Conduct of Institutional Biosafety Committee (IBC) Meetings, Content of IBC Meeting Minutes and Public Transparency Expectations of the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines)

Frequently Asked Questions (FAQs)

1. Conduct of IBC Meetings and Access to IBC Minutes

1.1. 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 or videoconferencing, which is often more convenient for participants. Techniques such as teleconferencing or videoconferencing 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*.

1.2. 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.

OBA recommends that at least one of the unaffiliated members of the IBC be present for each meeting and thus, as a best practice, the IBC quorum should require at least one unaffiliated member.

1.3. 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 for recombinant and synthetic nucleic acid research conducted at the institution to ensure compliance with the *NIH Guidelines* (Section IV-B-2-b-(5)).

2. Content of IBC Minutes

2.1. What is the expected content of IBC minutes?

The NIH system of oversight for recombinant and synthetic nucleic acid research described in the *NIH Guidelines* is based on expectations of transparency and public access to information about the biosafety oversight of the research activities. Institutions should prepare IBC meeting minutes that not only serve the institution's need for a record of the IBC's proceedings, but that also document for NIH and the public that the IBC is fulfilling the performance expectations of the *NIH Guidelines*.

The *NIH Guidelines* accord institutions latitude in the development of specific IBC administrative procedures and practices, including those regarding the preparation of minutes. The latitude notwithstanding, OBA expects IBCs to adequately document fulfillment of their review and oversight responsibilities described in Section IV-B-2-b of the *NIH Guidelines*.

Section IV-B-2-b describes a number of activities that the IBC must carry out on behalf of the institution including:

- Conducting an assessment of the containment levels required by the *NIH Guidelines* when reviewing proposed research;
- Assessing the facilities, procedures, practices, and training and expertise of personnel involved in recombinant or synthetic nucleic acid research; and
- Periodically reviewing recombinant or synthetic nucleic acid research to ensure compliance with the *NIH Guidelines*.

With respect to the review of proposed recombinant or synthetic nucleic acid research, the *NIH Guidelines* cite a number of matters that IBCs should consider as appropriate. These matters are described in Section II-A-3 and Section III of the *NIH Guidelines* and include:

- Agent characteristics (e.g. virulence, pathogenicity, environmental stability)
- Types of manipulations planned
- Source(s) of the nucleic sequences (e.g., species)
- Nature of the nucleic acid sequences (e.g., structural gene, oncogene)
- Host(s) and vector(s) to be used
- Whether and attempt will be made to obtain expression of a foreign gene, and if so, the protein that will be produced

Other information that should be documented includes:

- Principal Investigator (PI) name
- Project title
- Verification that the PI and laboratory staff performing the research have been appropriately trained in the safe conduct of the research
- Applicable section of the *NIH Guidelines* the research falls under (e.g. Section III-D-1, Section III-E-1, etc.)
- Containment conditions to be implemented (biosafety level and any special provisions)

In general, the IBC meeting minutes should offer sufficient detail about the discussion of these matters to document the committee's rationale for particular decisions.

2.2. 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.

3. Public Access to IBC Meetings and Minutes

3.1. What do the *NIH Guidelines* say about public attendance at IBC meetings?

Section IV-B-2-a-(6) of the *NIH Guidelines* states:

> *When possible and consistent with protection of privacy and proprietary interests, the institution is encouraged to open its Institutional Biosafety Committee meetings to the public*.

3.2. 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.*

3.3. 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 Office of Biotechnology Activities (OBA). 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.

3.4. Is it acceptable to require that an individual requesting access to IBC minutes come to the 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).

3.5. May an institution charge the public for copies of IBC 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.

3.6. 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.

3.7 If a state institution is required to follow state public disclosure laws in making institutional documentation publicly available upon request, would this be 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 below.

3.8 May an institution redact information from IBC documents before making 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.

Questions about this guidance can be addressed to NIH OBA by email to oba@od.nih.gov or by telephone at 301-496-9838.