Institutional Biosafety Committee Self-Assessment Tool

July 2017

Self-Assessment Tool for Institutional Biosafety Committees and Programs of Oversight of Recombinant or Synthetic Nucleic Acid Research

The National Institutes of Health (NIH) Office of Science Policy (OSP) is pleased to introduce its revised Institutional Biosafety Committee (IBC) self-assessment tool, which was originally published in 2009. The revised tool is a resource that institutions may use to evaluate their IBCs and programs of oversight for research involving recombinant or synthetic nucleic acid molecules for compliance with the requirements articulated in the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (*NIH Guidelines*).

Users of this resource should carefully consider the answers to each question in the checklist, which relate to specific standards and expectations or, in some cases, recommended best practices regarding implementation of the *NIH Guidelines*. As an evaluation exercise, institutions may wish to involve key personnel involved with the IBC (for example, IBC members and administrators, biological safety officers, veterinarians, and animal care staff, as well as investigators and laboratory staff) with responsibility for implementing the *NIH Guidelines* to obtain and share information. The answers given may be compared to the comments from NIH OSP provided on each question, and users may use the blank spaces provided to make notes about whether and how specific requirements are being fulfilled.

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

We hope you find this resource helpful. Comments are always welcomed and may be sent to NIH OSP at: NIHGuidelines@od.nih.gov

Question Number	*NIH Guidelines* Citation	Question	NIH Comments	Institution Comments/Notes
IBC MEMBERSHIP				
1	IV-B-2-a-(1)	How many members are currently on the institution's IBC?	The institution's IBC must be composed of no fewer than five members who collectively have experience and expertise in recombinant or synthetic nucleic acid molecule technology, the capability to assess the safety of research with recombinant or synthetic nucleic acid molecules, and the ability to identify any potential risk to public health or the environment. At least two of these individuals must not be affiliated with the institution except for their membership on the IBC.	
2	IV-B-2-a-(3)	Has the institution designated an IBC Chair?	The institution must file an annual report with NIH OSP which includes a roster of all members of the IBC and clearly indicates who is serving as the IBC Chair.	
3	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 research in which a single containment vessel has greater than 10 liters of volume). When required, the individual serving as the BSO should be indicated on the roster registered with NIH OSP.	

4	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 or Synthetic Nucleic Acid Molecule Research Involving Plants,* are conducted at the institution. When required, the individual serving as the plant expert should be indicated on the roster registered with NIH OSP.	
5	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 or Synthetic Nucleic Acid Molecule Research Involving Animals* are conducted at the institution. When required, the individual serving as the animal expert should be indicated on the roster registered with NIH OSP.	
6	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. These two individuals must be indicated on the roster registered with NIH OSP.	

7	IV-B-2-a-(3)	Has the institution designated an IBC contact person on the IBC?	NIH OSP requires institutions to designate a contact person on the IBC roster whom NIH OSP can contact with questions and important information regarding the institution's IBC.	
8	IV-B-2-a-(3)	Does the institution file a committee membership report annually with NIH OSP?	The institution must submit to NIH OSP 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. IBC registrations and annual updates can be submitted using the IBC Registration Management System (IBC-RMS).	
9	IV-B-6	Has the institution designated a human gene transfer expert on the IBC (if necessary)?	When conducting or sponsoring research with recombinant or synthetic nucleic acid molecules 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. This individual must be indicated on the roster registered with NIH OSP.	

10	Recommended Practice	Does the institution formally appoint IBC members?	A written policy should be in place that addresses the appointment of IBC members. Appointments of IBC members should be made by a senior institutional official.	
11	Recommended Practice	Are IBC members appointed for a fixed term?	NIH OSP recommends that members of the IBC be appointed for a fixed term of appointment, thus allowing for fresh perspectives to rotate periodically onto the IBC.	
12	Recommended Practice	How many staff members support the IBC and what are the lines of reporting for those staff?	Institutions should periodically 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.	
13	Recommended Practice	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.	

MEETINGS AND MINUTES				
14	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?	Section IV-B-2-a-(4) of the *NIH Guidelines* states that no member of an IBC may be involved 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. NIH encourages institutions to develop formal conflict of interest policies since this promotes attention to this matter and consistent approaches to dealing with it.	
15	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	IV-B-2-a-(6)	How would an interested member of the general public learn about future IBC meetings dates, times and location?	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. Such Information could be posted on the institution's website or be otherwise publically accessible.	

17	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.	
18	IV-B-2-a-(7)	Has the IBC ever received comments or questions from the general public about its activities? Are there policies or proceedures for how such comments or questions would be handled? Has the institution forwarded any such comments to NIH OSP?	When public comments are made on the IBC's actions, the institution must forward both the public comments and the IBC's response to NIH OSP.	
19	IV-B-2-a-(7)	Does the IBC record minutes for every meeting?	Minutes must be kept for every IBC meeting.	

20	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. NIH OSP recommends the institution develop a formal written policy for how requested minutes will be provided.	
21	IV-B-2-b	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.	IBCs adequately document fulfillment of their review and oversight responsibilities as articulated in Section IV-B-2-b of the *NIH Guidelines*	
22	Recommended Practice	With what frequency is the IBC convened?	While the *NIH Guidelines* do not speak to the frequency that the IBC should meet, NIH OSP encourages institutions assess the volume of their research and determine an appropriate frequency for the IBC to convene in order to ensure timely review of research.	
23	Recommended Practice	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. PI attendance can be particularly useful if the project is novel or especially complex and the IBC would benefit from a full description of the activities.	

24	Recommended Practice	Does the institution have written policies for the redaction of IBC meeting minutes before they are released to the public?	In keeping with Section IV-B-2-a-(6) of the *NIH Guidelines*, institutions may redact certain information from IBC minutes if there are privacy or proprietary concerns.	
PROTOCOL REVIEW AND RISK ASSESSMENT				
25	III-D	Does the institution have a form for registering protocols involving research with recombinant or synthetic nucleic acid molecules 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 nucleic acid, the nature of the inserted nucleic acid sequence, the host and vector to be used, and containment conditions.	
26	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 research with recombinant or synthetic nucleic acid molecules 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	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 or synthetic nucleic acid molecule 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. Many institutions register all recombinant DNA research and have the BSO or IBC Chair verify that the PIs initial determination is correct.	
28	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.	
29	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	Recommend Practice	How does the institution assess the IBC's performance and compliance with the *NIH Guidelines*?	NIH OSP 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	Recommend Practice	How do PIs submit registrations detailing their research with recombinant or synthetic nucleic acid molecules to the IBC for review? How are PIs informed of the procedures for submitting new research to the IBC?	NIH OSP recommends institutions have a formalized written policy that communicates how PIs should 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	Recommend Practice	What systems does the institution have in place to ensure that all research with recombinant or synthetic nucleic acid molecules that is subject to the *NIH Guidelines* and requires IBC review is being captured?	Various approaches can be used 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	Recommend Practice	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	Recommend Practice	Does the IBC ever grant approvals dependent upon certain conditions being 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	IV-B-2-b-(2)	How are PIs informed of the outcome of the IBC's review of their submitted research protocols involving recombinant or synthetic nucleic acid molecules?	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.	
36	Recommend Practice	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, NIH OSP 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	Recommend Practice	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 research with recombinant or synthetic nucleic acids subject to the *NIH Guidelines.*	
POLICIES AND PROCEDURES				
38	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 research with recombinant or synthetic nucleic acid molecules and ensure compliance with the *NIH Guidelines.*	

39	Recommend Practice	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*?	NIH OSP recommends that institutions develop an IBC charter or similar document that clearly articulates the responsibilities the IBC. The IBC charter is also an ideal mechanism for documenting IBC policies and procedures, such as managing conflict of interest, minute taking, etc.	
40	Recommend Practice	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 research that is not subject to the *NIH Guidelines* but nonetheless may pose a biohazard.	
TRAINING AND EDUCATION				
41	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.	

42	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 or synthetic nucleic acid molecules in the laboratory should be available to all applicable personnel.	
43	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.* NIH OSP has an informational brochure available that institutions can use to instruct their investigators in the requirements of the *NIH Guidelines*.	
44	IV-B-1-h	How are animal handlers informed of the risks associated with research involving recombinant or synthetic nucleic acid molecules used with animals? Are there postings in the rooms/cages etc?	It is the responsibility of the PI to ensure that laboratory staff and others involved in the conduct of research with recombinant or synthetic nucleic acid molecules are sufficiently trained regarding laboratory safety and the *NIH Guidelines.* Training programs should be in place that fulfill these expectations	

45	Recommended Practice	Does the institution keep records documenting the training individual personnel have undergone relative to the *NIH Guidelines*?	NIH OSP 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	IV-B-1-i	Does the institution have a health surveillance program for laboratory workers conducting research with recombinant or synthetic nucleic acid molecules?	The institution shall determine the necessity for health surveillance of personnel conducting research with recombinant or synthetic nucleic acid molecules; and if appropriate, establish 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 activities involving viable organisms containing recombinant or synthetic nucleic acid molecules which require BL3 or higher containment.	
47	IV-B-1-i	Does the institution have a health surveillance program for animal care workers involved in high containment research with recombinant or synthetic nucleic acid molecule research?	The institution must establish and maintain a health surveillance program for personnel engaged in animal research involving viable recombinant or synthetic nucleic acid molecules that require BL3 or higher laboratory containment.	

48	IV-B-1-j	Does the institution report significant incidents, violations and research-related accidents and illnesses to NIH OSP? Are such incidents reported to NIH OSP in the appropriate time frame?	The *NIH Guidelines* require that significant incidents, violations and research-related accidents and illnesses be reported to NIH OSP within thirty days or immediately depending on the nature of the incident. For information regarding incident reporting requirements please refer to our Incident Reporting FAQs.	
49	IV-B-2-b-(5)	Does the IBC keep track of all protocols falling under the *NIH Guidelines* currently registered with the IBC?	Section IV-B-2-b-(5) of the *NIH Guidelines* requires IBCs to periodically review research with recombinant or synthetic nucleic acid molecules conducted at the institution. By having mechanisms for tracking currently registered protocols, the institution can ensure compliance with this requirement.	

50	IV-B-2-b-(6) and B-7-a-(6)	Does the institution have plans or policies for the following if recombinant or synthetic nucleic acid molecules are involved: A) Personnel contamination, B) Research-related illness, C) Accidental spills, D) Loss of containment, E) Violations?	On behalf of the institution, the IBC must adopt emergency plans covering accidental spills and personnel contamination resulting from research with recombinant or synthetic nucleic acid molecules subject to the *NIH Guidelines.*	
51	IV-B-2-b-(7	What procedures are followed to ensure reporting of any significant violations of the *NIH Guidelines,* or significant research-related accidents/ illnesses to the appropriate institutional official and to NIH OSP? 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 NIH OSP 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 NIH OSP and by whom. This policy should be widely disseminated to PIs and laboratory staff and discussed during training.	

52	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	Recommended Practice	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	IV-B-7-e-(1) and Appendix G	Who determines the minimum required Personal Protective Equipment (PPE) for laboratory staff working with recombinant or synthetic nucleic acid molecules? 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	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.	
56	IV-B-2-b-(1)	Does the IBC review and approve plans for the renovation or construction of laboratories and other facilities where research with recombinant or synthetic nucleic acid molecules 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	Appendix G	How does the institution dispose of liquid and solid waste containing recombinant or synthetic nucleic acid molecules? Are there written Standard Operating Procedures (SOP) for waste disposal?	As part of standard microbiological practice, all liquid and solid laboratory waste containing recombinant or synthetic nucleic acid molecules must be decontaminated before disposal.	
58	Appendix G-II-C	Does the institution engage in research with recombinant or synthetic nucleic acid molecules at BL3 or higher? 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	Appendix G-II-D	Does the institution engage in recombinant or synthetic nucleic acid molecule 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	Appendix G	Does the institution have policies and procedures regarding the disposal of recombinant or synthetic nucleic acid molecule containing animal waste?	Appendix G-II-B-2-i and Appendix G-II-C-2-n require that all recombinant or synthetic nucleic acid molecule containing wastes (including transgenic animal carcasses) from laboratories and animal rooms are appropriately decontaminated before disposal. NIH OSP strongly recommends the institution have formalized written policies for how animal waste containing recombinant or synthetic DNA is disposed.	
61	Recommended Practice	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.	

PHYSICAL CONTAINMENT – LARGE SCALE RESEARCH				
62	Appendix K	Does the institution engage in large-scale research or production activities involving organisms containing recombinant or synthetic nucleic acid molecules? What is the largest volume? What BL is used? If the institution does conduct 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 or synthetic nucleic acid 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.	
EXPERIMENTS REQUIRING IBC, RAC REVIEW, AND NIH DIRECTOR APPROVAL				
63	III-A-1-a	Does the institution conduct any experiments that involve the deliberate transfer of a drug resistance trait to microorganisms not known to acquire that trait naturally?	Experiments involving the deliberate transfer of a drug resistance trait to microorganisms not known to acquire that trait naturally that could compromise the ability to control disease agents in humans, veterinary medicine, or agriculture, must be reviewed by the RAC and approved by the NIH Director before initiation. Additional information on Major Actions can be found in the Major Action FAQs.	

EXPERIMENTS REQUIRING NIH AND IBC APPROVAL				
64	III-B-1	Does the institution conduct research involving the deliberate formation of recombinant or synthetic acid molecules containing genes for the biosynthesis of toxin molecules lethal to vertebrates at an LD50 of less than 100 ng/kg of bodyweight?	Experiments involving the deliberate formation of recombinant or synthetic acid molecules containing genes for the biosynthesis of toxin molecules lethal to vertebrates at an LD50 of less than 100 ng/kg of bodyweight must be reviewed and approved by both NIH OSP and the IBC before initiation. A list of specific experiments already approved under Section III-B-1 may be obtained by contacting NIH OSP at: NIHGuidelines@od.nih.gov.	
65	III-B-2	Does the institution wish to conduct an experiment previously approved as a Major Action under Section III-A-1-a of the *NIH Guidelines?*	NIH OSP may determine that a proposed experiment is equivalent to an experiment that has previously been approved by the NIH Director. An experiment will only be considered equivalent if, as determined by NIH OSP, there are no substantive differences and pertinent information has not emerged since submission of the initial III-A-1-a experiment that would change the biosafety and public health considerations for the proposed experiments. If such a determination is made by NIH OSP, these experiments will not require review and approval under Section III-A, but will instead be subject to Section III-B.	

EXPERIMENTS INVOLVING HIGHLY PATHOGENIC INFLUENZA				
66	III-D-7	Does the institution conduct research involving Highly Pathogenic Influenza?	Research involving influenza viruses containing the H2 HA segment must be conducted at BL3 enhanced containment, while experiments with H2 HA gene in cold- adapted, live attenuated vaccine strains may be conducted at BL2 (III-D-7-a). Experiments involving influenza viruses containing a majority of genes and/or segments from HPAI H5N1 must be conducted at BL3 enhanced containment. Experiments with a minority of genes and/or segments from HPAI H5N1 influenza virus must be performed at BL3 enhanced unless a risk assessment determines that the can be safely conducted at BL2 (III-D-7-b). Experiments involving influenza viruses containing any gene or segment from 1918 H1N1 must be performed at BL3 enhanced containment (III-D-7-c).	
EXPERIMENTS INVOLVING HUMAN GENE TRANSFER				
67	Appendix M	Does the institution participate in or sponsor research with recombinant or synthetic nucleic acid molecules 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 research with recombinant or synthetic nucleic acid molecules from NIH.	

68	Appendix M	Has a PI at the institution ever submitted a human gene transfer protocol to the NIH OSP? Did the protocol undergo in-depth public review at one of the RAC meetings?	Research proposals involving the deliberate transfer of recombinant or synthetic nucleic acid molecules, or DNA or RNA derived from recombinant or synthetic nucleic acid molecules, into one or more human subjects must be registered with NIH OSP and may undergo review by the RAC if specific criteria are met. The IBC may not give final approval of a protocol until the registration process is complete. For protocols that undergo RAC review, the registration process is not complete until RAC review has occurred. This is to ensure that the PI and the IBC take the RACs recommendations into consideration before the protocol is approved.	
69	Appendix M	Does the institution have written policies for reporting serious adverse events on human gene transfer trials to the IBC?	Appendix M-I-C-4-a and Appendix M-I-C-4-b describe the content and format and time frame for reporting, respectively. NIH OSP recommends written policies and procedures be in place for reporting serious adverse events to the IBC.	

70	Appendix M	Does the institution have written policies for reporting serious adverse events that are associated with the use of human gene transfer products to NIH OSP? What is the required time frame for reporting serious adverse events as well as the threshold for determining what is a reportable event to NIH OSP?	Appendix M-I-C-4-a and Appendix M-I-C-4-b describe the content and format, and time frame for reporting, respectively. NIH recommends institutions have written policies and procedures in place for reporting serious adverse events to NIH OSP and other required entities.	
71	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?	Section III-C of the *NIH Guidelines* requires that the IBC approve human gene transfer protocols prior to subject enrollment. As part of this approval process IBCs should review the informed consent documentation from the perspective of risks associated with the use of recombinant or synthetic nucleic acid molecules.	
72	Recommended Practice	Does the institution encourage the use of the GeMCRIS database for the submission of annual reports and the reporting of adverse events on human gene transfer trials to NIH OSP?	For additional information, visit the GeMCRIS page on the NIH OSP Web site.	

PHYSICAL AND BIOLOGICAL CONTAINMENT FOR RESEARCH INVOLVING PLANTS				
73	Appendix P	Does the institution engage in research with recombinant or synthetic nucleic acid molecules 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 or synthetic nucleic acid molecules.	
74	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.* NIH OSP recommends having formalized written policies describing procedures to be followed when disposing of transgenic plants. These plans should be approved by the IBC.	
75	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.	

PHYSICAL AND BIOLOGICAL CONTAINMENT FOR RESEARCH INVOLVING ANIMALS				
76	Appendix Q	Does the institution engage in research with recombinant or synthetic nucleic acid molecules 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 modified recombinant or synthetic nucleic acid molecules have been introduced).	If the institution engages in recombinant or synthetic nucleic acid molecule 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.	
77	Appendix Q-1-B-2	Does the institution inventory and track large animals subject to Appendix Q to ensure proper disposal?	The *NIH Guidelines* require that institutions keep a permanent record of the experimental use and disposal of animals covered under Appendix Q.	
78	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*. NIH OSP recommends that the institution have formalized, IBC approved polices describing how large animals are to be disposed.	

79	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*. NIH OSP recommends that the institution have formalized, IBC approved polices describing how infectious animal wastes containing recombinant or synthetic nucleic acid molecules will be disposed.	
80	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 a responsible federal agency.	
RESOURCES				
81	Recommended Practice	Has the institution developed tools for communicating requirements for the conduct of research subject to the *NIH Guidelines*?	NIH OSP 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.	
82	Recommended Practice	Does the institution encourage attendance at professional or scientific conferences related to biosafety or the *NIH Guidelines*?	NIH OSP encourages support of professional development particularly for IBC members and staff.	

For general questions related to the *NIH Guidelines* and the submission of incident reports, please email:
NIHGuidelines@od.nih.gov

For questions related to human gene transfer protocols and all human gene transfer protocol related submissions, please email:
HGTprotocols@mail.nih.gov