



THE PREPARATION, RECORDING AND FINALIZATION OF IRB MEETING MINUTES

10/14/2008

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 will begin to prepare the minutes for the meeting using the format of the IRB Minutes Template.
- 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 his/her discretion, may cut and paste into the template from reviews received from the Primary Reviewers for the meeting.

Recording Minutes During the Meeting

- The Writer will enter and confirm all meeting attendees in the appropriate section of the minutes template. The Writer will note the time that quorum was declared by the Chair.
- The Writer will record when an alternate member replaces a primary member.
- The Writer will record: (i) a brief description of the educational presentation; (ii) visitor names and positions at Duke and/or reason for attending; and (iii) the time that protocol reviews began.
- The Writer will use his/her 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 resolution. 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), including the DHHS-approved sample consent document.
- The Writer will record the determinations required by regulations and protocol-specific findings justifying those determinations for:
 - Waiver or alteration of the consent process (unless included in the Primary Reviewer Checklist and filed with the protocol's supporting documents)
 - Approval of research involving a child
 - Approval of research involving a prisoner
 - Approval of research involving a pregnant woman, fetuses, or neonates.
- 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 time of departure of the Primary Reviewer shall be noted in the minutes along with the time that the discussion for this item was resumed.
- The minutes, together with the Voting Log, 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 minutes will document the vote for each protocol as numbers for, against, or abstaining.
- 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 Significant Risk/Nonsignificant Risk device determinations and subsequent approval or disapproval decisions for the clinical investigation.

Post-Meeting Finalization of Minutes

- Within three business days of the meeting, the Writer will add all required template language and vote totals to the minutes. The Writer will also use the submitted Primary Reviewer checklists to complete the list of modifications required for each agenda item. Within 10 business days of the meeting, the Writer will finalize the Discussion sections of the minutes.
- If a protocol that was voted "approved without modifications" at the meeting is later found to require minor administrative changes (for example, a minor change to standard language in the consent form), the Writer would list the modifications, change the vote to "approve with modifications" and indicate this change in approval status in the minutes. If the post-meeting changes are more than simply administrative, the writer makes a note to Chair so that when he/she reviews the protocol for final approval, the changes are determined either to be minor and are edited for approval, or to be not minor and therefore requiring reconsideration by the convened IRB.
- By the end of the 10th business day post-meeting, the Writer will send the draft minutes to the Chair and attending IRB members for review and comment. Attending members will have 1 week to return comments to the Writer.
- Within 3 business days of receiving members' comments to the draft minutes document, the Writer will incorporate the relevant comments and forward the final draft to the Chair. In the event of disagreement between a member and the Writer, the member, Writer and Chair will discuss and come to a resolution.
- The final version of the minutes will be presented for acceptance at the same IRB no later than one month from its date of record.
- After the vote of acceptance has been obtained, the final version of the minutes will be printed on departmental letterhead, signed by the presiding Chair, and placed in the hardcopy Meeting notebook for that IRB in the workroom. This action will occur within 3 business days after the meeting at which the minutes were accepted.
- The Writer will check off the minutes on the table on the front inner cover of the notebook log. After this action, the minutes will be considered finalized.
- A copy of the approved minutes is provided to the Associate Dean for Research Support Services (ADRSS) and the Institutional Official (IO), in fulfillment of the regulatory requirement to communicate the IRB's findings and actions to the institution in writing (45 CFR 46.103(b)(4)(i)). The ADRSS meets biweekly with the IO to discuss IRB findings and actions.
- Quarterly quality checks of finalized minutes will be made by an IRB Compliance Specialist with report to the Executive Director. These quality checks shall verify the accuracy of headers, vote counts, votes and standard language for each agenda item.

REFERENCES

45 CFR 46.115(a)(2)

21 CFR 56.115(a)(2)