1. What are the *NIH Guidelines*?

The *NIH Guidelines* detail safety practices and containment procedures for basic and clinical research involving recombinant or synthetic nucleic acid molecules, including the creation and use of organisms and viruses containing recombinant or synthetic nucleic acid molecules.

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2. When must institutions follow the *NIH Guidelines*?

An institution must follow the *NIH Guidelines* if it receives any funding from the NIH for research involving recombinant or synthetic nucleic acid molecules. Even if only one research project involving recombinant or synthetic nucleic acid molecules at an institution 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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3. 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 or synthetic nucleic acid molecules. Also, compliance with the *NIH Guidelines* is mandatory as a condition of receiving NIH funding for such research. Institutions that fail to comply with the *NIH Guidelines* risk:

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

synthetic nucleic acid molecules.

Many institutions that do not receive any NIH funding for research involving recombinant or synthetic nucleic acid molecules 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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4. Are there reporting requirements if an institution or investigator is found to be out of compliance with the *NIH Guidelines*?

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

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5. How do the *NIH Guidelines* apply to the containment or release of plants and animals containing recombinant or synthetic nucleic acid molecules (e.g. have been genetically modified or have had recombinant or synthetic nucleic acid molecules administered to them)?

The *NIH Guidelines* require physical and biological containment for experiments involving the use of transgenic plants and animals, including insects. As with other research involving recombinant or synthetic nucleic acid molecules, 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 transgenic animals and plants (or animals or plants that have had recombinant or synthetic nucleic acid molecules administered to them) 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 such 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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6. Are there any experiments with recombinant or synthetic nucleic acid molecules that are exempt from the *NIH Guidelines*?

Section III-F of the *NIH Guidelines* describes experiments that are exempt from the requirements. Details on certain other experiments that may be exempt, as well as exceptions to the exemptions, may be found in Appendix C of the *NIH Guidelines.*

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7. What is an IBC?

Institutional Biosafety Committees (IBCs) were established under the *NIH Guidelines* to provide local review and oversight of nearly all forms of research utilizing recombinant or synthetic nucleic acid molecules. 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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8. What are the responsibilities of institutions with regard to IBCs?

Each institution is responsible for ensuring that all research involving recombinant or synthetic nucleic acid molecules conducted at or sponsored by that institution is conducted in compliance with the *NIH Guidelines*. Indeed, the *NIH Guidelines* place much of the

authority, responsibility, and accountability for the safe conduct of the research at the local level. More specifically, each institution conducting or sponsoring research involving recombinant or synthetic nucleic acid molecules 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 (BSO), principal investigators (PI), and laboratory staff;
- Filing an annual report with the NIH OSP that includes (1) a roster of IBC members clearly indicating the chair, contact person and, as applicable, the BSO, plant expert, animal expert, and human gene transfer expert or *ad hoc* consultant; and (2)biographical sketches 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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9. What are the general responsibilities of IBCs? What matters should they consider in their review of research involving recombinant or synthetic nucleic acid molecules?

On behalf of the institution, IBCs review research involving recombinant or synthetic nucleic acid molecules 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
  - Appendix G – Physical Containment Appendix I – Biological Containment
  - Appendix K – Physical Containment for Large Scale Uses of Organisms Containing Recombinant or Synthetic Nucleic Acid Molecules

    - Appendix L – Physical and Biological Containment for Recombinant or Synthetic Nucleic Acid Molecule Research Involving Plants
    - Appendix M – Physical and Biological Containment for Recombinant or Synthetic Nucleic Acid Molecule Research Involving Animals
- Facilities;
- Institutional procedures and practices; and
- Training and expertise of personnel

IBCs should also:

- Notify the PI 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 research involving recombinant or synthetic nucleic acid molecules; and
- Report to OSP and institutional officials within any substantial problems or violations of the *NIH Guidelines*or significant research related accidents or illnesses.

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10. What is the role of the IBC in the review and approval of human gene transfer research?

For research subject to Section III-C of the *NIH Guidelines* (recombinant or synthetic nucleic acid molecule research involving research participants), the IBC must assess biosafety issues related to the research (e.g., administration, shedding).

Research may not be initiated until IBC approval at the clinical trial site, and all other applicable institutional and regulatory authorization(s) and approvals have been obtained.

IBC oversight may conclude after the last participant is administered the final dose of product. However, IBCs may choose to establish other end points for oversight, based on their biosafety assessment of the proposed research.

Additional information on IBC review of human gene transfer research is available in the "Points to Consider for IBCs Reviewing Human Gene Transfer Protocols" FAQ.

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11. The *NIH Guidelines* state that research subject to section III-E requires IBC notice simultaneous with initiation. Does this work require subsequent IBC review and approval?

Work covered under section III-E of the *NIH Guidelines* requires a registration document to be submitted to the IBC at the time the research is initiated.

Review and approval prior to initiation of the experiments is not required. Review and approval of the registration by the IBC is still required, but this review and approval does not need to take place before the experiment is initiated. This is in contrast to experiments which are covered under Sections III-A through III-D of the *NIH Guidelines*, where no work may commence until the IBC approval is given.

Only experiments that are exempt from the *NIH Guidelines* (Section III-F) can be conducted without the approval of the IBC. All experiments that are not exempt from the *NIH Guidelines* must be reviewed and approved by the IBC.

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12. How many members are required on an 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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13. When selecting members for an IBC, what qualifications or experience should be considered in potential candidates?

Collectively, the membership of an IBC should

- include: Experience and expertise in:

Recombinant or synthetic nucleic acid molecule research; and

Biosafety and physical containment

- Knowledge of:

  Institutional commitments and policies;

  Applicable laws;

  Standards of professional conduct and practice;

  Community attitudes; and

  Environmental considerations

- The capability to:

  Assess the safety of research involving recombinant and synthetic nucleic acid molecules; and

  Identify potential risks to public health and safety

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14. 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 below.

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

- BSO: If an institution is conducting any high containment research involving recombinant or synthetic nucleic acid molecules (BL 3 or 4) or research on a large scale (above 10 liters), there must be a BSO on the IBC.
- Plant Expert: If the institution is conducting research subject to Appendix L there must be a plant expert on the IBC. This person should have expertise in plant, plant pathogen, or pest containment principals. Appendix L describes research involving recombinant or synthetic nucleic acid molecule-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*
- Animal Expert: If the institution is conducting research subject to Appendix M there must be an animal expert on the IBC. This person should have expertise in animal containment principals. Appendix M describes research involving whole animals in which the animal's genome has been altered by the stable introduction of recombinant or synthetic nucleic acid molecules or recombinant or synthetic nucleic acid molecules are introduced into the germ-line (transgenic animals), or viable recombinant or synthetic nucleic acid molecule-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*.
- Expertise in human gene transfer: If the institution participates in or sponsors recombinant or synthetic nucleic acid molecule research involving human participants, the institution must ensure that the IBC has adequate expertise and training (using ad hoc consultants as deemed necessary).

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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15. 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 key.

If the individual under consideration works for an entity that has a business relationship with the institution, he or she would not be a suitable choice to serve on the IBC in an "unaffiliated" capacity. However, affiliation is not created by financial relationships alone. For example, visiting professors have an affiliation with the institution where they teach even if their salary comes from a source outside the institution.

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16. How do institutions register a new IBC with NIH OSP?

NIH encourages entities wishing to register a new IBC to utilize the Web-based Institutional Biosafety Committee Registration Management System (IBC-RMS).

IBC-RMS can be accessed at: http://ibc-rms.od.nih.gov

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17. What subsequent reports must be made to NIH OSP 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., chairperson, contact person, non-institutional members, special experts as relevant, etc.), and
- Biosketches for each new member on the committee

Institutions can file annual reports electronically utilizing IBC-RMS.

In addition to utilizing IBC-RMS to submit an annual report, the system can be used to notify NIH of membership changes that may occur on the IBC throughout the course of the year.

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18. What is the deadline for an IBC's annual report?

Institutions must report at least annually on their IBC's membership. The deadline for an annual update is one year after the approval date of the last report submission. If there is a change in the membership of the committee prior to the subsequent annual submission due date, the IBC is required to update the registration at the time of the change. To determine when the next IBC annual report is due, institutions may view their registration information on IBC-RMS or contact NIH OSP directly to obtain this information.

Entities that register their IBC's via IBC-RMS will be sent email reminders 15 days prior to their IBC registration due date and a subsequent "past due" notification the day it becomes past due (if the entity has not yet filed their report).

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19. If an institution does not receive NIH support for research involving recombinant or synthetic nucleic acid molecules; can it voluntarily register its IBC?

There are a number of reasons why entities not subject to the *NIH Guidelines* choose nonetheless to comply voluntarily. First, it demonstrates the entity adheres to high standards of safety in conducting recombinant or synthetic nucleic acid research. Second, adherence to the *NIH Guidelines* has been adopted as a requirement by other Federal agencies, so even if an institution does receive NIH funding, it may still be expected to

adhere to the *NIH Guidelines* if it receives funding from certain other agencies. Finally, if the institution adheres to the *NIH Guidelines* voluntarily, it will be poised to be compliant with this key requirement should it ever seek NIH funding for research subject to the *NIH Guidelines*.

It is important to note that, under voluntary compliance, NIH expects full adherence to all pertinent requirements. If an institution were to adhere only to certain elements of the *NIH Guidelines*, the NIH would not be in a position to say that the entity was compliant with the *NIH Guidelines*.

As part of full compliance, NIH would expect the entity to release its IBC minutes to the public upon request. The entity may redact information that is private or proprietary; however, redaction should be done judiciously and consistently. Some examples of information that may be redacted include trade secret information, the home telephone numbers or home addresses of IBC members, and specific information whose disclosure would directly compromise institutional or national security.

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20. Can an IBC registration be deactivated?

Entities that utilize the IBC-RMS may request to deactivate their IBC registration online.

Entities who choose not to utilize IBC-RMS, must request deactivation of their IBC in writing to NIH OSP. Deactivation requests may be emailed to NIHGuidlines@od.nih.gov

For further information about the requirements of the *NIH Guidelines*, please email: NIHGuidelines@od.nih.gov

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