Frequently Asked Questions Concerning IBCs

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What are the NIH Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines)?

The **NIH Guidelines** detail safety practices and containment procedures for basic and clinical research involving recombinant DNA, including the creation and use of organisms and viruses containing recombinant DNA. The **NIH Guidelines** are a "living" document that was first drafted in 1976 as an outcome of a meeting of scientists concerned about addressing the potential public health and environmental risks associated with this developing technology. Since that time, the **NIH Guidelines** have been frequently amended to reflect evolving scientific understanding of recombinant DNA and its applications.

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When must institutions follow the NIH Guidelines?

An institution must follow the **NIH Guidelines** if it is conducting or sponsoring any recombinant DNA research that is funded by the NIH. Even if only one project of recombinant DNA research benefits from NIH support, all such projects conducted at or sponsored by that institution must comply with the **NIH Guidelines**.

Also, adherence to the **NIH Guidelines** may be a condition of support from other federal agencies, or even private funders of research. Finally, regardless of NIH funding, institutions may be subject to local ordinances, federal or state regulations, or agency guidelines that require compliance with the NIH Guidelines.

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Why must institutions comply with the NIH Guidelines?

Compliance with the **NIH Guidelines** is important because it promotes the safe conduct of research involving recombinant DNA. Also, compliance with the **NIH Guidelines** is mandatory as a condition of receiving NIH funding. Institutions that fail to comply risk:

- suspension, limitation, or termination of financial assistance for:
  - non-compliant NIH projects;
  - NIH funding for other recombinant DNA research at the institution;
- having to obtain prior NIH approval for any recombinant DNA projects.

Many institutions that do not receive any NIH funding for recombinant DNA research nonetheless choose voluntarily to comply. These institutions recognize that following the **NIH Guidelines** promotes the safe and responsible practice of this research and gives the public confidence that the institution is attending to important safety matters.

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What do I do if my committee or the research project that my committee is reviewing does not comply with the NIH Guidelines?

First and foremost, you should attempt to rectify the problem by conforming to the requirements of the **NIH Guidelines**. In addition, when you recognize an occurrence of non-compliance with the **NIH Guidelines**, you must forward within 30 days a complete report of the incident along with any recommended actions to OBA. OBA staff will respond with comments on the incident and on the institutional response. In general, OBA will evaluate the adequacy of that response and make recommendations on any additional measures that should be taken.

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How do the NIH Guidelines apply to the containment or release of transgenic plants and animals?

The **NIH Guidelines** require physical and biological containment of experiments involving the use of transgenic plants and animals, including insects. As with other experiments involving recombinant DNA, the appropriate level of containment is graded according to the potential risks of the experiment.

The **NIH Guidelines** do not permit experiments involving the deliberate release of transgenics into the environment unless, as provided in **Section I-A-1**, another Federal agency has jurisdiction over the experiment and approves the proposed release. As part of overseeing adherence to the **NIH Guidelines**, IBCs should ensure that institutional policies and procedures prohibit the release of transgenic animals and plants into the environment when not otherwise Federally authorized. Further, institutions should ensure that investigators are educated about proper containment and disposal, as well as other aspects of the **NIH Guidelines**.

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Which experiments are exempt from the NIH Guidelines?

Experiments that employ recombinant DNA with the characteristics listed below are generally exempt from the NIH Guidelines and IBC review unless they also involve, for example,: (1) the deliberate transfer of a drug resistance trait to microorganisms that are not known to acquire the trait naturally, if such acquisition could compromise the use of the drug to control disease agents in humans, veterinary medicine or agriculture; (2) deliberate formation of recombinant DNA containing genes for the biosynthesis of toxin molecules lethal for vertebrates at an LD50 of less than 100 nanograms per kilogram of body weight, or (3) the deliberate transfer of recombinant DNA, or DNA or RNA derived from recombinant DNA into one or more human research subjects. Otherwise, per Section III F of the NIH Guidelines, experiments are exempt when they involve recombinant DNA that is:

- not in organisms and viruses,
- entirely DNA segments from a single nonchromosomal or viral DNA source,
- entirely from a prokaryotic host including its indigenous plasmids or viruses when propagated only in that host or when transferred to another host by well established physiological means,
- entirely from a eukaryotic host including its chloroplasts, mitochondria, or plasmids when propagated only in that host or a closely related strain of the same species,
- entirely segments from different species that exchange DNA by known physiological processes, though one or more may be a synthetic equivalent; see **Appendix A** of the **NIH Guidelines**; or
- not a significant risk to health or the environment as determined by the NIH Director; see **Appendix C** of the **NIH Guidelines** for a detailed listing.

Details on certain other experiments that may be exempt, as well as exceptions, may be found in **Appendix C** of the **NIH Guidelines**.

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What is an Institutional Biosafety Committee?

Institutional Biosafety Committees (IBCs) were established under the NIH Guidelines for Research Involving Recombinant DNA Molecules to provide local review and oversight of nearly all forms of research utilizing recombinant DNA. Over time, many institutions have chosen to assign their IBCs the responsibility of reviewing a variety of experimentation that involves biological materials (e.g., infectious agents) and other potentially hazardous agents (e.g., carcinogens). This additional responsibility is assigned entirely at the discretion of the institution.

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What are the responsibilities of institutions with regard to IBCs?

Each institution is responsible for ensuring that all recombinant DNA research conducted at or sponsored by that institution is conducted in compliance with the NIH Guidelines. Institutional authority and responsibility place accountability for the safe conduct of the research at the local level. More specifically, each institution conducting or sponsoring recombinant DNA research that is covered by the NIH Guidelines is responsible for:

- Establishing an IBC;
- Ensuring that the IBC has adequate expertise and training (using ad hoc consultants as necessary);
- Providing appropriate training for the IBC chair and members, Biological Safety Officer, principal investigators, and laboratory staff;
- Filing an annual report with the NIH Office of Biotechnology Activities that includes (1) a roster of IBC members clearly indicating the chair, contact person and, as applicable, the biological safety officer, plant expert, animal expert, and human gene transfer expert or ad hoc consultant; and (2) biographical sketches (e.g., curricula vitae or resume) of all IBC members, including community members;
- Establishing procedures that the IBC shall follow in its initial and continuing review and approval of applications, proposals, and activities; and making available to the public, upon request, all IBC meeting minutes and any documents submitted to or received from funding agencies that those agencies must make available to the public.

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What are the general responsibilities of IBCs and what matters do they consider in their review of research involving recombinant DNA?

On behalf of the institution, IBCs review recombinant DNA research projects for compliance with the NIH Guidelines. This entails examination of a number of matters, including:

- Containment levels; some useful resources to refer to when assessing containment levels are:
  - Appendices of the NIH Guidelines:
    - **Appendix B** - Table 1: Basis for the Classification of Biohazardous Agents by Risk Group (RG)
    - **Appendix G** - Physical Containment
    - **Appendix I** - Biological Containment
    - **Appendix K** - Physical Containment for Large Scale Uses of Organisms Containing Recombinant DNA Molecules
    - **Appendix P** - Physical and Biological Containment for Recombinant DNA Research Involving Plants
    - **Appendix Q** - Physical and Biological Containment for Recombinant DNA Research Involving Animals
  - CDC and NIH Biosafety in Microbiological and Biomedical Laboratories (BMBL)
  - American Biological Safety Association's Risk Group Classification for Infectious Agents.
    - Facilities;
    - Institutional procedures and practices; and
    - Training and expertise of personnel
  - For human gene transfer experiments, IBCs also are responsible for ensuring that:
    - All aspects of Appendix M of the NIH Guidelines have been addressed by the principal investigator;
    - Final IBC approval is granted after the RAC review process is complete; and

- Research projects are in compliance with the institution's health surveillance requirements and data and adverse event reporting requirements.

- IBCs should also:
  - Notify the principal investigator of IBC review and approval.
  - Set containment levels and modify containment levels for ongoing experiments as warranted;
  - Implement contingency plans for handling accidental spills and personnel contamination resulting from recombinant DNA research; and
  - Report to OBA and institutional officials within 30 days any:
    - Substantial problems or violations of the NIH Guidelines; and
    - Significant research related accidents or illnesses.

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What is the role of the IBC in human gene transfer research?

The IBC must review and approve all experiments involving the deliberate transfer of recombinant DNA, or DNA or RNA derived from recombinant DNA, into any human research participants. The investigator proposing this activity must submit to the IBC information on the source of the DNA, the nature of the inserted DNA sequences, the vectors to be used, information on whether an attempt will be made to obtain expression of a foreign gene (and if so, the protein that will be produced), and the containment conditions that will be implemented. The IBC must ensure that all aspects of Appendix M of the NIH Guidelines (requirements for human gene transfer experiments) have been addressed. The committee must also consider the issues raised and recommendations made during the course of RAC review, as applicable, along with any responses that the principal investigator may have prepared. No research participants may be enrolled in the study until the RAC review process has been completed and the investigator has obtained IBC approval from the clinical trial site, IRB approval, and all applicable regulatory authorizations.

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What are acceptable modes of convening IBCs? May IBCs conduct official business by email?

The NIH Guidelines do not prescribe how IBCs should be convened, but they do speak to the preparation of meeting minutes (Section IV-B-2-a-(7)), and they encourage institutions to accommodate public attendance at meetings (Section IV-B-2-a-(6)). Thus, IBCs should be convened in a manner that allows for fulfillment of these two expectations. In general, email exchanges cannot fulfill these expectations of the NIH Guidelines, and thus it is not acceptable for IBCs to "meet" by email.

One approach acceptable for satisfying the NIH Guidelines is the traditional face-to-face meeting. Another is for institutions to use technology, such as teleconferencing, which is often more convenient for participants. Techniques such as teleconferencing still allow the institution to create a written record of the meeting and to provide access through dial-in services, thereby fulfilling the expectations of the NIH Guidelines. Email can nonetheless be an important tool to aid the IBC in conducting certain activities. For example, it is acceptable for institutions to use email for distribution of protocol materials, to conduct pre-meeting reviews, to poll members about particular matters, and other similar tasks. However, when IBC members are voting on protocol approvals or otherwise conducting official business, they are expected to meet together in a manner whereby minutes are taken to record the committee's actions and to document its fulfillment of IBC duties as articulated in the NIH Guidelines.

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How often should IBCs meet?

The frequency of IBCs meetings should be commensurate with the volume of protocols needing review, the nature and risks of the research, and the need for continuing oversight. Although the NIH Guidelines do not set a minimum threshold for meeting frequency, IBCs are expected to meet as often as necessary to carry out the functions prescribed in Section IV-B-2-b, including periodically reviewing recombinant DNA research conducted at the institution to ensure compliance with the NIH Guidelines (Section IV-B-2-b-(5)).

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How have the roles and responsibilities of IBCs changed with the announcement of new Federal biosecurity initiatives, including the establishment of a National Science Advisory Board on Biosecurity (NSABB) and a proposed role for IBCs in the review of "dual-use" research?

The roles and responsibilities of IBCs have not changed. For the time being, IBCs should continue to carry out the duties outlined in the NIH Guidelines for Research Involving Recombinant DNA Molecules. The Federal government has proposed a future role for IBCs in the review of "dual use" research, or legitimate research that nonetheless has the potential to be misused in ways that could threaten public health.

The NSABB will be proposing guidelines for consideration by the Federal government that will eventually define a role for IBCs in the oversight of this arena of research. IBCs and other stakeholders will have a voice in the development of these guidelines. The IBC community will be notified directly of any future changes in their responsibilities. In addition, any relevant developments will be posted on this Web site.

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How many members are required on my IBC?

An IBC must consist of at least five members. There is no limit on the maximum number of members. Details on committee membership requirements may be found in Section IV-B-2-a of the NIH Guidelines.

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When selecting members for my IBC, what qualifications or experience should I look for in potential candidates?

Collectively, the membership of your committee should include:

- Experience and expertise in:
  - Recombinant DNA technology; and
  - Biosafety and physical containment
- Knowledge of:
  - Institutional commitments and policies;
  - Applicable laws;
  - Standards of professional conduct and practice;
  - Community attitudes; and
  - The environment
- The capability to:
  - Assess the safety of recombinant DNA research; and
  - Identify potential risks to public health and safety

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What special expertise or perspectives are either required or recommended for the IBC?

Every committee is required to have:

- Two members not affiliated with the institution who represent the interest of the surrounding community with respect to health and protection of the environment. These may be officials of state or local public health or environmental protection agencies, members of other local governmental bodies, or persons active in medical, occupational health, or environmental concerns in the community. For further guidance on non-affiliated membership, see Question 4 below.

Depending on the kind of research conducted at your institution, you may also be required to have:

- Biosafety Officer (BSO): If your institution is conducting any recombinant DNA research above biosafety level 2 or on a large scale (above 10 liters), you must have a Biosafety Officer on your committee.
- Plant Expert: If your institution is conducting research involving recombinant DNA-containing plants, plant-associated microorganisms, or plant-associated small animals (e.g. arthropods), whose size, quantity, or growth requirements prevent the use of standard laboratory containment conditions as described in Appendix G of the NIH Guidelines you must have a Plant Expert on your committee. This person should have expertise in plant, plant pathogen or pest containment principals.
- Animal Expert: If your institution is conducting research involving whole animals in which the animal's genome has been altered by stable introduction of recombinant DNA or recombinant DNA is introduced into the germ-line (transgenic animals), and viable recombinant DNA-modified microorganisms are being tested, and research animals' sizes or growth requirements prevent the use of the physical containment procedures and practices listed in Appendix G of the NIH Guidelines you must have a Animal Expert on your committee. This person should have expertise in animal containment principals.

It is also recommended that IBCs include:

- Experts in biosafety and containment,
- Persons knowledgeable in institutional policies and applicable laws,
- Individuals reflecting community attitudes,
- At least one representative member from the laboratory staff.

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What kinds of individuals are appropriate as "non-affiliated members" of the IBC?

Section IV-B-2-a-(1) of the NIH Guidelines states that at least two members of the IBC shall not be affiliated with the institution. These individuals are supposed to represent the interests of the surrounding community with respect to the environment and public health. The NIH Guidelines suggest several possibilities for non-affiliated members including officials of state or local public health or environmental protection agencies, members of other local governmental bodies, or persons active in medical, occupational health, or environmental concerns in the community.

Other possibilities are teachers from local schools, real estate agents, members of local churches, charitable organizations or local support groups. These are people who are often willing to volunteer their time and who generally have a broad perspective on the communities in which they live.

The NIH Guidelines state that unaffiliated members of the IBC should have no relationship with the institution other than their service on the IBC. The determination of whether an individual is unaffiliated is not always a straightforward matter, and good judgment is often key.

If the individual under consideration works for an entity that has a business relationship with your institution, he or she would not be a suitable choice to serve on your IBC in an "unaffiliated" capacity. However, affiliation is not created by financial relationships alone. For example, an adjunct professor whose salary comes from a source outside the institution nonetheless has an affiliation with the institution at which he or she teaches.

Whoever is selected to serve in this important capacity, the institution should be in a position to justify its selection of non-affiliated IBC members should the independence of those individuals ever be called into question.

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How do I register a new IBC with OBA?

Once you have identified the members of committee, simply submit the following information to OBA (see below for contact information):

- A complete roster listing all members of the IBC; your roster should contain complete contact information for each person, including:
  - Name
  - Title
  - Business mailing address
  - Phone number
  - Fax number
  - E-mail
- The role of each member, e.g., chair person, contact person, non-institutional members, special experts as relevant, etc.
- Biosketches (e.g., curricula vitae, resume) for every member on the committee

This information should be covered with a letter explaining that you are establishing a new IBC, and are submitting supporting documents for review of compliance with the NIH Guidelines.

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What subsequent reports must be made to OBA about the IBC?

The institution must file an annual report that includes:

- An updated committee roster indicating the role of each committee member (e.g., chair person, contact person, non-institutional members, special experts as relevant, etc.), and
- Biosketches (curricula vitae, resume) for each member on the committee

The cover letter for these documents should clearly indicate that this information is being submitted as the IBC's annual report.

Also, OBA should be notified of any changes in committee membership when they occur. This report should include:

- A revised roster, showing the new member(s) with complete contact information [see additional information about rosters under the first question above]; and
- Biosketches (e.g., curricula vitae, resume) for new members on the committee.

These documents should be covered with a letter explaining that they are being submitted to update the IBC's membership.

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What is the deadline for my committee's annual report?

You must report at least annually on your IBC's membership. So, the deadline for your next update is a year after your last report. If you are unclear on when your next IBC membership update is due, you may always contact OBA directly to obtain this information.

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Where should I send IBC submissions?

Listed below are various options for submitting information on your committee to OBA:

Mail:

Michelle Johnson-Lancaster
IBC Coordinator
National Institutes of Health
Office of Biotechnology Activities
6705 Rockledge Dr., Suite 750
Bethesda, MD 20892-7985

Express mail (FedEx, UPS, etc.):

Michelle Johnson-Lancaster
IBC Coordinator
National Institutes of Health
Office of Biotechnology Activities
6705 Rockledge Dr., Suite 750
Bethesda, MD 20817-1814

Fax: ATTN: Michelle Johnson-Lancaster
(301) 496-9839
Email: JohnsoM1@od.nih.gov

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What kinds of incidents involving recombinant DNA must be reported to the NIH OBA?

Section IV-B-2-b-(7) of the NIH Guidelines states that IBCs should report "...any significant problems, violations of the NIH Guidelines, or any significant research-related accidents and illnesses" to NIH OBA within 30 days. Appendix G of the NIH Guidelines specifies certain types of accidents that must be reported on a more expedited basis. According to Appendix G-II-B-2-k, spills or accidents in BL2 laboratories resulting in an overt exposure must be immediately reported to NIH OBA (as well as the IBC). According to Appendix G-II-C-2-q and Appendix G-II-D-2-k, spills or accidents occurring in high containment (BL3 or BL4) laboratories resulting in an overt or potential exposure must be immediately reported to NIH OBA (as well as the IBC, and BSO).

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Does this responsibility only apply to IBCs?

No. In addition to IBCs, incident reporting is also articulated as a responsibility of institutions, BSOs, and principal investigators under Sections IV-B-1-j, IV-B-3-c-(2), and IV-B-7-a-(3), respectively. Institutions have the discretion to determine which party should make these reports, and one report for each incident or set of information is generally sufficient.

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How serious must a problem be to warrant reporting to OBA?

Any spill or accident involving recombinant DNA research of the nature described in Appendix G (see above) or that otherwise leads to personal injury or illness or to a breach of containment must be reported to OBA. These kinds of events might include skin punctures with needles containing recombinant DNA, the escape or improper disposition of a transgenic animal, or spills of high-risk recombinant materials occurring outside of a biosafety cabinet. Failure by an investigator to adhere to the containment and biosafety practices articulated in the NIH Guidelines must also be reported to OBA. Minor spills of low-risk agents not involving a breach of containment that were properly cleaned and decontaminated generally do not need to be reported. OBA staff should be consulted if IBCs, investigators, or other institutional staff are uncertain whether the nature or severity of the incident warrants

reporting to OBA; we can assist in making this determination. To communicate with OBA, you may use the contact information at the end of this message.

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What information should incident reports include?

Incident reports should include sufficient information to allow for an understanding of the nature and consequences of the incident, as well as its cause. A detailed report should also include the measures that the institution took in response to mitigate the problem and to preclude its reoccurrence.

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What does OBA do with this information?

OBA staff review incident reports to assess whether the institutional response was sufficient. Depending on the adequacy of the institutional response, OBA may ask the institution to take additional measures as appropriate to promote safety and compliance with the NIH Guidelines.

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Do adverse events experienced by participants in human gene transfer trials fall under this incident reporting requirement?

No, adverse events in human gene transfer trials are subject to a separate set of reporting requirements. These are found in Appendices M-1-C-3 and M-1-C-4 of the NIH Guidelines. Serious adverse events that are unexpected and possibly associated with the gene transfer product should be reported to OBA within 15 calendar days of sponsor notification, unless they are fatal or life threatening, in which case they should be reported within 7 calendar days. Other serious adverse events should be reported to OBA as part of the principal investigator's annual report to OBA.

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