

**OKLAHOMA STATE UNIVERSITY
CENTER FOR HEALTH SCIENCES
COLLEGE OF OSTEOPATHIC MEDICINE**

**OFFICE OF RESEARCH AND SPONSORED PROGRAMS
INSTITUTIONAL REVIEW BOARD**

APPENDIX H IRB MEETING MINUTES FORMAT

FORMAT FOR ALL OSU-COM IRB MINUTES

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

Minutes of the OSU-COM IRB Meeting Held on (First Wednesday of the month)

Members Present:	_____	(Chair)_____
(indicate who is	_____	_____
a non-scientist,	_____	_____
non-OSU-COM,	_____	_____
affiliated etc.)	_____	_____
	_____	_____
	_____	_____
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 precise or summary:

a. Discussion:

General:

Specific: (include the following headings)

Scientific design (discuss and note that 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 OSU-COM IRB

Protocol Review Standards form.

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

Additional safeguards for vulnerable participants.

Minimization of risks to participants

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. (Follow same format as above for additional new protocols)

C. (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. (List additional expedited actions following above format)

C. (List additional expedited actions following above format)

D. (List additional expedited actions following above format)

5. CONTINUING REVIEWS (coordinator to have the entire protocol file available for reference at the meeting)

A. Principal Investigator:

Protocol Title:

Protocol Number:

Expiration Date:

Protocol Precise 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 OSU-COM IRB)

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

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

C. (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 a 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 participant accrual, etc.), and any necessary recommendations for further reporting (FDA or NIH officials, OHRP, Provost, etc.).

If the adverse events are reported from non-OSU-CHSsites 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.).