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.).