



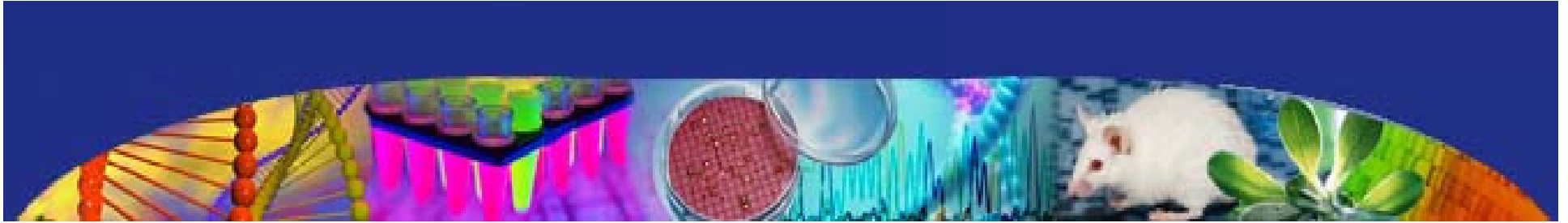
# **The NIH OBA IBC Site Visit Program**





# Site Visit Program

- **Proactive not-for-cause site visits:**
  - **Local**
    - Educate about IBC requirements
    - Provide on-site advice
    - Identify opportunities for institutional improvement
    - Inform OBA of institutional challenges
  - **National**
    - Develop a body of information on best practices and common compliance challenges
    - Create a self-assessment tool for IBCs



# Site Visit Program Methodology

- **Assessment of the institution's program for recombinant DNA research oversight**
  - **Review of the institutional documentation related to the recombinant DNA research program**
  - **Interviews with selected institutional personnel involved in the conduct or oversight of research subject to the *NIH Guidelines***



# Site Visit Program Methodology

## ■ Pre Site Visit

- Notification letter
- Questions regarding recombinant DNA research program
- Request for documentation



# Site Visit Program Methodology

## ▪ Site Visit

- Introductory meeting
- Interviews with institutional personnel
- Review of additional documentation
- Exit debriefing



# Site Visit Program Methodology

## ▪ Post Site Visit

### □ Report from OBA

- Positive characteristics and practices
- Considerations for possible changes/improvements
- Possible deficiencies or practices not in keeping with the *NIH Guidelines*

### □ Follow-up as required



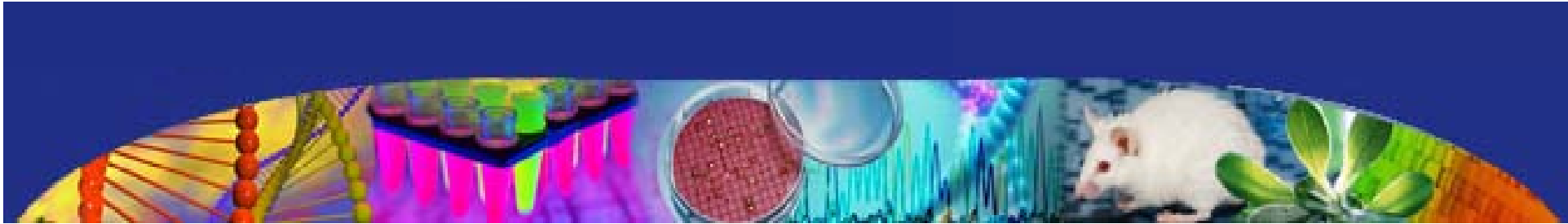
# Diversity of Institutions Visited

## Institutional Type

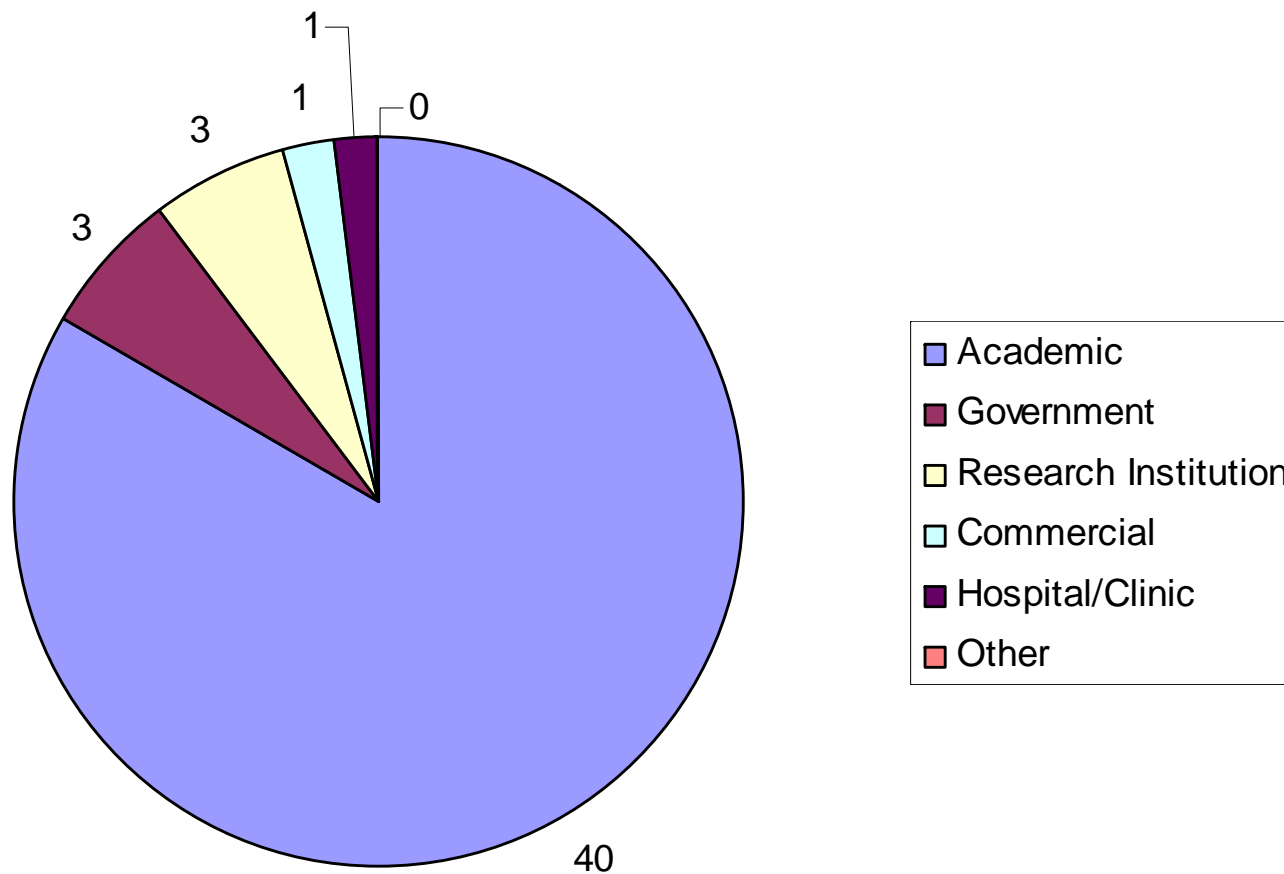
- **Academic**
  - **Public**
  - **Private**
- **Commercial**
- **Research institute**
- **Hospital/Clinic**

## Research Characteristics

- *In vitro*
- **Human gene transfer**
- **Animal**
- **Plant**
- **Biosafety level 1-4**



# Types of Institutions Visited





# IBC Site Visits





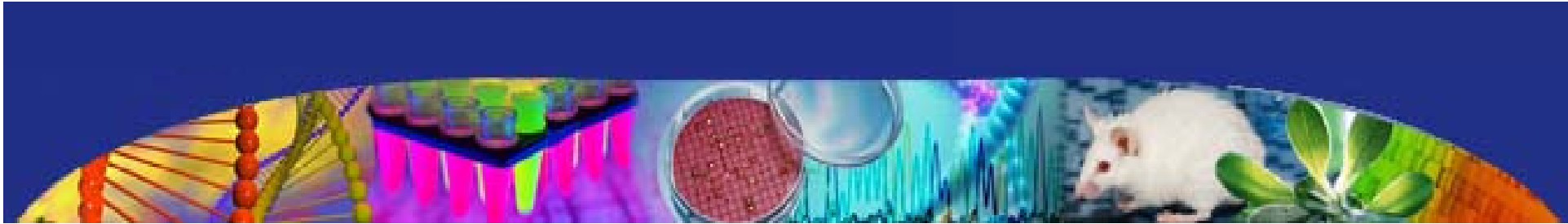
# **Self-Assessment Tool**

**Tool for the Assessment of the  
IBC and the Institutional Program of  
Oversight of Recombinant DNA Research**



# Self-Assessment Tool

- **Periodic self-assessment is key to maintaining the quality of the IBC program**



# Self-Assessment Tool



National Institutes of Health  
**Office of  
 Biotechnology  
 Activities**

## Tool for the Self-Assessment of the Institutional Biosafety Committee and Program of Oversight of Recombinant DNA Research

The NIH Office of Biotechnology Activities has developed the attached self-assessment form as a tool that institutions may use to evaluate their own Institutional Biosafety Committees and programs of oversight of recombinant DNA research. The form is based on the requirements articulated in the [NIH Guidelines for Research Involving Recombinant DNA Molecules \(NIH Guidelines\)](#).

Users of this tool should carefully consider the answers to the questions posed, which relate to specific standards and expectations or, in some cases, sound practices that can reinforce awareness and correct implementation of the *NIH Guidelines*. The form offers comments from OBA regarding each of the matters at hand, and then allows the institution to make its own notes about whether and how specific requirements are being fulfilled.

The tool is qualitative in nature; there is no "score" that results from the self-assessment process. Nonetheless, after completing the tool, institutional officials should have a good sense of where their programs are in line with the expectations, standards, and requirements of the *NIH Guidelines*, and where their programs may benefit from modification or augmentation.

We hope you find this tool helpful. Comments on the tool are always welcomed and may be sent to OBA at [oba@od.nih.gov](mailto:oba@od.nih.gov)

Amy P. Patterson, M.D.  
 Acting Director  
 NIH Office of Science Policy

## Tool for the Self-Assessment of the Institutional Biosafety Committee and Program of Oversight of Recombinant DNA Research

Question Number	Topic	NIH Guidelines Citation	Question	OBA Comments	Institution Comments/Notes
<b>IBC Membership</b>					
1	IBC Membership	IV-B-2-a-(1)	How many members are currently on the institution's IBC?	The institution's IBC must be comprised of no fewer than five members who collectively have experience and expertise in recombinant DNA technology and the capability to assess the safety of recombinant DNA research and to identify any potential risk to public health or the environment. At least two of these individuals must be non-affiliated with the institution.	
2	IBC Membership	IV-B-2-a-(3)	Has the institution designated an IBC Chair?	The institution must file an annual report with OBA which includes a roster of all members of the IBC and clearly indicates who is serving as the IBC Chair.	
3	IBC Membership	IV-B-2-a-(1)	Has the institution designated a BSO on the IBC (if necessary)?	A BSO must be appointed to the IBC if the institution conducts research at BL3, BL4, or conducts Large Scale research (defined as greater than 10 liters).	
4	IBC Membership	IV-B-2-a-(1)	Has the institution designated a plant, plant pathogen, or plant pest containment expert on the IBC (if necessary)?	The IBC must include at least one individual with expertise in plant, plant pathogen, or plant pest containment principles when experiments subject to Appendix P, <i>Physical and Biological Containment for Recombinant DNA Research Involving Plants</i> , are conducted at the institution.	
5	IBC Membership	IV-B-2-a-(1)	Has the institution designated an animal containment expert on the IBC (if necessary)?	The IBC must include at least one individual with expertise in animal containment principles when experiments subject to Appendix Q, <i>Physical and Biological Containment for Recombinant DNA Research Involving Animals</i> are conducted at the institution.	
6	IBC Membership	IV-B-2-a-(1)	How many IBC members are not affiliated with the institution but represent the interests of the surrounding community with respect to health and protection of the environment?	The IBC shall have at least two members who are not affiliated with the institution (apart from their membership on the IBC) and who represent the interests of the surrounding community with respect to health and protection of the environment.	
7	IBC Membership	IV-B-2-a-(3)	Has the institution designated an IBC contact person on the IBC?	OBA requires institutions to designate a contact person on the IBC roster whom OBA can contact with questions and important information regarding the institution's IBC.	

**Tool for the Self-Assessment of the  
Institutional Biosafety Committee and  
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# **Self-Assessment Tool**

**Available on OBA's Web site at:  
[http://oba.od.nih.gov/rdna\\_ibc/ibc.html](http://oba.od.nih.gov/rdna_ibc/ibc.html)**



# Self-Assessment Tool

- Use of the tool is voluntary (but a good idea!)
- Tool addresses all major requirements of the *NIH Guidelines for Research Involving Recombinant DNA Molecules*
- Same issues that OBA assesses during its site visits (hence, excellent preparation for a site visit)



**Questions?**





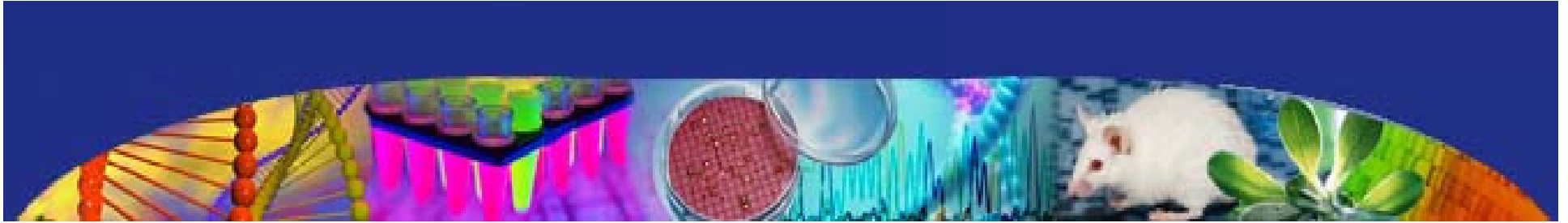
# **The NIH OBA IBC Site Visit Program Findings to Date**





## Positive Practices

- **IBC staff and member competencies**
  - **Service oriented**
  - **Accessible/responsive**
  - **Knowledgeable**



## Positive Practices

- **IBC charter, procedure manual or SOPs**
  - **Comprehensive SOPs help ensure that IBCs and others with biosafety responsibilities fulfill their duties consistently and correctly**
  - **SOPs can also facilitate successful training by articulating clear performance expectations**



## **Positive Practices**

- **Recognition of IBC service**
  - **Acknowledge in a highly visible way the value that the institution places on IBC service.**



## Positive Practices

- **IBC membership**

- **Adequacy of member competencies**

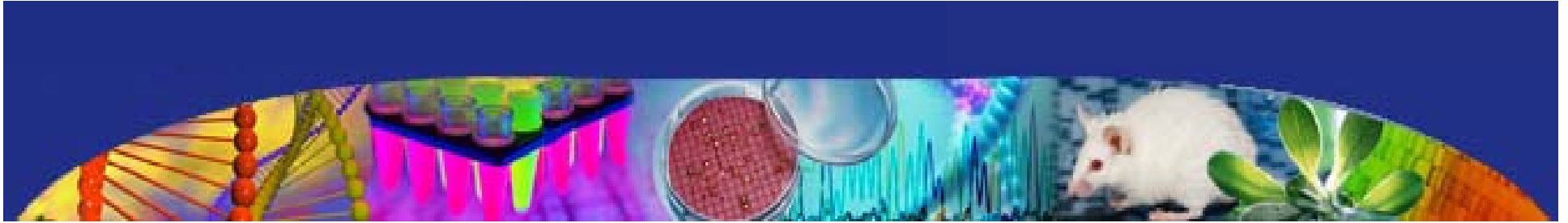
- **Broad array of expertise to compliment research portfolio**

- **Term of membership**



## Positive Practices

- **PI attendance at IBC meetings**
  - **Enables the IBC to gain a fuller understanding of protocol details**
  - **Serves to enhance the visibility of the activities of the IBC among PIs at the institution**



## **Positive Practices**

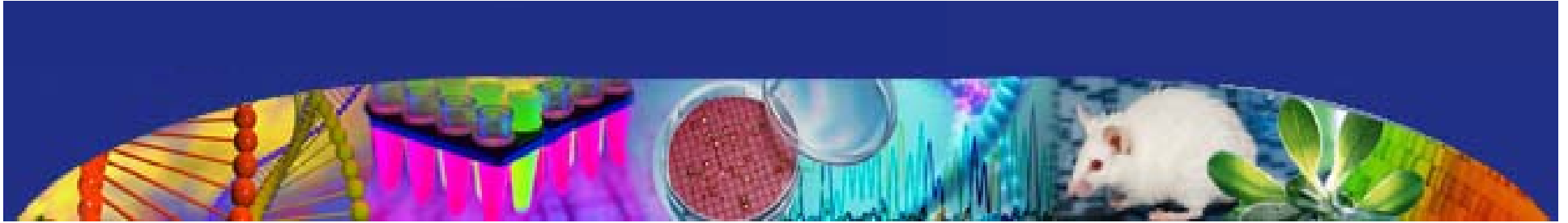
- **Formal IBC conflict of interest policy**
  - **Promotes attention to the topic and consistent approaches to dealing with it**



## Positive Practices

- **Public access to meetings**
  - **Transparency encourages public trust and support**





## **Positive Practices**

- **Senior institutional official on IBC**
  - **Enhances the authority and effectiveness of the IBC**
  - **Signals to the institutional research community the committee's importance**



## **Positive Practices**

- **Review of facilities construction and renovation by IBC**
- **Routine certification and maintenance of laboratory equipment**



## Positive Practices

- **Coordination between IBC, IACUC, IRB**
  - **Helps ensure that all recombinant DNA protocols are reviewed by the IBC**
- **Coordination with Grants and Contracts Office**
  - **Release of funds tied to IBC approval provides an additional checkpoint for compliance with the *NIH Guidelines***



# Compliance Challenges

- **Need for greater institutional resources**
  - Examine the staffing and other resources needed to fulfill review, oversight and training responsibilities under the *NIH Guidelines* and ensure that these resources are adequate to the tasks at hand.



## **Compliance Challenges**

- **Appropriateness of non-affiliated IBC members**
  - **Actual/perceived conflicts**
  - **Affiliations with the institution include associations with entities with which the institution has business arrangements**



## Compliance Challenges

- Meeting minutes should contain a level of detail sufficient to adequately document fulfillment of IBC responsibilities

**See OBA guidance on minute taking:**

[http://oba.od.nih.gov/oba/ibc/IBC\\_Minutes\\_Guidance\\_Feb\\_23\\_2007.pdf](http://oba.od.nih.gov/oba/ibc/IBC_Minutes_Guidance_Feb_23_2007.pdf)



# Compliance Challenges

- **Robust training for IBC members, research staff, and support staff (e.g., animal care):**
  - ❑ **Utilize slides on OBA's Web site**
  - ❑ **Take advantage of "IBC Basics" and other external training opportunities**
  - ❑ **Develop in-house programs that build on these resources**
  - ❑ **Devote explicit attention to recombinant DNA**
  - ❑ **Document attendance**



# Compliance Challenges

- Approval of all projects subject to Sections III-A through III-E of the *NIH Guidelines* at a convened meeting of a quorum of the IBC

**See OBA guidance on meetings**

<http://oba.od.nih.gov/oba/ibc/FAQs/FAQs%20of%20Interest%20to%20IBCs.pdf>





# Compliance Challenges

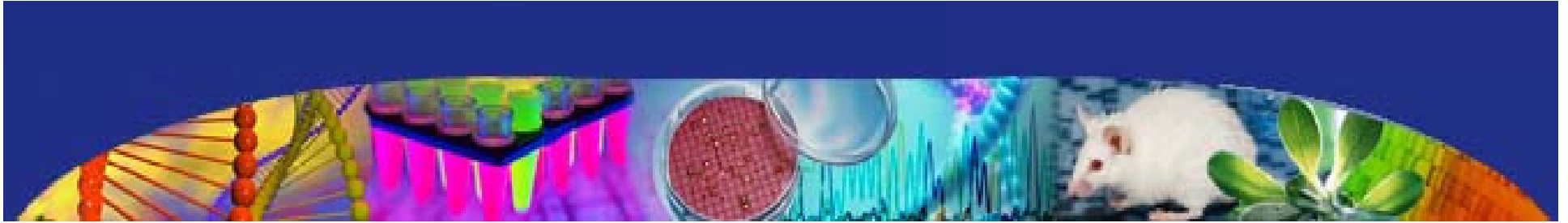
- **Awareness of incident reporting requirements:**
  - **Incorporate incident reporting into training programs**
    - **Report within 30 days to NIH OBA any significant problems, violations of the *NIH Guidelines*, or any significant research-related accidents and illnesses**
    - **Report immediately to NIH OBA certain incidents described in Appendix G-II**

See: <http://oba.od.nih.gov/oba/ibc/FAQs/FAQS%20about%20Incident%20Reporting.pdf>



# Compliance Challenges

- **Periodic review of recombinant DNA research**
  - **Have the IBC determine when project registrations should be renewed**
  - **Conduct rigorous laboratory inspections:**
    - **Documentation**
    - **Frequency**
    - **Qualification of inspector**
    - **Inspection standards**



## **Compliance Challenges**

- **Health surveillance programs, when required, for personnel involved in recombinant DNA research**
  - **Develop plans for high containment or large-scale research**
  - **Agent specific**



## **Compliance Challenges**

- **Proper disposal of recombinant DNA-containing waste, including transgenic plants and animals**
  - **Develop policies and procedures that preclude the entry of transgenic animals and plants into food stream**
  - **Rigorously train staff**



# Compliance Challenges

- **Human Gene Transfer Protocols**

- **Review of informed consent**

- **Ensure that human subjects are adequately informed of the possible risks, discomforts, and side effects that are associated with the use of gene transfer products.**

**See Informed Consent Guidance on OBA Web site:  
<http://oba.od.nih.gov/oba/rac/ic/index.html>**



## Compliance Challenges

- **Surveillance, emergency, and incident response plans**
  - IBC-approved emergency plans covering accidental spills and personnel contaminations resulting from recombinant DNA research specifically
  - Individual laboratories can tailor these plans to fit their special circumstances