

YYTitle of Presentation



Institutional Biosafety Committee 101

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8th Conference for Effective Compliance Systems in Higher
Education – April 2010 – Dallas, TX

EH&E – Unique Expertise



- 20 years of EH&S compliance management experience in critical environments
 - Manage and provide expert services for IBCs
- Currently manage compliance in >4MM square feet of research space
- Design review and commissioning of complex spaces (BL-3, research labs, vivariums, operating suites)

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IBC 101



- What are they?
- Why do we care?
- Why do they exist?
- Who are they?
- What do they do?
- What are their challenges?
- How do we address the challenges?

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

Institutional Biosafety Committees

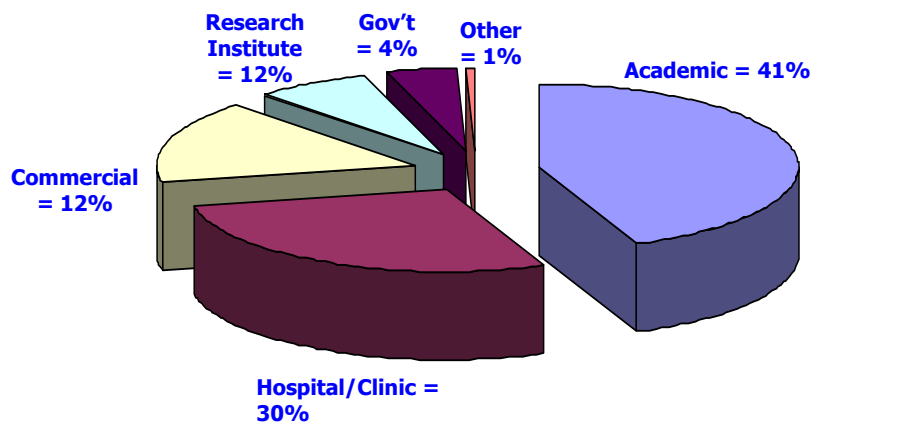


- Survey of IBCs (Hackney et al, 2007) showed:
 - ~30% of IBCs housed in EH&S Dept.
 - ~30% housed in Research Compliance Office
 - Since 2002 survey, increasing movement from EH&S to Research Compliance
 - ~30% meet at least monthly, 20% quarterly

IBC's Registered with the NIH - May 2007

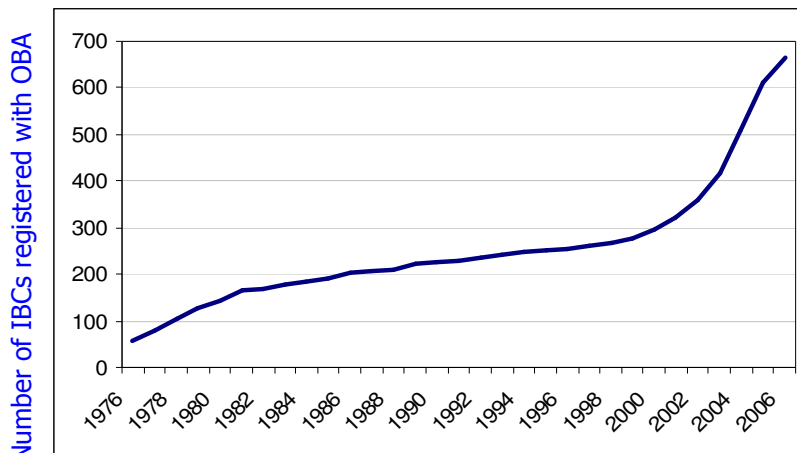


N = 699



Source: NIH OBA

Growing Significance of IBCs



Year

Source: NIH OBA

Biosafety



• Primary Goals

- Prevent exposure of individuals to infectious agents in the laboratory and in the surrounding community
- Prevent laboratory-associated infections (LAIs)
- Comply with federal, state, and local regulations



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Study of Ebola virus in U.S. lab halted

Facilities at Wisconsin university were not secure, NIH says

AP Associated Press
updated 2:59 p.m. ET, Thurs., Sept. 20, 2007


MADISON, Wis. - University of Wisconsin-Madison research on the deadly Ebola virus was conducted for a year in a less-secure laboratory than required, until the National Institutes of Health alerted the school to the problem.

February 21, 2008

Texas A&M to Pay \$1-Million Fine for Biosafety Violations

By Jeffrey Brainard

In its research on dangerous microbes that could be used for biological warfare, Texas A&M University at College Station did not play by the federal safety rule book. Now it will pay the price—a fine of \$1-million, the university announced on Wednesday. The institution hopes this first step toward resuming the research, which the government suspended last summer, as March.



Firefighters donned protective suits to investigate smoke inside a Boston University biomedical research building yesterday. (Globe Staff Photo / David L. Ryan)

U of S cancer researcher probed over use of mice

BY LORI COOLICAN, THE STARPHOENIX FEBRUARY 12, 2010

Documents reveal leaks and spills at national virus lab

BY JEN SKERRITT, WINNIPEG FREE PRESS FEBRUARY 27, 2010

BU delayed reporting possibly lethal exposure

By Stephen Smith, Globe Staff | January 20, 2005

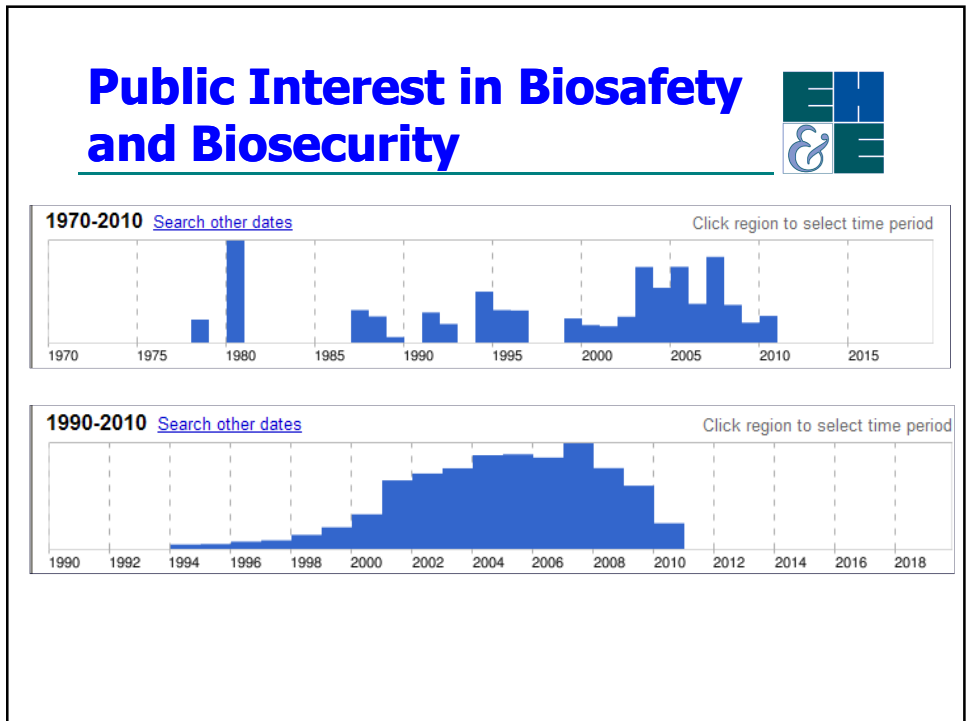
Boston University officials waited nearly two weeks to notify public health authorities that they had serious concerns that researchers might have been exposed to a potentially lethal bacterium while conducting experiments, a delay that could have violated laws requiring prompt reporting of suspected infectious disease cases.

Biomedical lab evacuated

Smoke emergency renews safety debate

The Boston Globe

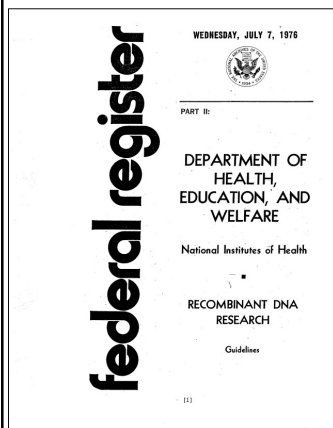
By Raja Mishra and John R. Ellement, Globe Staff | March 21, 2007



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NIH Guidelines For Research Involving Recombinant DNA Molecules (NIH Guidelines)



- Established in 1976 – continues to evolve with the latest changes made in 2009
- Specifies practices for constructing and handling rDNA molecules and organisms and viruses containing rDNA
- Applies to rDNA research funded by NIH or performed at or sponsored by an institution that received any NIH funding for rDNA research
- **Establishes Institutional Biosafety Committees for review of rDNA research**

Are the NIH Guidelines Optional?



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

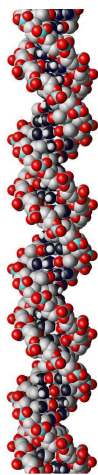
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Are the NIH Guidelines Optional?



- 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

Recombinant DNA (rDNA)



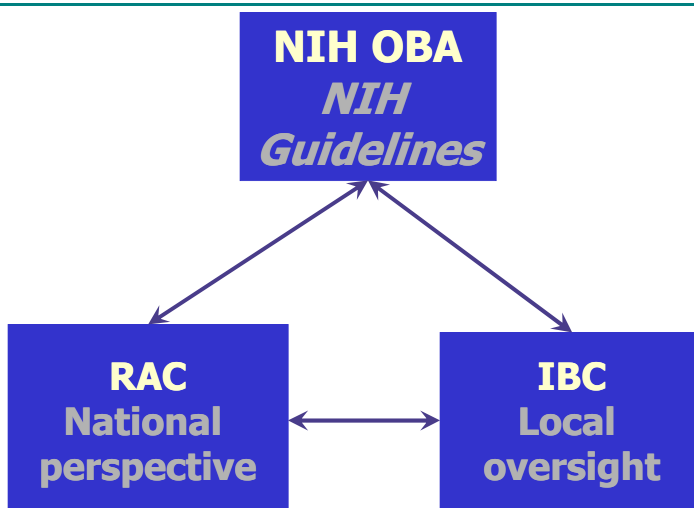
- In the context of the *NIH Guidelines*, recombinant DNA molecules are defined as either: (i) molecules that are constructed outside living cells by joining natural or synthetic DNA segments to DNA molecules that can replicate in a living cell, or (ii) molecules that result from the replication of those described in (i) above.

NIH Definitions



- Office of Biotechnology Activities (OBA)
 - Provides oversight of recombinant DNA research
 - Provides guidance, and resources for IBCs
- Recombinant DNA Advisory Committee (RAC)
 - Issues recommendations to the NIH Director that are conveyed through the NIH OBA

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



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 - 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

NIH Guidelines - Appendices



- 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

NIH Guidelines – Section I



- Scope
 - Specifies practices for constructing and handling
 - Recombinant DNA molecules
 - Organisms and viruses containing recombinant DNA molecules
- 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

NIH Guidelines – Section IV



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

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

Institutional Responsibilities Under the NIH Guidelines



- Establish and implement policies for the safe conduct of recombinant DNA research
- Establish an Institutional Biosafety Committee
- Appoint a Biosafety Officer (if working at BL3, BL4 or large scale)
- 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

IBC Responsibilities Under the NIH Guidelines



- IBCs must review:
 - Recombinant DNA research for conformity with the *NIH Guidelines*
 - Evaluate 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
 - Set containment levels

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

BSO Responsibilities Under the NIH Guidelines



- 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



- **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



- **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



- 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



- 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”

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
 - Provide staff with all written protocols describing potential biohazards and the precautions to be taken.
 - Instruct and train staff in:
 - Practices and techniques required to ensure safety,
 - Procedures for dealing with accidents.
 - 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

The IBC Review



The IBC reviews protocols and examine factors such as:

- Virulence/toxicity/pathogenicity/infectious dose
- Environmental stability and decontamination
- Route of spread, communicability
- Quantity/concentration/volume of agent used
- Vaccine/Treatment availability
- Medical Surveillance
- Engineering Controls
- Personal Protective Equipment Use
- Facility Design, both laboratory and vivaria
- Transportation of animals

Biosafety Levels



- Four biosafety levels: BL-1 to BL-4
- Recommended level depends on the biological agent used and its assigned risk group
- Biological agents include viruses, bacteria, and fungi

Biosafety Levels



Biosafety Level	Risk Group	Examples
BL-1	Individual Risk: LOW Community Risk: LOW	<i>Escherichia coli</i> Adeno-associated viruses <i>Bacillus subtilis</i>
BL-2	Individual Risk: MODERATE Community Risk: LOW	<i>Streptococcus</i> <i>Staphylococcus</i> Hepatitis B and C Viruses Adenoviruses Human cells and tissues
BL-3	Individual Risk: HIGH Community Risk: MODERATE	Hantaviruses <i>Yersinia pestis</i>
BL-4	Individual Risk: HIGH Community Risk: HIGH	Ebola virus Marburg virus

NIH Guidelines Section II Safety Considerations



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 III: Levels of Review



Level of Review	Example of Recombinant DNA Research	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	Human Gene Therapy Clinical Trial	III-C

NIH Guidelines Section III: Levels of Review



Level of Review	Example of Recombinant DNA Research	Relevant Section(s) of the NIH Guidelines
IBC approval before initiation	Creating stable germline alterations of an animal's genome, use of viable rDNA modified microorganisms, where BL-2 containment	III-D
IBC notice at initiation	Formation of rDNA containing less than 2/3 of a viral genome	III-E
Exempt from the NIH Guidelines.	Purchase or transfer of transgenic rodents	III-F

Human Gene Transfer Experiments



- Ensure all aspects of Appendix M have been appropriately addressed prior to submission of registration to IBC.
 - Submission of materials to the NIH Recombinant DNA Advisory Committee (RAC) for review
 - Abstract, clinical protocol, informed consent document, CV of PI(s)
- Comply with the reporting requirements for human gene transfer experiments (Appendix M-I-C, Reporting Requirements).
- Under Appendix M-VI-A, certain exemptions to Appendix M requirements exist for vaccine trials
 - However, exemption does not exempt trials from IBC review and approval

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IBCs and IRBs Human Gene Transfer Research



IRB Review	IBC Review
<ul style="list-style-type: none"> ▪ 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 	<ul style="list-style-type: none"> ▪ Recombinant DNA research for conformity with the <i>NIH Guidelines</i> ▪ 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 <i>NIH Guidelines</i> ▪ 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 <i>NIH Guidelines</i>

IBC and IACUC Review of Animal Research Utilizing Recombinant DNA



IACUC Review	IBC Review
<ul style="list-style-type: none"> ▪ Animal welfare <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 	<ul style="list-style-type: none"> ▪ Risks to human health <ul style="list-style-type: none"> ▫ Transfer of genetically altered material, viral vectors etc. ▪ Risks to the environment <ul style="list-style-type: none"> ▫ Escape and establishment in the wild ▫ Interbreeding with wild stock ▫ Consumption by other animals

Compliance Challenges



- Meeting policies and procedures
- Training requirements
- Reporting requirements
- Ensuring review of all applicable research
- Coordination between committees
- Increased IBC scope
- Lack of resources

Meeting Policies



- Meeting
 - Minutes must contain a level of detail sufficient to adequately document fulfillment of IBC responsibilities
 - Meetings and minutes must be made available to the public
- Conflict of interest policy
- Meetings must be interactive (e.g, face-to-face) not via email

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

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

Training Requirements



- Robust training for IBC members, PI's, research staff, and support staff (e.g., animal care)
- Devote explicit attention to recombinant DNA
 - Roles and responsibilities
 - Research covered by NIH Guidelines
 - Biosafety Levels/Risk Groups
 - Review and approval process
 - Document attendance

Reporting Requirements



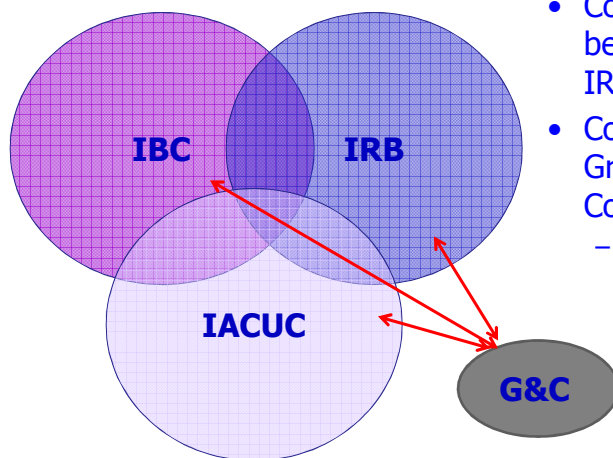
- Awareness of incident reporting requirements:
 - Incorporate incident reporting into training programs
 - Report within 30 days to NIH OBA any significant problems, violations of the *NIH Guidelines*, or any significant research-related accidents and illnesses
 - Report immediately to NIH OBA certain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

Human Gene Transfer Reporting



- Comply with the reporting requirements for human gene transfer experiments (Appendix M-I-C, Reporting Requirements).
 - Serious adverse events that are fatal or life-threatening, that is unexpected, and associated with the use of the gene transfer product must be reported to the NIH OBA as soon as possible, but not later than 7 calendar days.

Ensuring Review



- Coordination between IBC and IRB and IACUC
- Coordination with Grants and Contracts Office
 - Helps provide an additional checkpoint for compliance with the *NIH Guidelines*

Committee Interactions



- Certain studies must be reviewed and approved by both the IBC and the IACUC or the IRB
- Typically, IACUC and IRBs will not approve of research requiring review by IBC until IBC review is complete
- Interaction not prescribed in the NIH Guidelines
 - Institutions should determine best way for these committees to interact and share information

Periodic Review



- IBC determines when project registrations should be renewed
- Conduct rigorous laboratory inspections
 - Documentation
 - Frequency
 - Qualification of inspector
 - Inspection standards

Spontaneous Research



- Research collaborations
 - New animal model
 - New agent that doesn't "change the BSL"
 - Shared resources between Pis
- iGEM and synthetic biology
 - Is your IBC keeping up or prepared to keep up?

Do-It-Yourself Genetic Engineering



From left, City College of San Francisco's Leeza Sergeeva, Bowen Hunter, Angela Brock, Bertram Lee, Colby Sandate and Dirk VandePol.
By JON MODALLEM
Published: February 10, 2010



Increasing Oversight



- Increasing oversight by national, state and local government of biological research
- IBCs are and will be asked to review more research or consider additional aspects of research

Local Regulations – Massachusetts Medical Waste Regulation



480.200: continued

(1) The facility has organized and implemented an Institutional Biosafety Committee (IBC) which is specifically comprised of:

(a) no fewer than five members who collectively have experience and expertise in recombinant DNA technology and/or RG1 and RG2 agents as appropriate, as well as the capability to assess the safety of the biological research; and to identify any potential risk to public health or the environment posed by the biotechnology by-product effluent; and

(b) at least two members, not affiliated with the institution, apart from membership on the IBC, who shall represent the interests of the surrounding community with respect to health and environmental protection (such members may be officials of state or local public health or environmental protection agencies, members of other local governmental bodies, or persons in the community active in medicine, occupational health, or environmental science).

(2) The Institutional Biosafety Committee (IBC) shall meet, at a minimum, once a year to evaluate the public health and environmental risks associated with all biotechnology-by-product effluents generated by the facility and to determine the applicability of conditions, including appropriate effluent treatment requirements, for disposal of these wastes according to provisions of the Uniform State Plumbing Code (248 CMR);

(3) The IBC shall make recommendations to management regarding the appropriate effluent treatment requirements for facility waste at least once a year and document those recommendations in the required record-keeping log;

(4) IBC meetings may be open to the public; and

(5) Minutes of all IBC meetings shall be retained as an appendix to the required record-keeping log, as specified in 105 CMR 480.500(G).

GAO Review of Oversight of High- Containment Laboratories



October 4, 2007

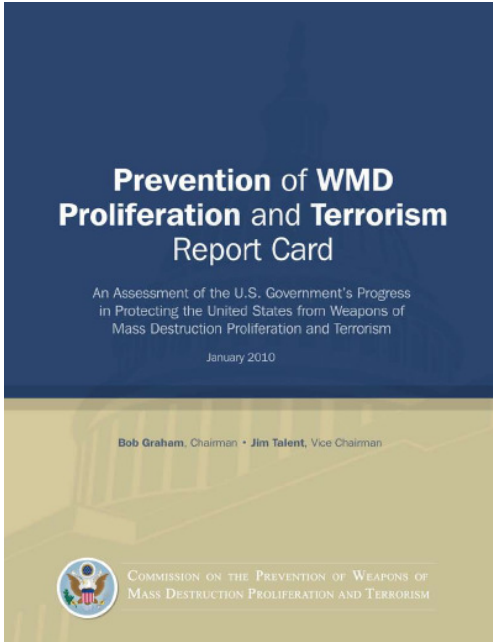
HIGH-CONTAINMENT BIOSAFETY LABORATORIES

Preliminary Observations on the Oversight of the
Proliferation of BSL-3 and BSL-4 Laboratories in the
United States


- Evaluated proliferation and oversight of high-containment laboratories
- Reviewed recent incidents
- Lessons learned included:
 - Identify and overcome barriers for reporting
 - Enhanced training needed
 - Develop mechanisms for informing medical providers about agents in use

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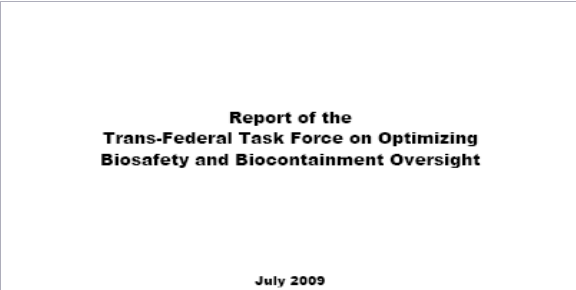


The image shows the cover of a report titled "Prevention of WMD Proliferation and Terrorism Report Card". The cover is divided into a dark blue top half and a light tan bottom half. The title is in white text on the blue background. Below the title, it says "An Assessment of the U.S. Government's Progress in Protecting the United States from Weapons of Mass Destruction Proliferation and Terrorism" and "January 2010". At the bottom of the blue section, it lists "Bob Graham, Chairman • Jim Talent, Vice Chairman". The bottom half of the cover features a stylized graphic of a building and the text "COMMISSION ON THE PREVENTION OF WEAPONS OF MASS DESTRUCTION PROLIFERATION AND TERRORISM" next to a circular seal.




- Grades:
 - Tighten government oversight of high-containment labs D+
 - Conduct a comprehensive review of the domestic program to secure dangerous pathogens A

Trans-Federal Task Force



The image shows the cover of a report titled "Report of the Trans-Federal Task Force on Optimizing Biosafety and Biocontainment Oversight". The cover is white with black text. The title is centered. Below the title, it says "July 2009".



- Enhance framework for biosafety oversight
- Encourage robust culture of accountability characterized by individual and institutional compliance
- Develop national strategy to ensure and enable appropriate training
- Establish national incident reporting system

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Lack of Resources



- Increasing demands beyond review of research
- Compare IBC resources to those of the IRB and IACUC; are they proportional to the volume of research?
 - 2007 survey showed >50% of IBCs have less than one FTE
- Need to increase efficiency
 - Review program with efficiency in mind
 - In order to streamline review process for both IBC and PI's, institutions should consider an electronic data system

Electronic Application Management



- Considerations
 - Many choices over a wide range of price points (Cost of ownership)
 - Work closely with your IT department
 - Security
 - Accessibility online for IBC staff and PIs
 - Willingness to change current process
 - Coordination with other committees and G&C office

Electronic Forms Submission



- Web-based form submission
- Can be duplicated exactly from existing forms
- Templates available for protocols, amendments

Protocol Management List



- Status allows BSO to control process
- Each step linked to series of alerts and required actions

Administrator's Dashboard

Customized statistics for each institution

NIH Site Visit Program

- 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*

NIH Site Visit Program



- Pre-visit
 - Notification letter
 - Questions regarding program
 - Request for documentation
- Site visit
 - Introductory meeting
 - Interviews with institutional personnel
 - Review of additional documentation
 - Exit briefing

NIH Site Visit Program



- Post-visit
 - Report from OBA
 - Positive characteristics and practices
 - Considerations for possible change or improvement
 - Possible deficiencies or practices not in keeping with the *NIH Guidelines*
 - **Report submitted to NIH Office of Extramural Research**
 - Follow up as required

IBC Audit



- Conduct internal or external audit of IBC program and documentation
 - Benchmark program to comparable institutions
- OBA IBC Self-Assessment Tool

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
IBC Membership					
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.	

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."

Conclusions



- Increasing need for robust IBC
- Compliance officials should be involved
- Determine if additional resources are needed or if process efficiencies can be implemented to ensure compliance

Contact Information



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