Institutional Review Board Minutes

IRB minutes will be forwarded and reviewed by the Medical Executive Committee at Woman's Hospital. The minutes of all IRB meetings shall be in sufficient detail to show:

Location

The minutes will document the location, date, time of the meeting beginning, and time of adjournment. The minutes from the previous meeting will be acknowledged. Any conflicts of interest will be requested for disclosure at this time.

Attendance at meetings, including:

- When a member leaves the room
- When a member absents themselves during the vote and leaves the room due to a conflict of interest;
- Initial and continued presence of a majority of members and continued documentation of a quorum, including at least one nonscientist member, nursing member (when nursing studies are presented for review), and a physician (for FDA-regulated studies). Any loss of a quorum will be documented.
- Any guests and administrative staff present
- Documentation of a quorum or loss of a quorum

At a meeting in which a member participates via telephone conference call, minutes must document that each participating IRB member has received all pertinent material prior to the meeting and can actively and equally participate in the discussion of all proposals.

Selection of the Adverse Event subcommittee:

The IRB Chair will announce the IRB members who are to serve as the Adverse Events Subcommittee for the coming month. Subcommittee members are chosen on a rotating basis.

Announcements and Education

A citation of the educational article(s) presented at the meeting will be included in the minutes, as well as a written summary of any announcements.

Actions taken by the IRB

Voting may be done by show of hand or verbal communication and will be recorded by the IRB Secretary.

Documentation of the vote on these actions, including the number of members voting for, against, and abstaining. In order to document the continued existence of a quorum, votes should be recorded in the minutes using the following format: Total Present = 11, Vote: For-10,

Opposed-0, Abstained –1 (NAME).

Minutes will also reflect when an alternate member acts for an absent primary member and for whom he/she is voting.

Revisions and disapprovals

The basis for requesting revisions to a research proposal or the disapproval of a research proposal will be documented in the minutes. Any revisions requested by the board will also document how the submitted revisions will be deemed satisfactory (such as review and approval by the IRB Chair).

Consultants

The minutes will document any consideration of comments from consultants, either written or presented at the meeting, and a brief discussion of the consultant's expertise. The minutes will also include documentation that that the consultant did not vote.

Initial review

The minutes will record the IRB's assessment of risk for all initial study reviews (minimum risk, moderate risk, high risk). The determination of the frequency of continuing review will be assessed and documented. The minutes will include a written summary of the discussion of any controverted issues and their resolution.

Continuing review determinations

The minutes of IRB meetings should clearly reflect the IRB's determination regarding which proposals require continuing review more often than annually, as appropriate to the degree of risk, and the approval period (review interval). Any discussion of a change in risk level will be documented. An assessment of the consent form and a determination that all requirements are met will also be documented. The minutes will include a written summary of the discussion of any controverted issues and their resolution.

Specific Findings

When specific findings on the part of the IRB are required, these findings shall be fully documented in the minutes and will include protocol-specific information justifying each IRB finding. For example:

> *Alteration or Waiver of Informed Consent*: When approving an alteration or waiver for the requirement of obtaining a signed informed consent form, the minutes will document that the IRB made the findings required by 45CFR46.116 (d) and 45CFR46.117(c).
> Waiver of Documentation of Informed Consent: When approving a waiver for the requirement of obtaining a signed consent form the minutes shall document that the IRB made the findings required by 45CFR46.117 (c).

Alteration or Waiver of Authorization: When approving an alteration or waiver of the requirement of obtaining authorization, the minutes will document the justification for the alteration or waiver as required by 45CFR164.512(i).

Documentation of decisions

The minutes should document decisions requiring continuing review or full board review in circumstances when such review is not required. The regulations do not prohibit applying standards that exceed those in the regulations, if the institution chooses to do so.

Research Involving Pregnant Women, Children, and Neonates

When approving research involving children, the minutes will document that the IRB made the findings required in 21CFR50.50 – 56 and 45CFR46.404 – 407, if applicable. When reviewing research involving children who are wards of the state or any other agency, institution, or entity, the IRB must find and document in the minutes that such research is:
1. related to their status as wards; **OR**
2. conducted in schools, camps, hospitals, institutions, or similar settings
in which the majority of children involved as subjects are not wards.

The minutes will document findings required in 45CFR46 Subpart B for any research involving pregnant women, fetuses, or neonates and Subpart D for research involving children.

Investigational New Drug Studies

All IND and IND exempt research reviewed at convened meetings will document any IRB determinations of exemption criteria.

Investigational Device Studies

All Investigational Device research reviewed at convened meetings will document any IRB determinations of exemption criteria. All SR/NSR determinations by the IRB will be documented in the minutes

Adverse Events / Unanticipated Problems / Protocol Deviations

Documentation that the IRB reviewed adverse events, unanticipated problems, and protocol deviations are recorded in the minutes for each meeting. Any discussion of a change in risk level and requested changes to the study will be documented.

Allegations of Serious or Continuing Noncompliance

The deliberations and determinations of the IRB regarding any allegations of serious or continuing noncompliance will be documented.

Confidentiality

The IRB minutes are not considered confidential by federal regulations and could be subject to inspection by the FDA. The IRB minutes will be accessible for viewing by anyone making the request; however, any information deemed confidential may be redacted by the IRB Chair. Requests to review IRB minutes should be submitted in writing, unless requested by a federal agency.

DATE	REVISIONS
2/7/2022	Added inclusion of IND, IDE, and Noncompliance determinations