

Southwest Regional Conference for IBC Best Practices: Today and Tomorrow
IBC Self-Assessment Tool
September 2, 2005

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The objective of this Institutional Biosafety Committee (IBC) Self-Assessment Tool is to assist an institution in analyzing its compliance with certain aspects of the *NIH Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines)* and with some consensus-driven Best Practices. This Self-Assessment Tool is strictly voluntary. The Conference Steering Committee is interested in receiving comments and suggestions from institutions that complete this Self-Assessment Tool as enhancements will be incorporated over the next several months (comment period closes November 30, 2005). Institutions are also encouraged to submit examples of policies, charters, monitoring plans, emergency plans, laboratory inspection checklists, education programs, risk assessment tools, etc. that exist so these can be posted to the conference website for others to access. Please submit comments and any documents to The University of Texas System Office of Health Affairs at oha-rdnaconference@utsystem.edu.


This Self-Assessment Tool has been developed by The University of Texas System and has not (at this time) been endorsed by the National Institutes of Health (NIH), PRIM&R, or Baylor College of Medicine.

Standard	Authoritative Guidance / Best Practice	Questions	Answers / Comments
<u>IBC GOVERNANCE</u>			
IBC Charter	Best Practice and <i>NIH Guidelines Section IV-A</i> – states “General recognition of institutional authority and responsibility properly establishes accountability for safe conduct of the research at the local level.”	Does your institution have an IBC Charter that highlights what the authority and responsibilities are for the institution, IBC, IBC Chair, IBC Members, Biological Safety Officer, and Principal Investigator as they relate to recombinant DNA research?	Does your institution have an IBC Charter you are willing to share with others? Send us an email with your Charter. oha-rdnaconference@utsystem.edu 
	<i>NIH Guidelines Section IV-B-2</i> – states “... the IBC responsibilities need not be restricted to recombinant DNA.”	Does your IBC have additional responsibilities other than recombinant DNA research? If so, are these responsibilities documented in the IBC Charter?	

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IBC Annual Review / Peer Review	Best Practices	Does your IBC conduct an annual review of its activities?	<i>Are you interested in participating (as a team member) in an IBC peer review? If so, please send us an email with your name and contact information.</i> oha-rdnaconference@utsystem.edu 
		Does your IBC conduct annual surveys of Principal Investigators or of members of the IRB and the IACUC to ascertain their overall satisfaction of the IBC?	
		Does your IBC have a periodic (i.e. every three years) external peer review?	
		Are the annual reviews and/or peer review results shared with executive management of the institution? If not, how does executive management ascertain IBC compliance to the <i>NIH Guidelines</i> and its overall effectiveness?	

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Membership	<i>NIH Guidelines Section IV-B-2-a – (1)</i>	Does your IBC have at least five members?	<p><i>What strategies have been successful in recruiting and in retaining external members? Send us an email with your comments.</i></p> <p>oha-rdnaconference@utsystem.edu</p> 
	<i>NIH Guidelines Sections IV-B-2-a – (1) and IV-B-2-a-(2)</i>	Do IBC Members 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 to the environment? Does the IBC include at least one member representing the laboratory technical staff?	
	<i>NIH Guidelines Section IV-B-2-a – (1)</i>	Does your IBC have at least two Members not affiliated with the institution and who represent the interest of the surrounding community with respect to health and protection of the environment?	


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Membership (cont)	<i>NIH Guidelines Section IV-B-2-a – (1)</i>	If your institution conducts recombinant DNA research at BL3, BL4, or Large Scale – is your Biological Safety Officer an IBC Member?* <i>(* -applicable if certain functions performed by the IBC)</i>	
	<i>NIH Guidelines Section IV-B-2-a – (1)</i>	If your institution conducts plant experiments using <i>NIH Guidelines Appendix P</i> – does your IBC have at least one individual with expertise in plant plant pathogen, or plant pest containment principles?* <i>(* -applicable if certain functions performed by the IBC)</i>	
	<i>NIH Guidelines Section IV-B-2-a – (1)</i>	If your institution conducts animals experiments using <i>NIH Guidelines Appendix Q</i> – does your IBC have at least one scientist with expertise in animal containments principles?* <i>(* -applicable if certain functions performed by the IBC)</i>	

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Membership (cont)	<i>NIH Guidelines Section IV-B-2-a – (1)</i>	<p>If your institution participates in or sponsors research involving humans using <i>NIH Guidelines Appendix M</i> – does your IBC Members have adequate expertise and education? If not, does your institution use ad hoc consultants?*</p> <p style="text-align: center;"><i>(* -applicable if certain functions performed by the IBC)</i></p>	
	<i>NIH FAQs on Submissions to the NIH OBA</i>	Does your institution submit a revised roster when the IBC membership changes (include biosketch for all new members)?	

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Membership (cont)	Best Practices	<p>Has your institution documented (i.e. in the IBC Charter or in a policy) the following:</p> <ol style="list-style-type: none"> 1) Who appoints or “charges” the IBC? 2) Who appoints the IBC Chair? 3) Who appoints the IBC Vice-Chair? 4) Who appoints other IBC Members? 5) How long do IBC Members serve? 6) Are there terms staggered to ensure some IBC Membership continuity? 7) Are external IBC Members indemnified? 	
Monitoring Activities	Best Practice and <i>NIH Guidelines Section IV-B-2-b-(1)</i>	<p>Does your institution have formal (i.e. documented) monitoring activities designed to ensure compliance with the <i>Section IV-B-2-b-(1)</i>?</p> <p>If not, how does your IBC monitor the following:</p> <ol style="list-style-type: none"> 1) Assessment of containment levels; 2) Assessment of facilities, 	<p><i>What monitoring strategies have assisted your IBC in complying with the NIH Guidelines? Send us an email with your comments.</i></p> <p>oha-rdnaconference@utsystem.edu</p> 


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Monitoring Activities (cont)		<p>procedures, practices, and training and expertise of personnel;</p> <p>3) Ensuring all aspects of Appendixes G, M, and Q have been appropriately addressed;</p> <p>4) Ensuring no research participant is enrolled in a human gene transfer experiment until all approvals (NIH RAC, IBC, IRB, other regulatory agencies) are obtained;</p> <p>5) Ensuring IBC final approval granted only after NIH RAC is completed; and</p> <p>6) Ensuring compliance with all surveillance, data reporting, and adverse event reporting requirements set forth in the <i>NIH Guidelines</i>?</p>	

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	Best Practice and <i>NIH Guidelines Section IV-B-2-b-(7)</i>	Does your institution have a policy that provides guidance on reporting any significant problems with or violations of the <i>NIH Guidelines</i> and any significant research-related accidents or illnesses to the appropriate institutional official and the NIH/OBA? If so, are reports issued within 30 days of the event? How has your institution defined a “significant” incident?	
	<i>NIH Guidelines Section IV-B-2-b-(6)</i>	Does your institution have emergency plans covering accidental spills and personnel contamination resulting from recombinant DNA research? If so, has your institution verified its content against the principles found in the <i>Laboratory Safety Monograph</i> ?	
	<i>NIH Guidelines Section IV-B-3-c-(1)</i>	Does your Biological Safety Officer (if applicable) have a formal process for periodic inspections to ensure laboratory standards are followed?	

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<u>ADMINISTRATIVE PRACTICES OF THE IBC AND INTERACTIONS WITH IACUC AND IRB</u>			
Administrative Issues: Policies, Procedures, Resources	<i>NIH Guidelines Section IV-B-1-a- (Examples include: policies on meetings and meeting minutes (see below); procedures the IBC follows in its initial and continuing review and approval of applications, proposals, and activities; etc.)</i>	Has your IBC established and implemented policies that provide for the safe conduct of recombinant DNA research and that ensure compliance with the <i>NIH Guidelines</i> ?	<i>Has your institution grouped and categorized all IBC policies and procedures? Are you willing to share your methodology (i.e. table of contents, rationale, etc) and policies with us? Send us an email with your examples.</i> oha-rdnaconference@utsystem.edu 
		Has your IBC developed additional procedures, as deemed necessary, to govern the institution and its components in the discharge of its responsibilities under the <i>NIH Guidelines</i> ?	


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Administrative Issues: Policies, Procedures, Resources (cont)	<i>NIH Guidelines Section IV-B-2-a-(3)</i>	Does your institution file an annual report with the NIH/OBA which includes: <ol style="list-style-type: none"> 1) a roster of all IBC Members clearly indicating the Chair, contact person, Biological Safety Officer (if applicable), plant expert (if applicable), animal expert (if applicable), human gene therapy expertise or <i>ad hoc</i> consultant(if applicable); and 2) biographical sketches of all IBC Members (including community members). 	
	<i>NIH Guidelines Section IV-B-1-j</i>	Does your institution understand its responsibility to report any significant problems, violations of the <i>NIH Guidelines</i> , or any significant research-related accidents and illnesses to the NIH OBA within 30 days?	

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Administrative Issues: Policies, Procedures, Resources (cont)	Best Practice	Does your institution maintain a log of such problems, violations, and accidents or illnesses? If so, are the lessons learned incorporated into policy updates and education programs?	
		Does your institution provide adequate resources to the IBC?	
		Does your IBC have sufficient support staff?	
		Do the IBC, IACUC, and IRB share common resources?	
		Does your IBC understand its reporting requirements to the NIH OBA as they relate to serious adverse events?	


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Meetings	<i>NIH Guidelines Section IV-B-2-a-(6)</i> states: “When possible and consistent with protection of privacy and proprietary interests, the institution is encouraged to open its IBC meetings to the public.”	Does your IBC offer accommodations so that the general public can attend meetings?	<p><i>How has your institution improved its IBC meetings over the last few years? Send us an email with your comments.</i></p> <p>oha-rdnaconference@utsystem.edu</p> 
		How does your IBC “notify” the general public of upcoming meetings?	
		Does your IBC allow sufficient time for public comments?	
	<i>NIH FAQs on IBC Roles and Responsibilities – Questions 5 & 6</i>	Are your IBC meetings in-person and/or via teleconferencing? If not, how do you accommodate the general public?	
	<i>NIH FAQs on IBC Roles and Responsibilities – Questions 5 & 6</i>	Does your institution use email only as a distribution tool, to poll members on particular matters, or other “non-official” matters?	

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Meetings (cont)	<i>NIH FAQs on IBC Roles and Responsibilities – Questions 5 & 6</i>	When public comments are made on IBC actions, does your institution understand those comments and the IBC response should be forwarded to the NIH OBA?	
	<i>NIH FAQs on IBC Roles and Responsibilities – Questions 5 & 6</i>	Does your IBC meet as often as necessary in order to carry out the functions prescribed in <i>Section IV-B-2-b</i> , including periodically reviewing recombinant DNA research conducted at the institution to ensure compliance with the <i>Section IV-B-2-b-(5)</i> ?	
	<i>NIH Guidelines Section IV-B-2-a-(7)</i>	Does your IBC understand its responsibility that when public comments are made on IBC actions those comments and the IBC responses are to be forwarded to the NIH OBA?	
Meeting Minutes	<i>NIH OBA Q&A Concerning Meeting Minutes dated May 14, 2004 – states “... the minutes should offer sufficient detail to serve as a record of major points of discussion and the committee’s</i>	Does your IBC record minutes of every meeting? Do the IBC minutes capture the following: 1) Date, time, and place of meeting;	<i>What procedures and practices has your institution developed recently to improve the minutes that substantiate IBC meetings? Send us an email with your comments. oha-rdnaconference@utsystem.edu</i>


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Meeting Minutes (cont)	rationale for particular decisions, documenting that the IBC has fulfilled its review and oversight responsibilities ...” In addition, it references <i>Robert’s Rules of Order</i> as generally accepted principles about minute-taking for various meetings.	2) Whether previous minutes were approved; 3) Identify all individuals in attendance; 4) Whether and why meeting was open or closed; 5) All major motions; 6) Major points of order; 7) Whether motions were approved; and 8) Time of adjournment?	
	<i>NIH OBA Q&A Concerning Meeting Minutes dated May 14, 2004</i>	Does your institution have a policy that indicates IBC minutes are open to public access?	
	<i>NIH OBA Q&A Concerning Meeting Minutes dated May 14, 2004</i>	Would your institution make available to an open records request the list of IBC Members and biographical sketches?	
	<i>NIH OBA Q&A Concerning Meeting Minutes dated May 14, 2004</i>	Does your institution have a policy to indicate what information could be redacted from IBC minutes before public release?	


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Meeting Minutes (cont)	<i>NIH OBA Q&A Concerning Meeting Minutes dated May 14, 2004</i>	Does your institution have a policy for making IBC minutes available for public viewing that would be deemed reasonable?	
	<i>NIH OBA Q&A Concerning Meeting Minutes dated May 14, 2004</i>	Does your institutional policy indicate whether to recover the cost of making copies available under a public request?	

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Conflicts of Interest	Best Practices and <i>NIH Guidelines Section IV-B-2-a-(4)</i>	<p>Does your institution have a policy on Conflicts of Interest?</p> <p>If not, how does your institution determine the following:</p> <ol style="list-style-type: none"> 1) Who must complete Conflicts of Interest statements? 2) When are these statements first required? 3) How often are these statements completed? 4) What must be reported (i.e. over \$10,000 of investments, over a certain percentage of ownership, more than \$250 in annual income, more than \$50 in annual gifts, etc)? 5) How is Conflict of Interests handled for family members? 	<p><i>What strategies does your institution pursue when monitoring for Conflicts of Interest? Send us an email with your comments.</i></p> <p>oha-rdnaconference@utsystem.edu</p> 
	Best Practices	How does your institution monitor for Conflicts of Interest?	
	Best Practices	Does your institution have a Conflict of Interest Committee?	


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IBC / IACUC / IRB Interactions	Best Practices	Does your institution encourage the IBC to conduct joint reviews with the IACUC over certain types of research?	<i>What strategies have been successful for your institution in improving the communication and coordination between the IBC, IACUC, and IRB? Email us your comments.</i> oha-rdnaconference@utsystem.edu 
		Does your institution encourage the IBC to conduct joint reviews with the IRB over certain types of research?	
		Does your institution have policies to promote this type of collaboration of the IBC and its sister oversight committees? If so, do your policies clearly outline the review and approval process?	
		How does your institution raise the awareness within the research community on how they should interact with the IBC, IACUC, and IRB?	

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IBC / IACUC / IRB Interactions (cont)	Best Practice	How does your IBC handle expedited reviews that involve either the IACUC or the IRB?	
		Does your institution attempt to coordinate annual reporting requirements for the IBC, IACUC, and IRB?	
		Does your institution have a common database or platform for ease of communication between the IBC, IACUC, and IRB?	
Health Surveillance Program	<i>NIH Guidelines Section IV-B-1-i</i>	Does your institution have a health surveillance program? If so, is the program documented? Has it been approved by the IBC?	
		How does your institution actively monitor the health surveillance program?	
		Does your institution understand its reporting responsibilities to the NIH OBA when issues are identified?	

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<u>EDUCATION</u>			
Education Responsibilities	<p><i>NIH Guidelines Section IV-B-1-h – states:</i></p> <ul style="list-style-type: none"> • IBC Chair is responsible for ensuring that IBC members are appropriately trained. • The Principal Investigator is responsible for ensuring that laboratory staff are appropriately trained. • The institution is responsible for ensuring that the Principal Investigator has sufficient training; however, this responsibility may be delegated to the IBC. 	<p>Does your institution have appropriate education programs in place for the IBC Chair and Members, BSO and other containment experts (when applicable), Principal Investigators, and laboratory staff?</p>	<p><i>Does your institution have educational programs you are willing to share with others? Send us an email with your examples.</i></p> <p>oha-rdnaconference@utsystem.edu</p> 
		<p>Does your IBC Chair understand they are responsible for ensuring IBC Members are appropriately trained? How is this evidenced?</p>	
		<p>Do your Principal Investigators understand they are responsible for ensuring laboratory staff is appropriately trained? How is this evidenced?</p>	


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Education Responsibilities (cont)		Does your designated institutional official understand they are responsible for ensuring all Principal Investigators are appropriately trained, or has this been delegated to the IBC? How is this evidenced?	
	<i>NIH Guidelines Sections IV-B-3-c-(3) and IV-B-3-c-(4)</i>	Does your Biological Safety Officer (if applicable) contribute to the education program by providing advice on laboratory security as well as providing technical advice to Principal Investigators and the IBC on research safety procedures?	
Education Program	Best Practice - the education program should address the following issues: 1) Who is being trained; 2) What is the training content; 3) Who will conduct the training; 4) How will the training be delivered; 5) How often is the training required; and 6) How will the participant's comprehension be measured.	Does your institution have a formal, documented education program?	<i>See Appendix A for key elements of an education program.</i>
		Has the IBC Chair teamed with other institutional personnel (i.e. an educational advisor and a computer programmer) to discuss education opportunities and to determine best solutions for your institution?	

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Learning Management System	<p>Best Practice:</p> <p>A learning management system (LMS) provides the platform for the institution's online learning environment by enabling the management, delivery and tracking of blended learning (i.e., online and traditional classroom) for employees, stakeholders and customers. A robust LMS should integrate with other departments so administrative and supervisory tasks can be streamlined.</p> <p>Furthermore, an LMS should support a collaborative learning community, offering multiple modes of learning—from self-paced coursework (Web-based seminars and classes, downloadable, CD-ROM and video content) to scheduled classes (live instruction in classroom settings or online) to group learning (online forums and chats).</p>	Does your institution have an LMS?	
		Does your LMS provide information on the following: <ul style="list-style-type: none"> • Who will receive training and which course(s) they should complete? • When individuals completed the training? • How well individuals performed on any examination materials? 	

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<u>RISK ASSESSMENT</u>			
Risk Groups	<i>NIH Guidelines Section II-A-1</i> states “the investigator must make an initial assessment based on the Risk Group (RG) of an agent.”	Does a mechanism exist for the investigator to report his or her initial risk assessment based on risk group?	
Risk Group Criteria	<i>NIH Guidelines Section II-A-2</i> states “classification of agents is based on the potential effect... on a healthy human adult...”	Does a mechanism exist to address considerations for those possibly exposed that are not healthy human adults?	
Comprehensive Risk Assessment	<i>NIH Guidelines Section II-A-3</i> states “the initial risk assessment... should be followed by a thorough consideration of the agent itself and how it is manipulated.”	Is the initial risk assessment determination followed up by an assessment of the actual use and manipulation of the agent?	<p><i>Has your institution developed decision-tree tools to assist researchers in determining what risk group their research falls into? Send us an email with your examples.</i></p> <p>oha-rdnaconference@utsystem.edu</p> 

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Comprehensive Risk Assessment (cont)	<p>“Factors to be considered in determining containment include factors such as: virulence, pathogenicity, infectious dose, environmental stability, route of spread, communicability, operations, quantity, availability of vaccine or treatment, and gene product effects such as toxicity, physiological activity and allergenicity.”</p>	<p>Are these specific issues addressed in the subsequent consideration: virulence, pathogenicity, infectious dose, environmental stability, route of spread, communicability, operations, quantity, availability of vaccine or treatment, and gene product effects such as toxicity, physiological activity and allergenicity?</p>	
	<p>“Any strain that is known to be more hazardous than the parent (wild type) strain should be considered for handling at a higher containment level”</p>	<p>Is consideration given to strains more hazardous than the parent (wild type)?</p>	

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Comprehensive Risk Assessment (cont)	“A final assessment of risk based on these considerations is then used to set the appropriate containment conditions for the experiment” “The IBC must approve the risk assessment and the biosafety containment level...”	Does the IBC receive and review the complete final risk assessment and vote on the assigned biosafety level?	
	Are considerations given to possible elevation of risk through manipulations such as animal inoculation or transmission studies?	Does the IBC’s consideration of the complete final risk assessment include consideration to the types of manipulations, such as animal inoculations or transmission studies, of certain higher Risk Group agents?	
	Individual working with...bloodborne pathogens should consult...29 CFR 1910.1030.	Are the requirements of the bloodborne pathogens standard 29 CFR 1910.1030 considered when the work involves the use these pathogens or potentially contaminated specimens?	

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Comprehensive Risk Assessment (cont)	Exotic plant pathogens and animal pathogens of domestic livestock and poultry are restricted and may require special laboratory design, operation and containment features.	Do exotic plant or animal pathogens importation, possession, and use also get reviewed for compliance with the USDA Animal and Plant Health Inspection Service permit requirements?	
Containment	<i>NIH Guidelines Section II-B</i> identify three components of complementary containment: (1) lab facilities and equipment, (2) practices and techniques, and (3) biological barriers	As part of the IBC's assessment of the overall risk of the proposed operations, are the three types of containment considered both separately and in combination?	

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Education Program Appendix A

1. **Audience(s):** All individuals who are involved in recombinant DNA research should be identified, grouped by function, and required to participate in the educational opportunities. The institution should accurately identify appropriate employees to determine the remaining aspects of the training program (curriculum, trainers, delivery method, frequency, and testing method).
2. **Curriculum:** The training curriculum may vary depending on the audience. For example, IBC Chair and Members, Principal Investigators, Biological Safety Officer, lab personnel, etc. all need training on their responsibilities, but there may also be unique aspects of their primary responsibilities. In addition, an institution should pay special attention to reasons for non-compliance discovered during the monitoring activities. Once these reasons are understood, the institution should adjust the training program accordingly.
3. **Trainer(s):** The selection of trainers may be determined by the expertise retained at each institution and of the curriculum to be delivered. Trainers may be institutional employees, consultants retained by the institution, individuals from an association (i.e. American Association of School Administrators), or a combination thereof.
4. **Delivery Methodology:** Individual or one-on-one training, group sessions, web-based training, power points, and streaming video and audio are all viable training methods, depending on the audience and the culture of the institution.
5. **Frequency:** Each institution should determine how frequently identified employees will receive training. The frequency should be determined for recurring training of existing employees, for new employees, for significant changes in rules and regulations, and for additional training required when non-compliance is identified.
6. **Testing:** The institution should measure the effectiveness of the trainer and of the training content. The testing of knowledge transferred during the training may include multiple choice tests or scenario-based tests provided at the end of the training. The goal is to ensure the material and delivery method was adequate and effective.