Sheet 16: NIH INSTITUTIONAL REVIEW BOARD (IRB) MINUTES

The Federal regulations for the protection of human subjects (45 CFR 46.115(2)) require that "Minutes of IRB meetings . . . shall be in sufficient detail to show attendance at the meeting; actions taken by the IRB; the vote on these actions including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussion of controverted issues and their resolution." These requirements are minimal.

However, the NIH does not believe it can be assumed that all regulatory requirements for review of research have taken place at an IRB meeting unless the IRB minutes record that they were considered and discussed. Good minutes should enable a reader who was not present at the meeting to determine exactly how and with what justification the IRB arrived at its decisions. They should also provide the IRB itself with sufficient detail to help it reconstruct its discussions at a later date, if necessary, and thus protect not only the IRB, but NIH as a whole. Comprehensive minutes also demonstrate respect for the human subjects of research.

Therefore, at NIH, IRB minutes must uniformly document that the IRB considered all the regulatory review requirements as set forth in the OHSR IRB Review Standards Form, Chapter 3-4 of the Standard Operating Procedures for NIH IRBs, http://ohsr.od.nih.gov/irb/procedures.html

The level of risk determined by the IRB for each protocol must also be documented. In order to facilitate discussion, some NIH IRBs have found it useful to have Principal Investigators address each regulatory review requirement when presenting their new protocols to the IRB.

IRBs are authorized to act only when a quorum is present. A quorum is defined as a majority of the voting members (fifty percent plus one) including at least one member whose primary concerns are in nonscientific areas. The Chair is included as a member of the quorum but votes only to break a tie. Protocol approval requires the approval of a majority of the IRB's quorum. The IRB meeting may not start absent a quorum, and if the quorum is lost during the meeting for any reason, no votes may be taken. Changes in the quorum that occur during the meeting should be noted. Because NIH IRBs sometimes lose a quorum at the end of long meetings, OHSR recommends that continuing reviews be reviewed at the beginning of meetings in order to ensure that continuing review due dates are met.

If the vote of the IRB is not unanimous, the minority opinion must be recorded in or attached to the minutes and accompany the majority decision when forwarded for final institutional review and approval.

IRB minutes are subject to the Freedom of Information Act; therefore they should be written impersonally, and opinions expressed by members should not be attributed to them. Members should only be identified by name when they are recused from a particular review or leave the meeting for any reason.

The NIH format for IRB minutes is attached. A template for this format may be downloaded from the forms section of OHSR's website at http://ohsr.od.nih.gov/info/minutes.html.

Attachment: NIH format for IRB minutes

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FORMAT FOR ALL NIH IRB MINUTES

(The order in which agenda items are reviewed is at the discretion of IRB Chairs)

Minutes of the (Institute) IRB Meeting Held on (date)

Members Present: (indicate who is a non-scientist, non-NIH affiliated, etc.)	_____ (Chair)	_____
	_____	_____
	_____	_____
	_____	_____
	_____	_____
	_____	_____
	_____	_____
	_____	_____
Members Absent:	_____	_____
	_____	_____
	_____	_____
	_____	_____
	_____	_____
Guests: (include affiliation)	_____	_____
	_____	_____
	_____	_____

The meeting convened at --:-- (a.m./p.m.) with a quorum present.

1. MINUTES OF THE MEETING HELD ON (DATE). (The minutes must be voted on and any changes documented.)

2. ANNOUNCEMENTS

3. INITIAL REVIEWS.

A. Principal Investigator:
Protocol Title:

Protocol precis or summary:

(a) Discussion:

General discussion:

Specific discussions: (include the following headings)

Scientific design (discuss and note that Institute pre-scientific review has been done)

Risks/benefits (assign a level of risk here or at the time of the IRB decision and vote, [(d) below] consistent with page 2, OHSR IRB Protocol Review Standards form. If children are to be enrolled, cite the regulatory reference)

Subject selection (discuss populations to be studied & recruitment plan)

Additional safeguards for vulnerable subjects

Minimization of risks to subjects

Privacy & confidentiality.

Consent document (document that all required elements are present)

Additional considerations (e.g., ionizing radiation; collaborative research; IND, other. State if these considerations do not apply)

(b) Stipulations (number the stipulations)

(c) Recommendations (number the recommendations)

(d) IRB Decision and Vote

State whether the vote is unanimous; if not, state how many members voted for, against or abstained. Document in or attach to the minutes the reason(s) for the minority opinion(s). Members who are affiliated with the protocol must recuse themselves from the IRB discussion and vote, and leave the room during the discussion and when the vote is taken. The minutes should state which member(s) left the room. If a quorum is lost because members recuse themselves, no action may be taken on the protocol.

If the protocol is approved with stipulations and/or recommendations, the minutes must state whether the IRB votes that the stipulations and/or recommendations are to be reviewed by the Chair, by a subcommittee of the IRB, or by the full IRB.

B., C., etc. (Follow same format as above for additional new protocols)

4. EXPEDITED INITIAL REVIEWS, EXPEDITED CONTINUING REVIEWS OR EXPEDITED AMENDMENTS

A. Principal Investigator:
Title and type of expedited action:
Date approved by IRB Chair or designee:

Description of expedited action: (Expedited actions must be listed separately in the minutes. The Chair should provide a brief explanation of any expedited actions. A vote is not required but the IRB has the prerogative to discuss, rescind or amend expedited actions.)

B., C. etc. (List additional expedited actions following the above format

5. CONTINUING REVIEWS (it is useful for the primary or secondary reviewer or the IRB Administrator to have the entire protocol file available for reference at the meeting)

A. Principal Investigator:
Protocol Title:
Protocol Number:
Expiration Date:

Protocol Precis or Summary (if not provided in discussion at (a) below):

(a) Discussion:

(b) Stipulations (number the stipulations)

(c) Recommendations (number the recommendations)

(d) IRB Decision and Vote (Include IRB's reaffirmation of the level of risk or establishment of a new risk level consistent with the OHSR Protocol Review Standards form, page 2)

B., C. etc. (Follow the same format as above for additional continuing reviews)

6. AMENDMENTS

A. Principal Investigator:
Protocol Title:
Protocol Number:
Expiration Date:

Description of the amendment:

(a) Discussion:

(b) Stipulations (number the stipulations)

(c) Recommendations (number the recommendations)

(d) IRB Decision and Vote (include a statement indicating whether or not the protocol's level of risk is altered by the amendment)

B., C. etc. (Follow the same format as above for additional amendments)

7. REPORT OF ADVERSE EVENT(S)

Principal Investigator:
Protocol Title:
Protocol Number:
Date of Adverse Event(s):

Description of the adverse event(s):

Document IRB's acknowledgement of receipt of the adverse event report(s) and discussion. Discussion of serious adverse events occurring on an NIH protocol should include immediate actions taken as a result of the event by the PI; recommendations for further actions, if any, by the IRB (e.g., suspension of subject accrual, etc.), and any necessary recommendations for further reporting (FDA or NIH officials, OHSR, Director CC, etc.).

If the adverse events are reported from non-NIH sites for the IRB's information only, and no action is required on the IRB's part, acknowledgement of the report(s) should be documented.

8. INFORMATION ITEMS

(a) Single Patient Exemption(s)

(b) Other

9. ADJOURNMENT The meeting adjourned at --:-- (a.m./p.m.).