Frequently Asked Questions (FAQs) of Interest to IBCs

Contents

4.1. How do I register a new IBC with NIH OBA?

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

4.3. What is the deadline for my IBC annual report?

4.4. Where should I send IBC submissions? Can I register an IBC online?

4.5. Our institution does not receive NIH support for recombinant DNA research; can we voluntarily register our IBC?

4.6. How do I deactivate an IBC registration?

5. Conduct of IBC Meetings and Access to IBC Minutes

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

5.2. What constitutes an appropriate quorum for the purpose of convening an IBC meeting?

5.3. How often should IBCs meet?

5.4. What do the *NIH Guidelines* say about public access to minutes of IBC meetings?

5.5. What documents are encompassed by the language, "...and any documents submitted to or received from funding agencies which the latter are required to make available to the public"?

5.6. May we redact information from these documents before we make them available to the public?

5.7. Is it acceptable to require that an individual requesting access to IBC minutes come to our institution and view the minutes on site in a reading room?

5.8. May we charge the public for copies of our minutes?

5.9. Who should be considered a member of "the public"? Are private organizations considered members of the public? Is the concept of "public" limited to our neighborhood, city, or state?

5.10. We are a state institution and, as an entity of state government, we are required to follow our state public disclosure laws in making institutional documentation publicly available upon request. Is this in conflict with the public access provisions of the *NIH Guidelines*?

5.11. How detailed should the minutes of IBC meetings be?

6. Submitting Reports of Incidents, Accidents, or Violations to NIH OBA

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

6.2. Does the responsibility to report incidents only apply to IBCs?

6.3. How serious must an incident be to warrant reporting to NIH OBA?

6.4. What information should incident reports include?

6.5. What does NIH OBA do with the information from incident reports?

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

6.7. Where should I send incident reports?

1 *NIH Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines)*

1.1 What are the *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.

1.2 When must institutions follow the *NIH Guidelines*?

An institution must follow the *NIH Guidelines* if it receives any funding from the NIH for recombinant DNA research. 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*.

1.3 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 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.

1.4 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 concerning any additional measures that should be taken.

1.5 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*.

1.6 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.

1.7 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 LD_{50} 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, Section III-F of the *NIH Guidelines* exempts experiments 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*.

2 IBC Roles and Responsibilities

2.1 What is an IBC?

IBCs were established under the *NIH Guidelines* 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.

2.2 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*. 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 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 (BSO), principal investigators (PI), and laboratory staff;
- Filing an annual report with the NIH OBA 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 (e.g., curricula vitae or résumé) 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.

2.3 What are the general responsibilities of IBCs? 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
        - 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 (requirements for human gene transfer experiments) of the *NIH Guidelines* have been addressed by the PI;
- Final IBC approval is granted after the Recombinant DNA Advisory Committee (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 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 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.

2.4 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 PI 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* 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 PI 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, Institutional Review Board (IRB) approval, and all applicable regulatory authorizations.

2.5 How have the roles and responsibilities of IBCs changed with the announcement of new Federal biosecurity initiatives, including the establishment of the 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*. The Federal government has proposed a possible 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 possible 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.

3 IBC Membership

3.1 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*.

3.2 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
  - Environmental considerations

- The capability to:
  - Assess the safety of recombinant DNA research; and
  - Identify potential risks to public health and safety

3.3 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 interests 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 3.4 below.

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

- BSO: If your institution is conducting any high containment recombinant DNA research (BL 3 or 4) or research on a large scale (above 10 liters), you must have a BSO on your committee.
- Plant Expert: If your institution is conducting research subject to Appendix P you must have a Plant Expert on your committee. This person should have expertise in plant, plant pathogen, or pest containment principles. Appendix P describes 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*
- Animal Expert: If your institution is conducting research subject to Appendix Q you must have an Animal Expert on your committee. This person should have expertise in animal containment principles. Appendix Q describes 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*.

It is also recommended that IBCs include:

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

3.4 Who is responsible for ensuring that IBC members are adequately trained to fulfill their responsibilities under the NIH Guidelines?

Section IV-B-1-h of the *NIH Guidelines for Research Involving Recombinant DNA* (*NIH Guidelines*) states that the institution must ensure appropriate training for the IBC Chair and members, Biological Safety Officer and other containment experts regarding laboratory safety and implementation of the *NIH Guidelines*. The IBC Chair is responsible for ensuring that IBC members are appropriately trained.

This training may be accomplished in a number of ways. One is to have the institution 'train a trainer' by

sending someone to one of the training events conducted by staff from the NIH Office of Biotechnology Activities (OBA). This individual can, in turn, train IBC members utilizing OBA-produced materials along with institution-specific information. OBA training opportunities are posted on the OBA web site at http://www4.od.nih.gov/oba/IBC/IBCindexpg.htm. OBA slide sets and FAQs are also available on these pages, and institutions should also feel free to download and use any of these training materials.

3.5 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 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, visiting professors have an affiliation with the institution where they teach even if their salary comes from a source outside the institution.

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.

4 Submitting IBC Registration Information to the NIH OBA

4.1 How do I register a new IBC with NIH 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
    - Email
    - The role of each member, e.g., chair person, contact person, non-institutional members, special experts as relevant, etc.

- Biosketches (e.g., curricula vitae, résumé) 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*.

4.2 What subsequent reports must be made to NIH 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, résumé) 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, résumé) for new members on the IBC.

These documents should be covered with a letter explaining that they are being submitted to update the

IBC's membership.

4.3 What is the deadline for my IBC's annual report?

You must report at least annually on your IBC's membership. Thus, 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.

4.4 Where should I send IBC submissions?

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

Mail :	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 20892-7985	Michelle Johnson-Lancaster IBC Coordinator National Institutes of Health Office of Biotechnology Activities 6705 Rockledge Dr., Suite 750 Bethesda, MD 20817-1814
Fax:	Email:
ATTN: Michelle Johnson-Lancaster (301) 496-9839	JohnsoM1@od.nih.gov

4.5 Our institution does not receive NIH support for recombinant DNA research; can we voluntarily register our 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 DNA 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 recombinant DNA research.

It is important to note that, under voluntary compliance, we do expect 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, we would expect the entity to release its 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.

4.6 How do I deactivate an IBC registration?

If for any reason, an institution decides to deactivate its IBC registration with OBA, we ask that the institution notify OBA of that fact in writing. This allows us to keep current the status of all IBC registrations.

5 Conduct of IBC Meetings and Access to IBC Minutes

5.1 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*.

5.2 What constitutes an appropriate quorum for the purpose of convening an IBC meeting?

A "quorum" is the minimum number of members who must be present to conduct an IBC meeting. The *NIH Guidelines* do not define a quorum. Many committees consider a quorum to be a simple majority (>50%) of voting members. We encourage institutions to clearly define a quorum in their policies and procedures and to adhere this policy.

In addition to specifying the minimum number of members who must be present, the IBC policies should also take into account the necessary expertise that must be present. For example, the IBC must include an individual with expertise in plant, plant pathogens or plant containment principles when experiments utilizing Appendix P of the *NIH Guidelines* are being conducted. When such research is being reviewed, a plant expert should be present. Similarly if research covered under Appendix Q is being reviewed, animal containment expertise would be required.

5.3 How often should IBCs meet?

The frequency of IBC 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)).

5.4 What do the *NIH Guidelines* say about public access to minutes of IBC meetings?

Section IV-B-2-a-(7) of the *NIH Guidelines* states:

> *Upon request, the institution shall make available to the public all Institutional Biosafety Committee meeting minutes and any documents submitted to or received from funding agencies which the latter are required to make available to the public.*

5.5 What documents are encompassed by the language, "...and any documents submitted to or received from funding agencies which the latter are required to make available to the public"?

Under Section IV-B-2-a-(3) of the *NIH Guidelines*, IBCs must submit committee rosters and biographical sketches of members to the NIH. The NIH would be required to disclose that information in response to a request under the Federal Freedom of Information Act. Thus, under the *NIH Guidelines*, IBCs are required

to make rosters and biographical sketches that have been submitted to NIH available to the public upon request.

5.6 May we redact information from these documents before we make them available to the public?

Section IV-B-2-a-(6) of the *NIH Guidelines* acknowledges that the protection of private or proprietary information is a legitimate consideration in deciding whether to open IBC meetings to the public. Since minutes are a record of the meeting, it is logical to extend this concept to information captured in those documents. Institutions may, therefore, redact proprietary or private information, but must do so judiciously and consistently for all requested documents. Articulating criteria for redaction in IBC operating procedures can help promote consistency and proper redaction practices. Some examples of information that may be redacted include trade secret information and other confidential commercial information, home telephone numbers and home addresses of IBC members, and specific information whose disclosure would directly compromise institutional or national security.

5.7 Is it acceptable to require that an individual requesting access to IBC minutes come to our institution and view the minutes on site in a reading room?

Access to minutes should not be overly burdensome to the public. Requiring a member of the public to travel to the site is generally not appropriate since this can often entail significant time, effort, and travel expenses. There are, however, multiple ways to make minutes available that are relatively unburdensome to both the institution and the requestor. Minutes can be sent by U.S. mail, email or made available on the institution's Web site (either openly, or through special access provided to requestors only).

5.8 May we charge the public for copies of our minutes?

An institution may charge an amount sufficient to cover the costs of providing minutes. However, charges should not be excessive or used as a deterrent to access.

5.9 Who should be considered a member of "the public"? Are private organizations considered members of the public? Is the concept of "public" limited to our neighborhood, city, or state?

Since the *NIH Guidelines* are nationally applied, and no limitations were placed on the notion of "public" when they were first promulgated, "public" should be interpreted in its broadest sense - as referring to all people and entities.

5.10 We are a state institution and, as an entity of state government, we are required to follow our state public disclosure laws in making institutional documentation publicly available upon request. Is this in conflict with the public access provisions of the *NIH Guidelines*?

The *NIH Guidelines* do not preclude institutions from complying with any applicable laws in responding to public requests for IBC minutes. A provision in state law, Federal law, or institutional policy that requires an institution to follow specific procedures in responding to requests for institutional records is not inherently in conflict with any provision of the *NIH Guidelines*. A conflict with the *NIH Guidelines* would occur, however, if any of these laws precluded an institution from providing the minutes altogether. Redaction of certain information is permissible under the *NIH Guidelines*, as discussed above.

5.11 How detailed should the minutes of IBC meetings be?

The *NIH Guidelines* do not prescribe the level of detail that must be captured in IBC meeting minutes. However, there are some generally accepted principles about minute-taking, including the type of information that minutes should capture, that can be found in such references as *Robert's Rules of Order*. In keeping with those principles, minutes should reflect the date and place of the meeting, whether minutes of the prior meeting were approved, individuals in attendance, whether and why the meeting was open or closed, all major motions, major points of order, and whether motions were approved, and the time of meeting adjournment.

In general, the minutes should offer sufficient detail to serve as a record of major points of discussion and the committee's rationale for particular decisions, documenting that the IBC has fulfilled its review and oversight responsibilities as outlined under Section IV-B-2-b of the *NIH Guidelines*. Minutes do not need to be transcripts or kept at a level of detail that attributes each remark to a specific individual.

6 Submitting Reports of Incidents, Accidents, or Violations to NIH OBA

6.1 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).

6.2 Does the responsibility to report incidents only apply to IBCs?

No. In addition to IBCs, incident reporting is also articulated as a responsibility of institutions, BSOs, and PIs 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.

6.3 How serious must an incident be to warrant reporting to NIH OBA?

Any spill or accident involving recombinant DNA research of the nature described in Section IV-B-2-b-(7), 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.

6.4 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.

6.5 What does NIH OBA do with the information from incident reports?

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*.

6.6 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 PI's annual report to OBA.

6.7 Where should I send incident reports?

Mail : Dr. Kathryn Harris National Institutes of Health Office of Biotechnology Activities 6705 Rockledge Dr., Suite 750 Bethesda, MD 20892-7985	Express mail (FedEx, UPS, etc.): Dr. Kathryn Harris National Institutes of Health Office of Biotechnology Activities 6705 Rockledge Dr., Suite 750 Bethesda, MD 20817-1814
Fax: ATTN: Dr. Kathryn Harris (301) 496-9839	Email: HarrisKath@od.nih.gov