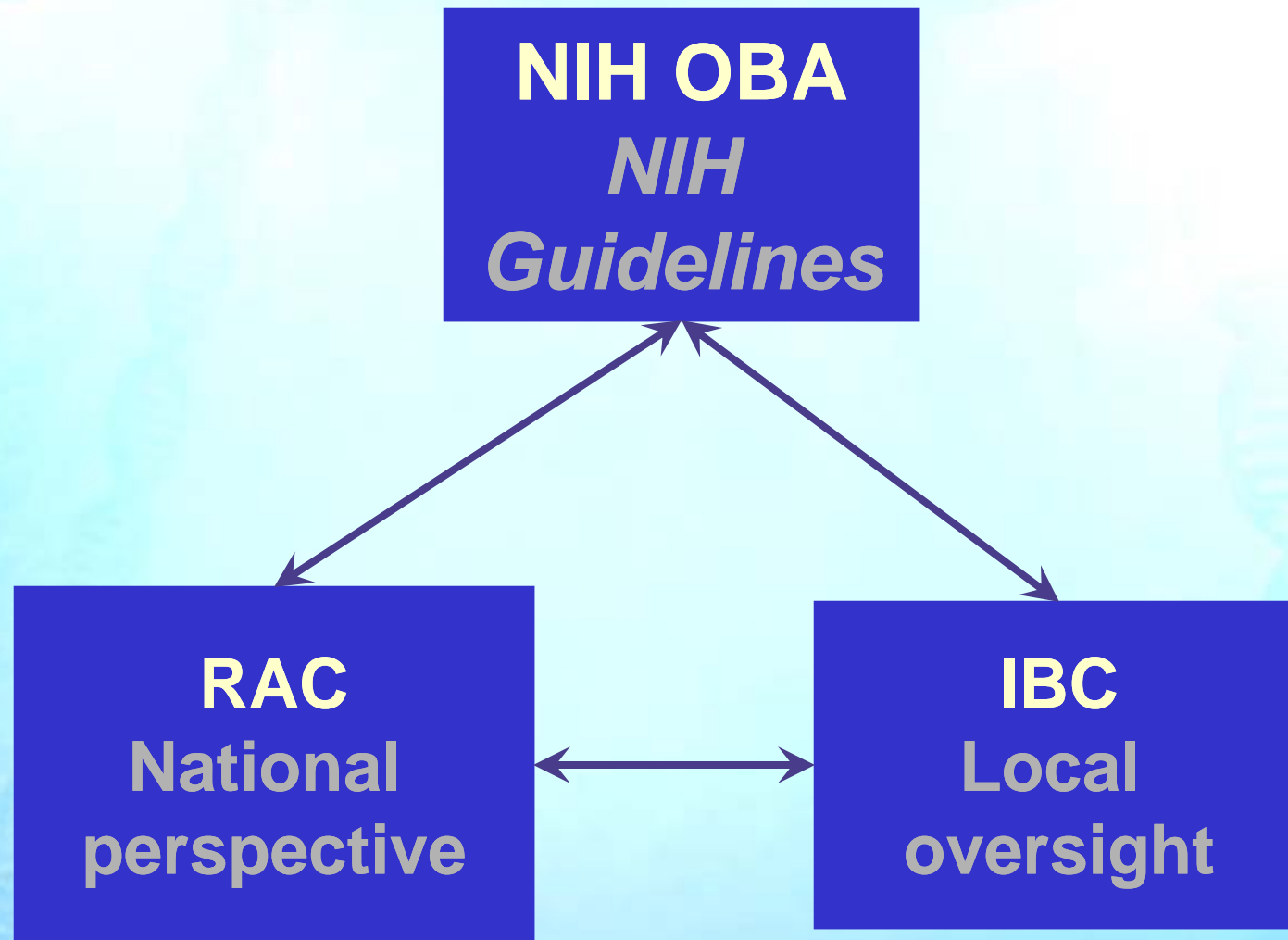
Requirements for IBCs in the *NIH Guidelines*



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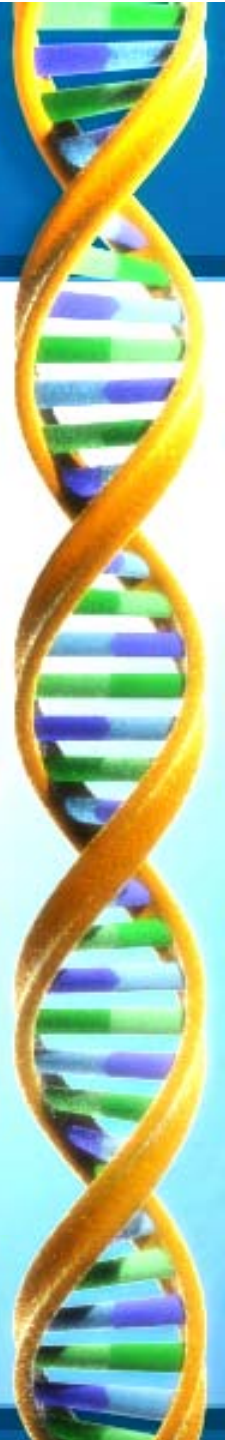


IBCs and NIH - Partners in the Oversight of Recombinant DNA Research



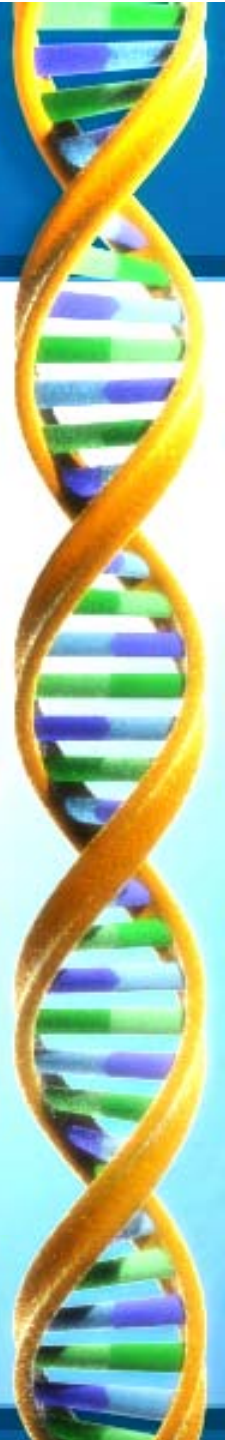
IBCs and NIH OBA

- **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

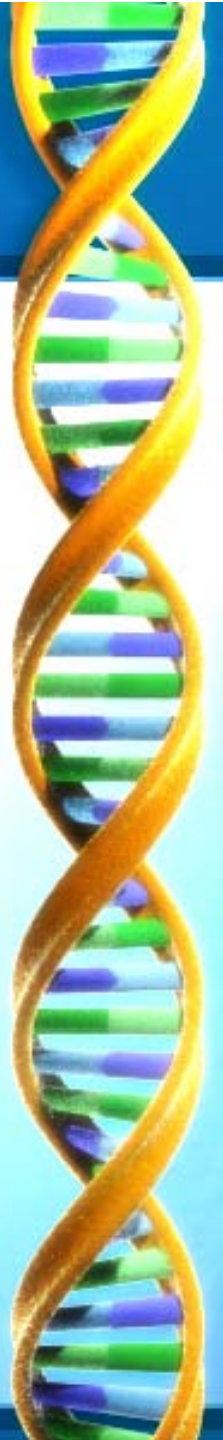
- **Membership**

- **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**



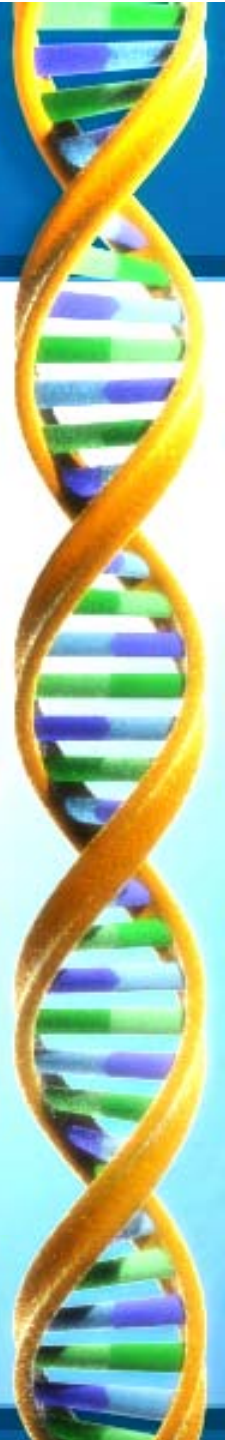
Assembling an IBC

- **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 IBCs on research safety procedures**



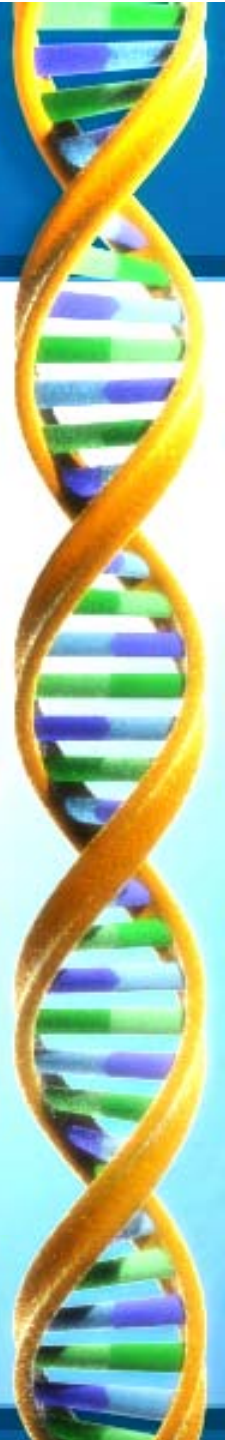
Assembling an IBC

- **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.**



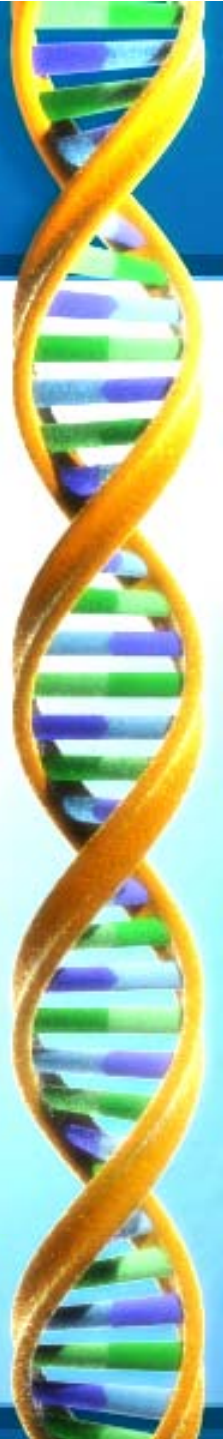
Registering an IBC

- **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**

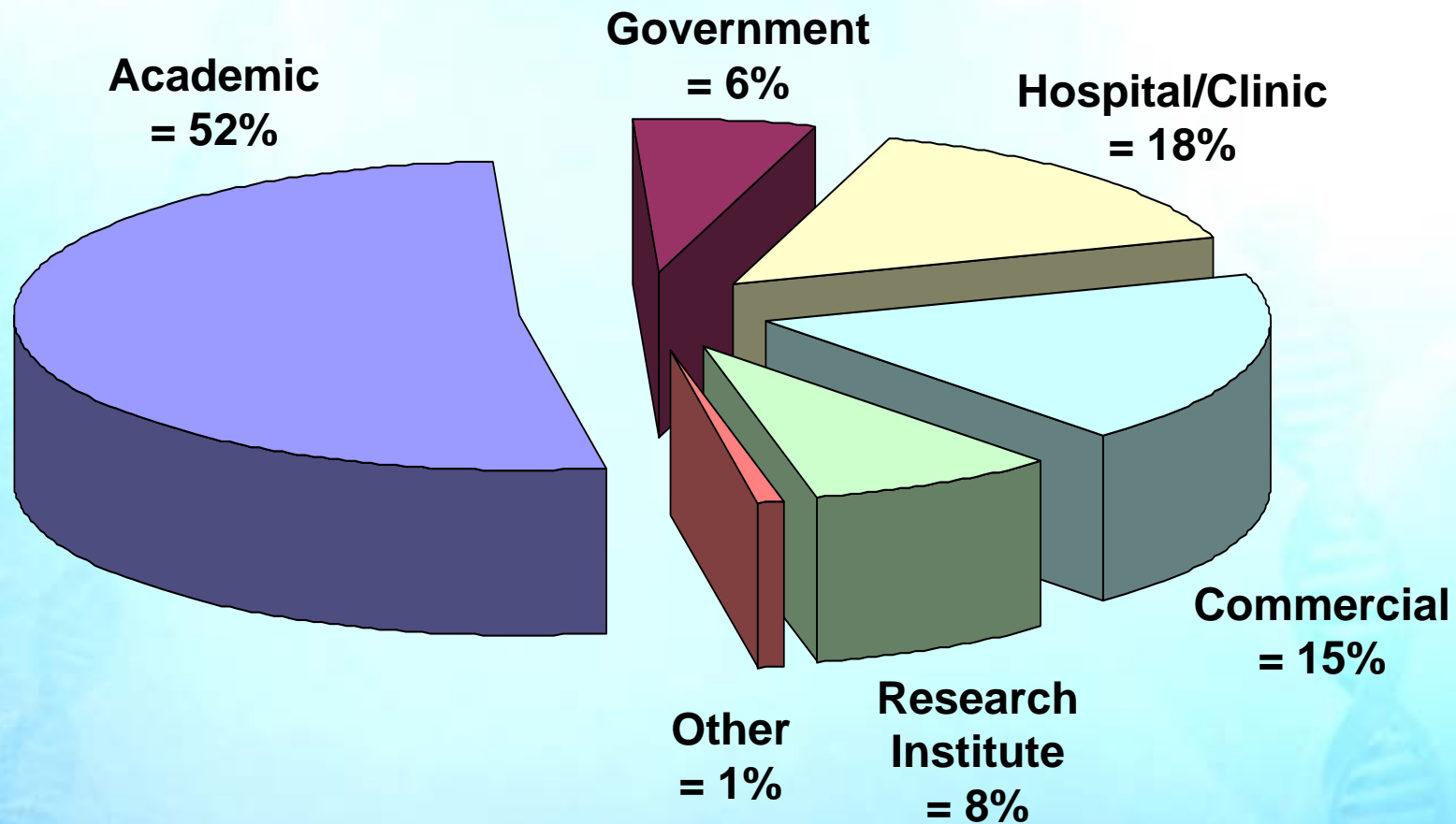


Registering an IBC

- **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



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**



IBC Responsibilities

- **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**



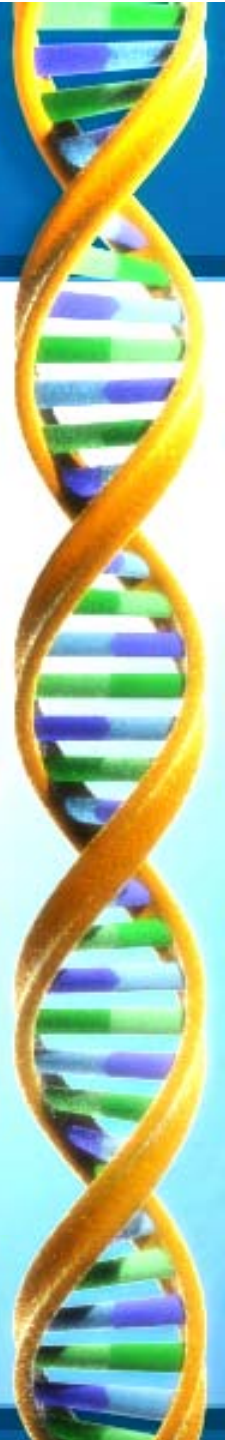
IBC Responsibilities

- **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**



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**



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.**



IBCs and Exempt Research

- **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**

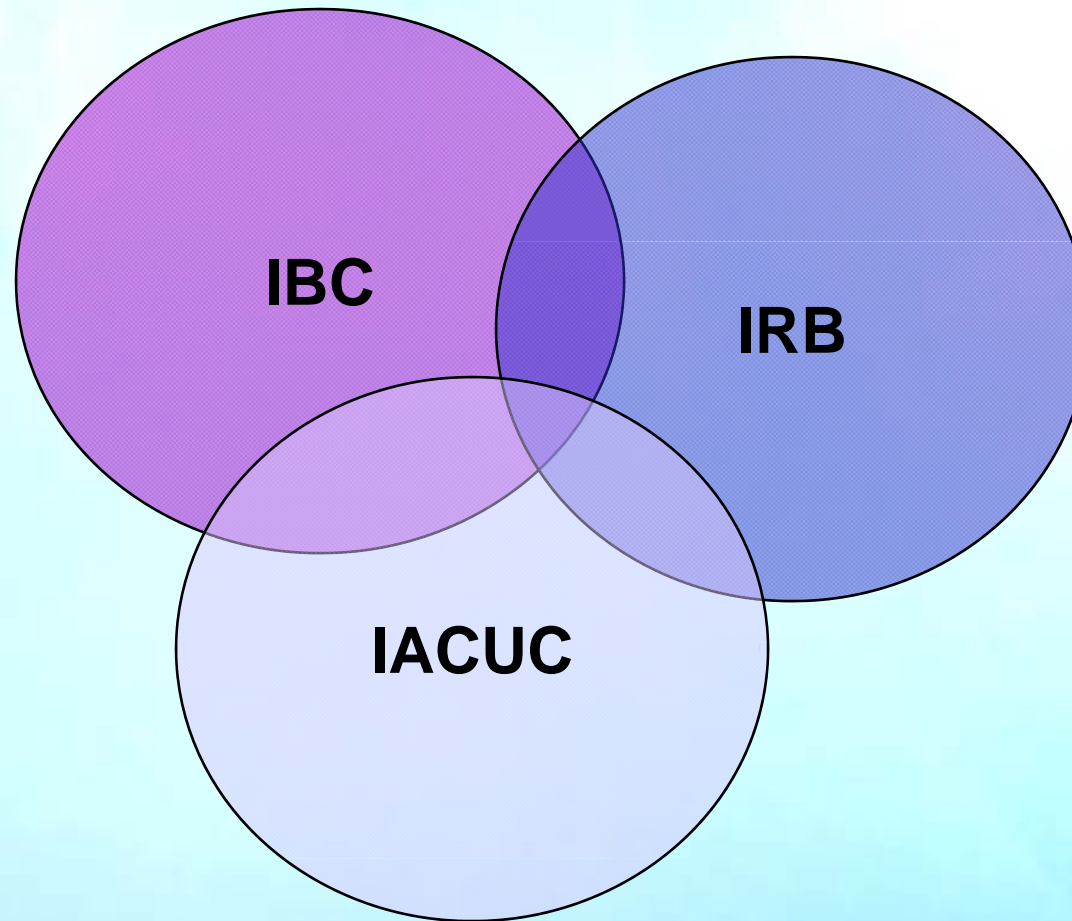


Current Issues Concerning IBCs

- **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



IBCs and Other Research Oversight Committees

- **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



IBC Review	IACUC Review
<p>Risks to human health</p> <ul style="list-style-type: none">– Transfer of genetically altered material, viral vectors etc. <p>Risks to the environment</p> <ul style="list-style-type: none">– Escape and establishment in the wild– Interbreeding with wild stock– Consumption by other animals	<p>Animal welfare</p> <ul style="list-style-type: none">– Pain and distress from adverse phenotypes (behavioral, anatomical and physiological abnormalities)– Risks to other animals in the facility from the inadvertent spread of vectors 

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



IRB Review	IBC Review
<ul style="list-style-type: none">▪ Possible risks to subjects▪ Anticipated benefits to subjects and others▪ 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	<ul style="list-style-type: none">▪ Recombinant DNA research for conformity with the <i>NIH Guidelines</i>▪ Potential risk to environment and public health▪ Containment levels per <i>NIH Guidelines</i>▪ Adequacy of facilities, SOPs, PI and other personnel training▪ Institutional and investigator compliance (e.g., adverse event reports)

IBCs and IRBs

Human Gene Transfer Research



IBC	IRB
<p data-bbox="191 610 884 748">Approves/disapproves HGT protocols</p> <p data-bbox="191 808 894 1097">Final approval contingent, in part, on completion of NIH RAC review process</p>	<p data-bbox="970 610 1663 748">Approves/disapproves HGT protocols</p> <p data-bbox="970 808 1690 1097">Approval can come before or after RAC review (IRBs do receive information from RAC)</p> <p data-bbox="970 1157 1696 1373">IRB approval necessary before enrollment can begin in HGT trials</p>

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?**



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**



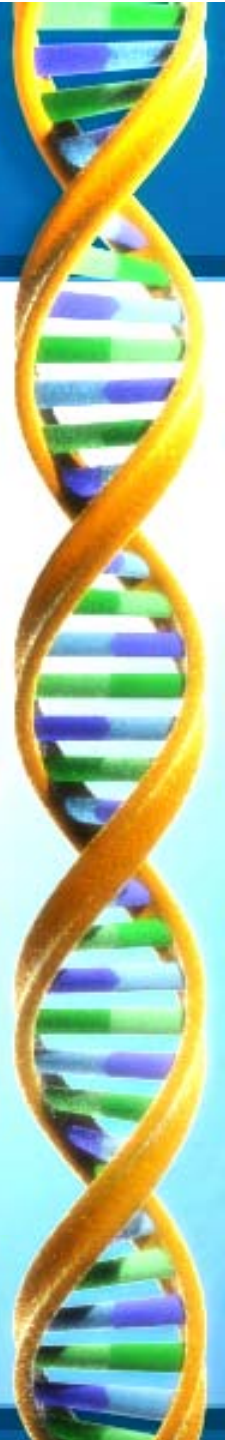
Convening an IBC

- **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)**



Convening an IBC

- **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 documents¹ 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**



Preparation of, and Access to, Minutes

OBA Guidance

Connect to:

http://www4.od.nih.gov/oba/IBC/IBC_Minute_Q_A.pdf



Training, Professional Development, and Outreach

- **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.**



OBA Outreach and Education

- **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

Office of Biotechnology Activities

OBA Home

Recombinant DNA

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

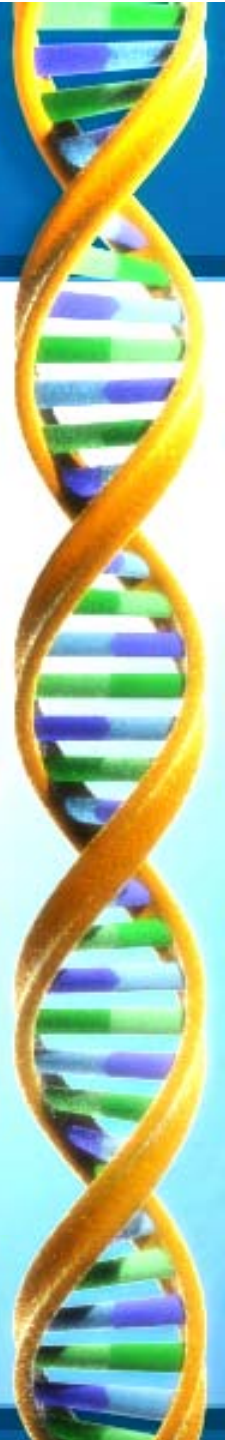
IBC Resources – Training Materials

- **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



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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**





OPEN FORUM



BREAK !