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.	
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, *Physical and Biological Containment for Recombinant DNA Research Involving Plants,* 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, *Physical and Biological Containment for Recombinant DNA Research Involving Animals* 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.	

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8	IBC Membership	IV-B-2-a-(3)	Does the institution file a committee membership report annually with NIH/OBA?	The institution must submit to NIH/OBA at least annually (i) a roster of all IBC members clearly indicating the Chair, contact person, biological safety officer (BSO - if applicable), plant, animal or human gene transfer experts (if applicable) and non-affiliated members; and (ii) biographical sketches for all IBC members.	
9	IBC Membership	IV-B-2-a-(3)	Has the institution designated a human gene transfer expert on the IBC (if necessary)?	When the institution participates in or sponsors recombinant DNA research involving human subjects, the institution must ensure that there is an IBC member who has adequate experience and training in the field of human gene transfer.	
10	IBC Membership	Recommended Strategy	Are IBC members appointed for a fixed term?	OBA recommends that members of the IBC have a fixed term of appointment, thus allowing for fresh perspectives on the IBC.	
11	IBC Membership	Recommended Strategy	How many staff members support the IBC and what are the lines of reporting for those staff?	Institutions should conduct a thorough assessment of the resources necessary for the IBC to fulfill all of its responsibilities as articulated in Section IV-B of the *NIH Guidelines* , taking into account not only the protocol submission and review process, but also training and surveillance responsibilities as required under Sections IV-B-1-h and IV-B-2-b-(5) of the *NIH Guidelines* respectively.	
12	IBC Membership	Recommended Strategy	Does the institution formally appoint IBC members?	OBA recommends that institutions have a written policy in place that addresses the appointment of IBC members. This information could be contained in an IBC charter or similar document. Appointments should be made formally and by a senior institutional official.	
13	IBC Membership	Recommended Strategy	What does the institution do to recognize or promote service on the IBC?	The ability to retain and recruit qualified IBC members is critically important for an IBC program to succeed. Recognition of service on the IBC is valuable not only for encouraging faculty to join the committee when invited to serve, but also for acknowledging institution-wide the value that the institution places on the IBC's role. At many institutions, IBC service counts toward service requirements that are a consideration for promotion and tenure.	

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Meetings and Minutes					
14	Meetings and Minutes	IV-B-2-a-(4)	How does the IBC identify and handle potential conflicts of interest between IBC members and the review or approval of a research project in which they have a personal or financial interest? Is there a written policy for conflicts of interest?	No member of an IBC may be involved (except to provide information to the IBC) in the review or approval of a project in which he or she has been or expects to be engaged or has a direct financial interest. OBA recommends institutions develop formal written Conflict of Interest policies, since this promotes attention to this matter and consistent approaches to dealing with it.	
15	Meetings and Minutes	IV-B-2-a-(6)	Are members of the public (other than non-institutional IBC members) permitted to attend IBC meetings?	When possible and consistent with the protection of privacy and proprietary interests, the institution is encouraged to open its IBC meetings to the public.	
16	Meetings and Minutes	IV-B-2-a-(6)	How would an interested member of the general public learn about future IBC meetings dates, times and location?	Methods for advertising IBC meetings are not proscribed by the *NIH Guidelines* but when possible and consistent with the protection of privacy and proprietary interests, the institution is encouraged to make information regarding meeting times and locations available and to also open its IBC meetings to the public.	
17	Meetings and Minutes	IV-B-2-a-(6) and IV-B-2-a-(7)	Is the conduct of official IBC business (e.g., protocol review and approval) done at a convened meeting (e.g., interactive/real-time/in-person)?	The *NIH Guidelines* do not prescribe how IBCs should be convened, but they do speak to the preparation of meeting minutes, and they encourage institutions to accommodate public attendance at meetings. Thus, IBCs should be convened in a manner that allows for fulfillment of these two expectations. Email exchanges cannot fulfill these expectations and thus are not an acceptable manner for the IBC to conduct official business. For further information regarding the conduct of IBC meetings, please visit: http://oba.od.nih.gov/oba/ibc/FAQs/FAQs%20of%20Interest%20to%20IBCs.pdf	

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18	Meetings and Minutes	IV-B-2-a-(7)	Has the IBC ever received comments or questions from the general public about its activities? Is there a policy for how such comments or questions would be handled? Has the institution forwarded any such comments to OBA?	When public comments are made on the IBC's actions, the institution must forward both the public comments and the IBC's response to OBA.	
19	Meetings and Minutes	IV-B-2-a-(7)	Does the IBC record minutes for every meeting?	Upon request, the institution shall make available to the public all IBC meeting minutes. For information regarding OBA's expectations on content of meeting minutes please refer to: http://oba.od.nih.gov/oba/ibc/IBC_Minute_Q_A.pdf and http://oba.od.nih.gov/oba/ibc/IBC_Minutes_Guidance_Feb_23_2007.pdf	
20	Meetings and Minutes	IV-B-2-a-(7)	Is any information pertaining to the IBC meeting routinely not captured in the meeting minutes (e.g., select agent information, PI names, research agent descriptors, location of agents)? If so, please describe.	For information regarding OBA's expectations on the content of meeting minutes please refer to: http://oba.od.nih.gov/oba/ibc/IBC_Minute_Q_A.pdf and http://oba.od.nih.gov/oba/ibc/IBC_Minutes_Guidance_Feb_23_2007.pdf	
21	Meetings and Minutes	IV-B-2-a-(7)	Are IBC meeting minutes available to the public upon request? If so, how are they provided?	Upon request, the institution shall make IBC meeting minutes available to the public. OBA recommends the institution have a formal written policy for how it will distribute requested minutes.	
22	Meetings and Minutes	Recommended Strategy	With what frequency is the IBC convened?	While the *NIH Guidelines* do not speak to the frequency that the IBC should meet, OBA encourages institutions to look at the volume of their research and determine an appropriate frequency for the IBC to convene in order to ensure timely review of research.	
23	Meetings and Minutes	Recommended Strategy	Are PIs encouraged to attend IBC meetings where their research is discussed?	PI participation in the IBC meeting can not only enrich the discussion of the research at hand, but also raises the profile of the IBC within the investigator community.	

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24	Meetings and Minutes	Recommended Strategy	Does the institution have written policies for the redaction of IBC meeting minutes before they are released to the public?	OBA recommends the institution have a formal written policy for redacting meeting minutes. Articulating the criteria for redaction in IBC operating procedures can help ensure redaction is performed consistently for all requestors.	
Protocol Review and Risk Assessment					
25	Protocol Review and Risk Assessment	III-D	Does the institution have a form for registering protocols involving recombinant DNA with the IBC?	The *NIH Guidelines* require that PIs submit a registration document to the IBC with pertinent information regarding their protocols. This information includes, but is not limited to, the source of the DNA, the nature of the inserted DNA sequence, the host and vector to be used, and containment conditions.	
26	Protocol Review and Risk Assessment	IV-B-2-b-(1)	Does the IBC use delegated or expedited reviews whereby any individual or subcommittee approves research on behalf of the IBC?	The IBC is responsible for reviewing all recombinant DNA research conducted at or sponsored by the institution that is subject to the *NIH Guidelines*. Expedited reviews or approvals by a subgroup of the IBC on behalf of the entire IBC for research subject to the *NIH Guidelines* is not in keeping with the requirements of the *NIH Guidelines*. Such formal business should only be conducted when a quorum of the IBC is present at a convened meeting.	
27	Protocol Review and Risk Assessment	IV-B-2-b-(1) and IV-B-7-c-(3)	Do PIs determine whether their research is exempt from the *NIH Guidelines*? Is the determination verified by the BSO or IBC? Are PIs required to register exempt work with the IBC?	Recombinant DNA research that is exempt from the *NIH Guidelines* under section III-F need not be registered with the IBC, however the institution is responsible for ensuring PIs are correctly determining under which section of the *NIH Guidelines* their research falls. This can be accomplished in a number of ways, e.g. ensuring PIs are adequately trained to make the determination. Many institutions register all recombinant DNA research and have the BSO or IBC Chair verify that the PIs initial determination is correct.	
28	Protocol Review and Risk Assessment	IV-B-7-c-(3)	Do PIs register all research subject to Section III-A though III-E of the *NIH Guidelines*?	PIs must submit the initial research protocol and any subsequent changes if covered under Section III-A, III-B, III-C, III-D, or III-E to the IBC for review and approval or disapproval.	

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29	Protocol Review and Risk Assessment	IV-B-7-c-(3) and IV-B-7-a-(2)	Does the registration document require PIs to identify what section of the *NIH Guidelines* their research is subject to?	PIs must submit the initial research protocol and any subsequent changes if covered under Section III-A, III-B, III-C, III-D, or III-E to the IBC for review. Thus it is incumbent upon PIs to be able to identify the appropriate section of the *NIH Guidelines* their research falls under.	
30	Protocol Review and Risk Assessment	Recommended Strategy	How does the institution assess the IBC's performance and compliance with the *NIH Guidelines*?	OBA recommends that institutions have mechanisms in place that allow senior administration to assess the performance of the IBC. For example, annual reports to the Institution's Responsible Official.	
31	Protocol Review and Risk Assessment	Recommended Strategy	How do PIs go about submitting new recombinant DNA research projects to the IBC? How are PIs informed of the procedures for submitting new research to the IBC?	OBA finds that a good practice is to have a formalized written policy that communicates the process of how PIs submit their registrations to the IBC for review and approval. Furthermore, the Institution should develop training for PIs in order to communicate these requirements.	
32	Protocol Review and Risk Assessment	Recommended Strategy	What systems does the institution have in place to ensure that all recombinant DNA research that requires IBC review is being captured?	Various strategies can be employed to ensure that all research requiring IBC review and approval is being captured. These include coordination and sharing of information between the IBC, IACUC, and the IRB. Coordination with the grants and contracts office and surveying relevant academic departments.	
33	Protocol Review and Risk Assessment	Recommended Strategy	Is the IBC empowered with the authority to enforce the *NIH Guidelines* and ensure that IBC approved conditions are adhered to?	The IBC should be granted the appropriate authority to fully investigate potential violations or compliance problems. The IBC's authority should be articulated in an IBC charter or similar document.	
34	Protocol Review and Risk Assessment	Recommended Strategy	Do the IBC ever grant approvals dependent upon certain conditions being met? If so, how does the IBC verify that those conditions are met?	If the IBC grants approvals based on specific conditions being met then there should be a formal mechanism for verifying the conditions are indeed fulfilled.	
35	Protocol Review and Risk Assessment	Recommended Strategy	How are PIs informed of the outcome of the IBC's review of their submitted research protocols involving recombinant DNA?	Section IV-B-2-b-(2) requires the IBC to notify PIs of the results of the IBC's review and approval. For example, sending a formal letter stating the approval conditions, protocol expiration date and other pertinent information.	

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36	Protocol Review and Risk Assessment	Recommended Strategy	Do registrations have an expiration date? How long is approval granted for? Does the IBC require periodic (annual) updates? How are PIs made aware of these requirements?	Because research is typically dynamic, OBA recommends that protocol registrations have an expiration date, after which time a new registration document must be submitted. Many institutions also have a periodic (annual) update form or an amendment form for registering any changes to the protocol.	
37	Protocol Review and Risk Assessment	Recommended Strategy	Does the institution encourage communication and coordination between the IBC and other institutional oversight committees (such as the IRB and IACUC)?	Communication between the IBC, the IRB, and the IACUC can be one of an array of mechanisms for institutions to ensure that they are capturing all recombinant DNA research subject to the *NIH Guidelines.*	
Policies and Procedures					
38	Policies and Procedures	IV-B-1-A	What policies are in place to ensure that the institution is in compliance with the *NIH Guidelines?*	The *NIH Guidelines* require that institutions establish and implement policies that provide for the safe conduct of recombinant DNA research and ensure compliance with the *NIH Guidelines.*	
39	Policies and Procedures	Recommended Strategy	Has the institution developed a charter or other document defining IBC member roles and responsibilities, and policies and procedures for the general implementation of the *NIH Guidelines*?	OBA recommends that institutions develop an IBC charter or similar document which clearly articulates the responsibilities the IBC. The IBC charter is also an ideal mechanism for documenting IBC policies and procedures, such as conflict of interest, minute taking etc,	
40	Policies and Procedures	Recommended Strategy	What review activities, if any, beyond those described in the *NIH Guidelines* have been delegated to the IBC by the institution?	Although not required by the *NIH Guidelines*, many IBCs review non-recombinant DNA research that may pose a biohazard.	
Training and Education					
41	Training	IV-B-7-d-(2)	Does the institution provide resources to investigators to assist them in conducting training for laboratory staff regarding laboratory safety and the implementation of the *NIH Guidelines*?	The *NIH Guidelines* require that institutions ensure appropriate training for laboratory staff regarding laboratory safety and implementation of the *NIH Guidelines*. Many institutions offer a standard general biosafety course (including material addressing requirements under the *NIH Guidelines*) to assist investigators with the training requirements.	

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42	Training	IV-B-7-d-(2)	How do PIs instruct and train laboratory staff in the procedures for dealing with research-related accidents/ illnesses in the laboratory?	PIs are required to train their laboratory staff in the practices and techniques required to ensure safety and the procedures for dealing with accidents. IBC-approved written policies for dealing with accidents involving recombinant DNA in the laboratory should be available to all applicable personnel.	
43	Training	IV-B-1-h	Does the institution conduct training with respect to the *NIH Guidelines* (e.g. content, format, timing, requirements) for PIs and laboratory staff?	The *NIH Guidelines* require that the institution ensure appropriate training for PIs and laboratory staff regarding laboratory safety and implementation of the *NIH Guidelines*. Furthermore, institutions should provide training to PIs regarding the responsibilities and expectations of PIs under the *NIH Guidelines*. OBA has an information brochure available that institutions can use to instruct their investigators in the requirements of the *NIH Guidelines*.	
44	Training	IV-B-1-h	How are animal handlers informed of the risks associated with research involving recombinant DNA-modified microorganisms used with animals? Are there postings in the rooms/cages?	It is the responsibility of the PI to ensure that laboratory staff and others involved in recombinant DNA research are sufficiently trained regarding laboratory safety and the *NIH Guidelines*. Training programs should be in place that fulfill these expectations	
45	Training	Recommended Strategy	Does the institution keep records documenting the training individual personnel have undergone relative to the *NIH Guidelines*?	OBA recommends keeping records of training that individual personnel have undergone relative to the *NIH Guidelines.* This includes laboratory specific training given by the PI.	
Surveillance, Emergency Planning, and Response					
46	Surveillance, Emergency Planning, and Response	IV-B-1-i	Does the institution have a health surveillance program for laboratory workers conducting recombinant DNA research?	The institution shall determine the necessity for health surveillance of personnel involved in connection with recombinant DNA projects; and if appropriate, conduct a health surveillance program for such projects. The institution must establish and maintain a health surveillance program for personnel engaged in large-scale research or production activities involving viable organisms containing recombinant DNA molecules which require BL3 containment.	

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47	Surveillance, Emergency Planning, and Response	IV-B-1-i	Does the institution have a health surveillance program for animal care workers involved with recombinant DNA research?	The institution must establish and maintain a health surveillance program for personnel engaged in animal research involving viable recombinant DNA containing microorganisms that require BL3 or higher laboratory containment.	
48	Surveillance, Emergency Planning, and Response	IV-B-1-j	The *NIH Guidelines* require that significant incidents, violations and research-related accidents and illnesses be reported to OBA within thirty days or immediately depending on the nature of the incident. Have any such incidents occurred? If so, were any reported to the NIH / OBA? What criteria are used when determining what a reportable event is?	Detailed information about incident reporting requirements may be found in a set of FAQ's at: http://oba.od.nih.gov/oba/ibc/FAQs/FAQs%20of%20Interest%20to%20IBCs.pdf	
49	Protocol Review and Risk Assessment	IV-B-2-b-(5)	Does the IBC keep track of currently registered protocols falling under the *NIH Guidelines*?	Section IV-B-2-b-(5) of the *NIH Guidelines* requires IBCs to periodically review recombinant DNA research conducted at the institution. By having mechanisms for tracking currently registered protocols, the institution can ensure compliance with this requirement.	
50	Surveillance, Emergency Planning, and Response	IV-B-2-b-(6) and B-7-a-(6)	Does the institution have plans or policies for the following if recombinant DNA is involved: A) Personnel contamination, B) Research-related illnesses, C) Accidental spills, D) Loss of containment, E) Violations? Have these plans been reviewed and approved by the IBC?	On behalf of the institution, the IBC must adopt emergency plans covering accidental spills and personnel contamination resulting from recombinant DNA research.	

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51	Surveillance, Emergency Planning, and Response	IV-B-2-b-(7)	What procedures are followed to report any significant violations of the *NIH Guidelines,* or significant research-related accidents / illnesses to the appropriate institutional official and to OBA? How has this policy been conveyed to the lab personnel?	Significant problems with, or violations of, the *NIH Guidelines* and any significant research related accidents or illnesses must be reported to OBA within 30 days (or immediately depending on the nature of the incident). The most effective way to ensure this provision is met is to have a formalized institutional policy describing how these incidents will be reported to OBA and by whom. Also, this policy should be widely disseminated to PIs and laboratory staff.	
52	Surveillance, Emergency Planning, and Response	IV-B-3-c-(1)	Are periodic inspections conducted to ensure that laboratory standards and containment conditions required by the IBC are rigorously followed? If so, how often and by whom? Are problems communicated to the IBC?	The Biological Safety Officer is charged with performing periodic inspections to ensure that laboratory standards are rigorously followed. Any significant problems that are encountered as a result of these inspections should be promptly reported to the IBC.	
53	Surveillance, Emergency Planning, and Response	Recommended Strategy	Does the institution have a laboratory inspection checklist?	Section IV-B-3-c-(1) requires periodic inspections to ensure that laboratory standards are rigorously followed. Having an inspection checklist can help ensure standardized inspection practices.	
Physical Containment - Laboratory Environment					
54	Laboratory Containment and Safety	IV-B-7-e-(1) and Appendix G	Who determines the minimum required Personal Protective Equipment (PPE) for laboratory staff working with recombinant DNA? Who trains personnel in the proper use of PPE? How is compliance monitored?	Determining the minimum PPE required for laboratory staff is a responsibility of the PI. Training for the proper use of PPE should also be conducted by the PI. The PI is also responsible for supervising the safety performance of the laboratory staff. This would include monitoring PPE compliance.	
55	Laboratory Containment and Safety	IV-B-7-e-(4)	Does the institution ensure that laboratory equipment (cabinets, HEPA filters) are properly maintained and functioning properly?	The PI is responsible for ensuring the integrity of the physical containment (e.g. biosafety cabinets) and the biological containment (e.g. purity and genotypic and phenotypic characteristics). The institution should consider a policy of periodic certification and maintenance of laboratory equipment.	

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56	Laboratory Containment and Safety	IV-B-2-b-(1)	Does the IBC review and approve plans for the renovation or construction of laboratories and other facilities where recombinant DNA research is conducted?	IBCs are responsible for assessments of facilities contemplating research. The IBC's review of construction plans can help ensure that new facilities comport with the conditions and containment measures described in the *NIH Guidelines* .	
57	Laboratory Containment and Safety	Appendix G	How does the institution dispose of liquid and solid waste containing recombinant DNA? Are there written Standard Operating Procedures (SOP) for waste disposal?	As part of standard microbiological practice, all liquid and solid laboratory waste containing recombinant DNA must be decontaminated before disposal.	
58	Laboratory Containment and Safety	Appendix G-II-C	Does the institution engage in recombinant DNA research at BL3? If so, has a BSO been appointed?	Appendix G-II-C discusses the standard microbiological practices, the special practices, containment equipment and laboratory facilities requirements for research being conducted at BL3. A BSO must be appointed when conducting research at BL3 or higher.	
59	Laboratory Containment and Safety	Appendix G-II-D	Does the institution engage in recombinant DNA research at BL4? If so, has a BSO been appointed?	Appendix G-II-D discusses the standard microbiological practices, the special practices, containment equipment and laboratory facilities requirements for research being conducted at BL4. A BSO must be appointed when conducting research at BL3 or higher.	
60	Laboratory Containment and Safety t	Appendix G	Does the institution have policies and procedures regarding the disposal of recombinant DNA containing animal waste?	Appendix G-II-B-2-I and Appendix G-II-C-2-n require that all recombinant DNA containing wastes (including transgenic animal carcasses) from laboratories and animal rooms are appropriately decontaminated before disposal. OBA strongly recommends the institution have formalized written policies for how animal waste containing recombinant DNA is disposed.	
61	Laboratory Containment and Safety	Recommended Strategy	Does the institution have any autoclave verification program?	Autoclave verification programs should be employed in order to ensure that autoclaves are working properly and effectively. The institution should consider having a written SOP detailing the methodology and frequency of testing.	

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Physical Containment - Large Scale Uses of Organisms Containing Recombinant DNA Molecules					
62	Physical Containment (Large Scale)	Appendix K	Does the institution engage in large-scale research or production activities involving organisms containing recombinant DNA molecules? What is the largest volume? What BL is used? If the institution does engage in Large Scale Research has a BSO been appointed?	Appendix K specifies physical containment guidelines for large scale (greater than 10 liters of culture) research or production involving viable organisms containing recombinant DNA molecules. Appendix K applies to large scale research or production activities as specified in Section III-D-6 of the *NIH Guidelines* . If the institution is performing large scale research, a BSO must be appointed.	
Human Gene Transfer					
63	Human Gene Transfer Research	Appendix M	Does the institution participate in or sponsor recombinant DNA research involving human subjects?	The requirements of Appendix M apply to human gene transfer research conducted at or sponsored by an institution that receives any support for recombinant DNA research from NIH.	
64	Human Gene Transfer Research	Appendix M	Has a PI at the institution ever submitted a human gene transfer protocol to OBA for NIH Director's Recombinant DNA Advisory Committee (RAC) review? Was the protocol selected for in-depth public review at one of the RAC meetings?	Research proposals involving the deliberate transfer of recombinant DNA, or DNA or RNA derived from recombinant DNA, into human subjects will be considered through a review process involving both OBA and the RAC. Protocols requiring RAC review cannot be approved by the IBC until the RAC review is completed.	
65	Human Gene Transfer Research	Appendix M	Does the institution have written policies for reporting serious adverse events on human gene transfer trials to the IBC?	PIs must submit a written report on: (1) any serious adverse event that is both unexpected and associated with the use of a gene transfer product; and (2) any finding from tests in laboratory animals that suggest a significant risk for human research participants. Appendix M-I-C-4-a and Appendix M-I-C-4-b describe the content and format and time frame for reporting, respectively. OBA recommends written policies and procedures be in place for reporting serious adverse events to the IBC.	

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66	Human Gene Transfer Research	Appendix M	Does the institution have written policies for reporting serious of adverse events that are associated with the use of human gene transfer products to OBA? What is the required time frame for reporting serious adverse events as well as the threshold for determining what is a reportable event to OBA?	PIs must submit a written report on: (1) any serious adverse event that is both unexpected and associated with the use of a gene transfer product; and (2) any finding from tests in laboratory animals that suggest a significant risk for human research participants. Appendix M-I-C-4-a and Appendix M-I-C-4-b describe the content and format and time frame for reporting, respectively. OBA recommends institutions have written policies and procedures in place for reporting serious adverse events to OBA and other required entities.	
67	Human Gene Transfer Research	Appendix M	Does the IBC review informed consent documents to ensure that human subjects are adequately informed of the possible risks, discomforts, and side effects that are associated with the use of gene transfer agents?	Appendix M-1-C-1 of the *NIH Guidelines* requires that the IBC approve human gene transfer protocols prior to their initiation. As part of this approval process IBCs should review the informed consent documentation from the perspective of risks associated with the use of recombinant DNA.	
68	Human Gene Transfer Research	Appendix M	Does the institution utilize the guidance on informed consent for human gene transfer research on OBA's website?	For more information visit http://oba.od.nih.gov/rdna/informed_consent_intro.html	
69	Human Gene Transfer Research	Appendix M	If the institution has ever submitted a protocol to OBA that warranted RAC review, did the IBC take into account the RAC's recommendations in their final approval?	If the protocol requires RAC review, the IBC must await the RAC's recommendations before approving the protocol.	
70	Human Gene Transfer Research	Recommended Strategy	Does the institution encourage the use of the GeMCRIS database for reporting adverse events on human gene transfer trials to OBA?	For more information regarding GeMCRIS please visit: http://oba.od.nih.gov/rdna/adverse_event_oba.html	
Physical and Biological Containment for Recombinant DNA Research Involving Plants					
71	Plant Research	Appendix P	Does the institution engage in recombinant DNA research involving plants subject to Appendix P of the *NIH Guidelines*?	Appendix P of the *NIH Guidelines* specifies the physical and biological containment conditions and practices suitable to the greenhouse conduct of plant experiments involving recombinant DNA.	

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72	Plant Research	Appendix P	Does the institution have policies and procedures regarding the proper disposal of transgenic plants?	Transgenic plants and associated organisms must be decontaminated in accordance with the requirements of Appendix P of the *NIH Guidelines.* OBA recommends having formalized written policies describing procedures to be followed when disposing of transgenic plants. These plans should be approved by the IBC.	
73	Plant Research	Appendix P	Has the institution ever allowed the field release of a transgenic plant? If so, was authorization obtained from the proper agency?	The *NIH Guidelines* address contained research only. Experimental field releases require proper authorization from a responsible federal agency. In terms of transgenic plants the appropriate agency would be USDA APHIS.	
Physical and Biological Containment for Recombinant Research Involving Animals					
74	Animal Research	Appendix Q	Does the institution engage in recombinant DNA involving large animals subject to Appendix Q of the *NIH Guidelines*? (Large animals subject to Appendix Q include transgenic animals and animals into which viable recombinant DNA-modified microorganisms have been introduced).	If the institution engages in recombinant DNA experiments involving large animals then the institution is required to follow the procedures of Appendix Q of the *NIH Guidelines.* Appendix Q pertains to research involving animals of a size or having growth requirements that preclude the use of containment for laboratory animals.	
75	Animal Research	Appendix Q-1-B-2	Does the institution inventory and track large animals subject to Appendix Q to ensure proper disposal?	The *NIH Guidelines r* equire that institutions keep a permanent record of the experimental use and disposal of animals covered under Appendix Q.	
76	Animal Research	Appendix Q	Does the institution have policies and procedures regarding the proper disposal of transgenic animals covered under Appendix Q?	Large animals must be disposed of in accordance with the procedures of Appendix Q of the *NIH Guidelines* . OBA recommends that the institution have formalized, IBC approved polices describing how large animals are to be disposed.	
77	Animal Research	Appendix Q	Does the institution have policies and procedures regarding the disposal of infectious animal waste covered under Appendix Q?	Infectious animal wastes must be disposed of in accordance with Appendix Q of the *NIH Guidelines* . OBA recommends that the institution have formalized, IBC approved polices describing how infectious animal wastes containing recombinant DNA will be disposed.	

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78	Animal Research	Appendix Q	Has the institution conducted the field release of a transgenic animal covered under Appendix Q? From what agency was authorization obtained?	The *NIH Guidelines* address contained research only. Experimental field releases require proper authorization from the appropriate federal agency.	
Resources					
79	Resources	Recommended Strategy	Has the institution developed any tools for communicating recombinant DNA research requirements?	OBA recommends that the institution develop a method for disseminating information regarding the *NIH Guidelines* to those faculty and staff in need of such information. Effective methods include newsletters, email blasts and FAQ's.	
80	Resources	Recommended Strategy	Does the institution encourage attendance at professional development conferences, or scientific symposia related to biosafety or the *NIH Guidelines*?	OBA encourages support of professional development particularly for IBC members and staff.	