DUKE UNIVERSITY HEALTH SYSTEM
Human Research Protection Program

THE PREPARATION, RECORDING AND FINALIZATION OF IRB MEETING MINUTES

11/20/2023

This document is meant to serve as guidance for the preparation, recording, and finalization of minutes for convened meetings of the Duke University Health System Institutional Review Board (DUHS IRB).

Preparation for Meeting

- At least one week prior to a scheduled IRB meeting, the agenda and protocols will be available to the assigned Writer for the meeting.
- The Writer or designee will begin to prepare the minutes for the meeting using the IRB Minutes Template format.
- The minutes template will have completed headers and completed summaries for all agenda items prior to the beginning of the IRB meeting.
- The Writer, at their discretion, may cut and paste into the template reviews received from the Primary Reviewers for the meeting.

Recording Minutes During the Meeting

- The Writer will note the time that quorum was declared by the Chair. The Writer will note that the Chair asked if any member has a conflict of interest with any of the agenda items. The names of IRB members in attendance will be documented on the voting log.
- The Writer will record: (i) a brief description of the educational presentation; (ii) visitor names and positions at Duke and/or reason for attending; new IRB members attending their first and second observations; conflict of interests with any protocols on the agenda as duly noted by members; and (iii) acceptance of prior month minutes.
- The Writer will use their best efforts to record all relevant discussion points in the "Discussion" section of the minutes template for each agenda item. This includes full documentation of controverted issues raised and their resolutions. In the event that no controverted issues are discussed by the convened IRB, the minutes shall contain a statement as such.
- The Writer will record all actions taken by the IRB, and help ensure that a separate vote is taken for each action.

- The Writer will record the basis for requiring changes in research, and/or of disapproving research.

- The Writer will record the Board's justification for any deletion or substantive modification of information concerning risks or alternative procedures contained in the consent document(s).

- Unless included in the application, or in the Primary Reviewer Checklist and filed with the protocol's supporting documents, the Writer will record the determinations required by regulations and protocol-specific findings justifying those determinations for:

    - Waiver or alteration of the consent process
    - Approval of research involving a child
    - Approval of research involving an imprisoned person
    - Approval of research involving a pregnant person, fetus, or neonate
    - Approval of research involving subjects with diminished capacity.

- The Writer will record the name of any consultants invited to attend the meeting, and will record a summary of the remarks of the consultant.

- The Writer will record the meeting completion time in the appropriate section of the minutes template.

- If, at any time, a member announces a conflict with an agenda item and leaves the room, this shall be noted in the minutes, including the name of the person, and that the person's conflicting interest prompted the person's departure. If an agenda item is discussed, and the discussion is temporarily stopped while the Primary Reviewer leaves to consult with the research team, the Writer will note this in the minutes.

- The minutes will document, for initial and continuing reviews, the degree of risk and the approval period (review interval), to reflect the determination of which protocols require continuing review more often than annually, as appropriate to the degree of risk.

- The minutes will document the rationale for IDE determinations and associated Significant Risk/Non-significant Risk device determinations, as appropriate, and subsequent approval or disapproval decisions for the clinical investigation.

- In addition, the minutes or associated review documentation will document IND determinations, pediatric risk determinations, and the appropriateness of inclusion of certain vulnerable populations in the research.

Post-Meeting Finalization of Minutes

- Within 21 days post-meeting, the Writer will finalize the draft minutes. The final draft of the minutes will include the finalized voting log, which will provide sufficient information about the members entering and leaving the meeting to allow reconstruction of who was present for each vote, but not how individual members voted. The voting log will document the vote for each protocol as numbers for, against, or abstaining.

- If a protocol that was voted "approve" (without modifications) at the meeting is later found to require minor administrative changes (e.g., a minor change to standard language in the consent form, or an ethics credentialing requirement), the minutes and Voting Log will reflect the vote for approval, but the IRB Specialist or Writer will send a request for completion of the change to the study team in iRIS using the modification process. The approval letter will be withheld until the study team completes the administrative change.

- If the needed post-meeting changes are other than simple administrative changes, the IRB Staff will make a note to the Chair/Vice Chair so that when they review the protocol for final approval, the changes must be determined either to be minor and treated as described above in this paragraph, or to be not minor and therefore requiring reconsideration by the convened IRB.

- Within 21 days post-meeting, the Writer will send the draft minutes to the Chairs and attending IRB members for review and comment. Attending members and the Chairs will have 1 week to return comments to the Writer. The Writer must receive comments by 5 pm on Monday for a Wednesday IRB meeting, and by 5 pm on Tuesday for a Thursday IRB meeting.

- The Writer will incorporate the relevant comments and upload the final version in iRIS prior to the meeting at which they will be presented for a vote. In the event of disagreement between a member and the Writer, the Chair will make the final decision with input from the Writer and/or member as needed.

- The final version of the minutes will be presented for a vote of acceptance at the same IRB at its next scheduled meeting. Ordinarily this will be no later than one month from the date of record for those minutes. Exceptions to this may be for: 1) an IRB whose meeting schedule is affected by a holiday, or by inclement weather, such that its next regularly scheduled meeting will occur in two months, or 2) for the Rapid Response IRB when that IRB is not scheduled for another meeting within the next two months. In the latter case, those minutes will be reviewed at the meeting of any regularly scheduled IRB at which at least two members who attended that Rapid Response IRB meeting are in attendance.

- After the vote of acceptance has been obtained, the final version of the minutes will be signed by the presiding Chair (or Vice Chair, if the Chair is unavailable for signature) within 3 business days.

- Quality checks of finalized minutes will be made by an IRB Compliance Specialist or designee with report to the Executive Director. These quality checks include verifying the accuracy of headers, checking for required language, reading for comprehension, verifying that the voting log has been correctly attached, and performing other quality checks as directed by the Executive Director.

- If a significant error is found during the quality checks, the issue is brought to the Chair's attention, and correction to the minutes is made in order to reflect concordance with the supporting documents. The corrected minutes are reviewed and signed by the Chair and scanned and placed on the IRB's shared (S://) drive. If only minor editorial corrections are made during the quality checks, the minutes are corrected, scanned and placed on the IRB's shared (S://) drive.

- The minutes will then be scanned, converted to PDF format and placed on the IRB's shared (S://) drive. The signed hardcopy will be placed in the Meeting notebook for that IRB in the workroom or stored electronically on the IRB's shared drive.

REFERENCES

45 CFR 46.115
21 CFR 56.115

Previous Version Date(s): 10/14/2008, 1/30/2009, 6/4/2011, 3/7/2016, 7/15/2021