



CHECKLIST: Minutes Quality Improvement Assessment

NUMBER

12.107 (HRP-431)

DATE

04.04.2024

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The purpose of this checklist is to support HRPP Quality Assurance and Evaluation (QA&E) Team efforts to conduct quality assurance audits of IRB minutes.

IRB Number

Meeting Date

Name of Audit Analyst Completing
Checklist

Date Completed

1 General Minutes Requirements:

☐ Yes ☐ No

Does "Attendance" Table record each voting member (regular members and alternates) and all other attendees present at the meeting at any time?

☐ Yes ☐ No

Does the "Attendance Table" record each member's name and all other attendees?

☐ Yes ☐ No

Does the "Attendance Table" record which members were chairs or vice chairs?

☐ Yes ☐ No

Does the "Attendance Table" record each member's status as a scientific member or non-scientific member?

☐ Yes ☐ No

Does the "Attendance Table" record the presence of a non-scientific member to satisfy quorum?

☐ Yes ☐ No

When a member is a representative of a vulnerable population, does the "Attendance Table" record that member's representative capacity (e.g. *Prisoners, children, cognitively impaired adults, other*) [This information is captured in the Member Profile, and can be verified there.].

☐ Yes ☐ No ☐ N/A

Does the "Attendance Table" record for each alternate member the name of IRB member for whom alternate is substituting. ("N/A" if no alternate members are substituting for an IRB member) .

☐ Yes ☐ No

Does the "Attendance Table" record whether any members were present by tele- or video-conference and if so indicate them by name?

☐ Yes ☐ No

Do the minutes record the total number of members present on the current IRB roster?

☐ Yes ☐ No

Do the minutes correctly record the number of members required for a quorum? (*Divide the number of members by two and select the next whole number. For example, if there are 10 IRB members on the roster, then $10/2 = 5$ and the next whole number is 6. If there 11 IRB members on the roster, then $11/2=5.5$ and the next whole number is 6.*)

Attendance info to be
listed

☐ Yes ☐ No ☐ N/A

Do the minutes indicate whether members present by tele- or video-conference received all pertinent material before the meeting and were able to actively and equally participate in all discussions? ("N/A" if no members were present by tele- or video-conference) [45 CFR 46.108b].

☐ Yes ☐ No

Do the minutes record the meeting start time?

☐ Yes ☐ No

Do the minutes record the meeting end time?

☐ Yes ☐ No

Do the minutes record a summary of each business item that was discussed?

☐ Yes ☐ No

Do the minutes reflect IRB member comments in ways that do not reveal individual member's identities.

2 Requirements for Each Protocol Reviewed:

☐ Yes ☐ No

Do the minutes record a protocol ID?

☐ Yes ☐ No

Do the minutes record a protocol title?

☐ Yes ☐ No

Do the minutes record an investigator name?

☐ Yes ☐ No ☐ N/A

Do the minutes record a type of review as either initial review, continuing review, or review of modifications to previously approved research?

☐ Yes ☐ No ☐ N/A

Do the minutes list the names of IRB members who were excused or recused? ("N/A" if no members were excused or recused.

☐ Yes ☐ No

Does the "Attendance Table" record each member's status as a non-affiliated member or affiliated member?

☐ Yes ☐ No ☐ N/A

If the minutes record a consultant report, does it summarize the key information provided by the consultant. ("N/A" if there were no consultant reports).

☐ Yes ☐ No ☐ N/A

Do the minutes record controverted issues (when the IRB members express a difference of opinion among themselves)? ("N/A" if there were no controverted issues.)

☐ Yes ☐ No ☐ N/A

If the minutes record controverted issues, do the minutes summarize the controverted issues and their resolution? ("N/A" if there were no controverted issues) [45 CFR 46.115(a)(2); 21 CFR 56.115(a)(2)]



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<input type="checkbox"/> Yes <input type="checkbox"/> No	Do the minutes record a motion as one of the following: Approved, Approved with Conditions or Stipulations, Deferred/Tabled, Disapproved?
<input type="checkbox"/> Yes <input type="checkbox"/> No	For initial or continuing review do the minutes record the period of approval for the motion?
<input type="checkbox"/> Yes <input type="checkbox"/> No	Do the minutes record the vote as the number of members for, against, abstaining, excused, or recused?
<input type="checkbox"/> Yes <input type="checkbox"/> No	When an alternate member substitutes for a primary member, do the minutes identify the name of the primary member for whom the alternate member is substituting?
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	If both a regular IRB member and the alternate IRB member are present at the meeting do the minutes record the vote of just one? (" N/A " if both a regular IRB member and the alternate IRB member were not present at the meeting).
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	If both a regular IRB member and the alternate IRB member are present at the meeting do the minutes indicate which voted? (" N/A " if both a regular IRB member and the alternate IRB member were not present at the meeting).
<input type="checkbox"/> Yes <input type="checkbox"/> No	Is the sum total of the number of members for, against, abstaining, absent, or recused constant among votes and equal to the number of people listed in the attendance table?
<input type="checkbox"/> Yes <input type="checkbox"/> No	Do minutes document the level of risk determined by the convened IRB as either <u>Minimal Risk</u> or Minor Increase of Minimal Risk or Greater than <u>Minimal Risk</u> ?
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	If the research involves waiver or alteration of consent, waiver of written documentation of consent, children, pregnant women, neonates, prisoners, or cognitively impaired adults do the minutes either state the applicable checklist determinations or state that the completed applicable checklist(s) is found in eIRB+. (" N/A " if the research did not involve completion of checklist(s)).
<input type="checkbox"/> Yes <input type="checkbox"/> No	Do the minutes reflect that the criteria for approval were reviewed?
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	Are applicable completed checklist(s) found in the appropriate e-IRB workspace? (" N/A " if the research did not require completion of a checklist(s)).
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	Do minutes justify any deletion or substantive modification of information concerning risks or alternative procedures contained in the proposed informed consent form? (" N/A " if deletion/modification of information to required informational elements in the consent document were proposed or if a consent form was not reviewed).
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	Do minutes document the rationale for a significant/non-significant device determination? (" N/A " if abbreviated IDE devices were not reviewed).
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	When minutes document modifications required to secure approval do the minutes include a reason (basis) for each modification? (" N/A " if there were no modifications required to secure approval).
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	When minutes document modifications required to secure approval, do the minutes describe the required modifications in such a way that an IRB staff member can determine whether an investigator has made the required changes without judging whether a change meets the regulatory criteria for approval? (" N/A " if there were no modifications required to secure approval or when IRB required convened board re-review).
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	If a protocol was tabled, do the minutes indicate this and provide the reason for tabling? (" N/A " if there were no tabled protocols).
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	If a protocol was deferred or disapproved do the minutes document the reasons? (" N/A " if there were no deferred or disapproved protocols).
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	If a protocol was deferred do the minutes document recommended changes? (" N/A " if there were no deferred or disapproved protocols).
3 Requirements for Each Reportable Event (Reportable New Information) Reviewed (<input type="checkbox"/> N/A if no problems were reviewed)	
<input type="checkbox"/> Yes <input type="checkbox"/> No	Do the minutes describe the Reportable Event?
<input type="checkbox"/> Yes <input type="checkbox"/> No	Do the minutes describe whether the Reportable Event was serious or continuing non-compliance, an <u>Unanticipated Problem Involving Risks to Subjects or Others</u> , or a <u>Suspension of IRB Approval</u> or <u>Termination of IRB Approval</u> ?
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	Do the minutes record a protocol ID? (" N/A " if there were no specific protocol involved).
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	Do the minutes record a protocol title? (" N/A " if there were no specific protocol involved).
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	Do the minutes record an investigator name? (" N/A " if there were no specific investigator involved).
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	Do the minutes record controverted issues (when the IRB members express a difference of opinion among themselves)? (Indicate " N/A " if there were no controverted issues).
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	If the minutes record controverted issues do the minutes summarize each controverted issue and their resolution? (" N/A " if there were no controverted issues).
<input type="checkbox"/> Yes <input type="checkbox"/> No	Do the minutes document the motion?



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☐ Yes ☐ No

Do the minutes record the vote as the number of members for, against, abstaining, excused, or recused?

☐ Yes ☐ No

When an alternate member substitutes for a primary member, do the minutes identify the name of the primary member for whom the alternate member is substituting?

☐ Yes ☐ No ☐ N/A

If both a regular IRB member and the alternate IRB member are present at the meeting do the minutes record the vote of just one? (“N/A” if both a regular IRB member and the alternate IRB member were not present at the meeting).

☐ Yes ☐ No ☐ N/A

If both a regular IRB member and the alternate IRB member are present at the meeting do the minutes indicate which voted? (“N/A” if both a regular IRB member and the alternate IRB member were not present at the meeting).

☐ Yes ☐ No

Is the sum total of the number of members for, against, abstaining, absent, or recused constant among votes and equal to the number of people listed in the attendance table?

4 Minutes Efficiency

Indicate the number of days between the meeting and the finalization of the minutes: