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May 14, 2004

TO:

Members and Staff of Institutional Biosafety Committees

FROM:

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Director

NIH Office of Biotechnology Activities

SUBJECT:

Minutes of Institutional Biosafety Committee Meetings

Recently, the NIH Office of Biotechnology Activities has received a number of queries concerning preparation of, and public access to, minutes of Institutional Biosafety Committee (IBC) meetings.

Minute-taking is an aspect of IBC administration that the NIH Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines) do not prescribe in detail. In this and other areas, institutions are accorded latitude to develop specific procedures and practices that are in keeping with their local circumstances and organizational considerations, as well as the overall spirit and intent of the NIH Guidelines. In doing so, however, it is also paramount that institutions apply sound judgment and consistent practices.

To assist institutions in developing policies and practices for the preparation of IBC meeting minutes that are in keeping with the intent of the *NIH Guidelines* and that are acceptable to the NIH, we have prepared the attached questions and answers. We also have posted this information to the IBC page on our Web site: http://www4.od.nih.gov/oba/IBC/IBCindexpg.htm.

If you have any questions about this material, do not hesitate to contact Allan C. Shipp, Director of Outreach, NIH Office of Biotechnology Activities, by email at shippa@od.nih.gov or by telephone at 301-435-2152.

NIH Office of Biotechnology Activities Questions and Answers Concerning Institutional Biosafety Committee (IBC) Meeting Minutes May 14, 2004

Preparation of IBC minutes

Q: How detailed should the minutes of IBC meetings be?

A: 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.

Access to IBC Minutes

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

A: 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.

Q: 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.

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

A: 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.

Q: 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?

A: 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).

Q: May we charge the public for copies of our minutes?

A: 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.

Q: 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?

A: 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.

Q: 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*?

A: 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.