



HRP-431 | 1/1/2024

CHECKLIST: Minutes Quality Improvement Assessment

The purpose of this checklist is to allow individuals to conduct a quality improvement self-assessment of IRB minutes.

Minutes Information

Minutes Information	Response
Meeting Date	Click or tap here to enter text.
Name of Person Completing Checklist	Click or tap here to enter text.
Date Completed	Click or tap here to enter text.

1. General Minutes Requirements

Response	Requirement
<input type="checkbox"/> Yes <input type="checkbox"/> No	Does the "Attendance Table" record each voting member (regular members and alternates) present at the meeting at any time?
<input type="checkbox"/> Yes <input type="checkbox"/> No	Does the "Attendance Table" and/or specific minutes record any member in attendance who did not vote at any time?
<input type="checkbox"/> Yes <input type="checkbox"/> No	Does the "Attendance Table" record each member's name?
<input type="checkbox"/> Yes <input type="checkbox"/> No	Does the "Attendance Table" record which members were chairs of the convened meeting?
<input type="checkbox"/> Yes <input type="checkbox"/> No	Does the "Attendance Table" record each member's status as an unaffiliated member or affiliated member? ⁱ OR, does the IRB Roster attached to the minutes include this information?
<input type="checkbox"/> Yes <input type="checkbox"/> No	Does the "Attendance Table" record each member's status as a scientific member or non-scientific member? OR, does the IRB Roster attached to the minutes include this information?
<input type="checkbox"/> Yes <input type="checkbox"/> No	When a member is a representative of a vulnerable population, does the "Attendance Table" record that member's representative capacity? (Prisoners, children, cognitively impaired adults) OR, does the IRB Roster attached to the minutes include this information?
<input type="checkbox"/> Yes <input type="checkbox"/> No	Does the "Attendance Table" record for each alternate member the name of IRB member for whom alternate is substituting.
<input type="checkbox"/> Yes <input type="checkbox"/> No	Does the "Attendance Table" record whether all attendees were present by teleconference?
<input type="checkbox"/> Yes <input type="checkbox"/> No	Do the minutes indicate the members present on the current IRB roster excluding alternate IRB members?
<input type="checkbox"/> Yes <input type="checkbox"/> 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.)
<input type="checkbox"/> Yes <input type="checkbox"/> No	Do the minutes indicate whether members present by teleconference received all pertinent material before the meeting and were able to actively and equally participate in all discussions?
<input type="checkbox"/> Yes <input type="checkbox"/> No	Do the minutes record the meeting start time?
<input type="checkbox"/> Yes <input type="checkbox"/> No	Do the minutes record the meeting end time?
<input type="checkbox"/> Yes <input type="checkbox"/> No	Do the minutes record a summary of each business item that was discussed?

2. Requirements for Each Protocol Reviewed

Response	Requirement
<input type="checkbox"/> Yes <input type="checkbox"/> No	Do the minutes record a protocol ID?
<input type="checkbox"/> Yes <input type="checkbox"/> No	Do the minutes record a protocol title?
<input type="checkbox"/> Yes <input type="checkbox"/> No	Do the minutes record an investigator name?
<input type="checkbox"/> Yes <input type="checkbox"/> No	Do the minutes record a type of review as either initial review, continuing review, or review of modifications to previously approved research?
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA	If the minutes record a consultant report, does it summarize the key information provided the consultant. (NA if there were no consultant reports)
<input type="checkbox"/> Yes <input type="checkbox"/> No	Do the minutes record controverted issues (when the IRB members express a difference of opinion among themselves) or indicate None?
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA	If the minutes record controverted issues, does what is recorded qualify as a "Controverted Issue" and "Resolution"? (NA if there were no controverted issues)
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA	If the minutes record controverted issues does the information sufficiently describe the controverted issue? (NA if there were no controverted issues)
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA	If the minutes record controverted issues does the Controverted Issue include a resolution or a statement that there was no resolution? (NA if there were no controverted issues)
<input type="checkbox"/> Yes <input type="checkbox"/> No	Do the minutes record a motion as one of the following: Approved, Contingent Approval, Deferred, Disapproved?
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA	For initial or continuing review do the minutes record the period of approval for the motion?
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA	Do the minutes record the vote as the number of members for, against, or abstaining?
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA	Do the minutes list the names of IRB members who were absent or recused?
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA	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? (NA 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"/> NA	If both a regular IRB member and the alternate IRB member are present at the meeting do the minutes indicate which voted? (NA 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, or abstaining, absent and/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 Minimal Risk or greater than Minimal Risk?
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA	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 include determinations and protocol specific findings? (NA if no research requiring documented findings was reviewed)

<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA	If the research involves waiver or alteration of consent, waiver of written documentation of consent, children, pregnant women, neonates, prisoners, or cognitively impaired adults, is the corresponding completed checklist(s) in the IRB records? (NA if no research requiring documented findings was reviewed)
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA	Do minutes justify any deletion or substantive modification of information concerning risks or alternative procedures contained in the DHHS-approved sample consent document? (NA if a DHHS-approved sample consent form was not reviewed)
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA	Do minutes document the rationale for a significant/non-significant device determination? (NA if abbreviated IDE devices were not reviewed.)
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA	Do minutes document modifications required to secure approval, and if so are the modifications described in the minutes? (NA if there were no modifications required to secure approval)
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA	When minutes document modifications required to secure approval does the description include a reason (basis) for each modification? (NA if there were no modifications required to secure approval)
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA	When minutes document modifications required to secure approval are the required modifications described 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? (NA if there were no modifications required to secure approval)
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA	If a protocol was tabled, do the minutes indicate this and provide the reason for tabling? (NA if there were no tabled protocols)
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA	If a protocol was deferred or disapproved do the minute document the reasons? (NA if there were no deferred or disapproved protocols)
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA	If a protocol was deferred do the minutes document recommended changes? (NA if there were no deferred or disapproved protocols)

3. Requirements for Each Problem Reviewed (NA if no problems were reviewed)

Response	Requirement
<input type="checkbox"/> Yes <input type="checkbox"/> No	Do the minutes describe the problem?
<input type="checkbox"/> Yes <input type="checkbox"/> No	Do the minutes describe whether the problem was serious or continuing non-compliance, an Unanticipated Problem Involving Risks to Subjects or Others, or a Suspension of IRB Approval or Termination of IRB Approval?
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA	Do the minutes record a protocol ID? (NA if there were no specific protocol involved)
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA	Do the minutes record a protocol title? (NA if there were no specific protocol involved)
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA	Do the minutes record an investigator name? (NA if there were no specific investigator involved)
<input type="checkbox"/> Yes <input type="checkbox"/> No	Do the minutes record controverted issues (when the IRB members express a difference of opinion among themselves) and their resolution or indicate None?
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA	If the minutes record controverted issues, does what is recorded qualify as a "Controverted Issue" and "Resolution"? (NA if there were no controverted issues)
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA	If the minutes record controverted issues does the information sufficiently describe the controverted issue? (NA if there were no controverted issues)
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA	If the minutes record controverted issues does the Controverted Issue include a resolution or a statement that there was no resolution? (NA if there were no controverted issues)
<input type="checkbox"/> Yes <input type="checkbox"/> No	Do the minutes document the motion?
<input type="checkbox"/> Yes <input type="checkbox"/> No	Do the minutes record the vote as the number of members for, against, or abstaining?
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA	Do the minutes list the names of IRB members who were absent or recused?

<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA	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? (NA 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"/> NA	If both a regular IRB member and the alternate IRB member are present at the meeting do the minutes indicate which voted? (NA 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, or abstaining, absent and/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: [Click or tap here to enter text.](#)

ⁱ For ease of review, OHRP and FDA recommend that attendance information be listed at the beginning of the minutes and include the full name and representative capacity (e.g., scientist, nonscientist, unaffiliated) of each IRB member present at the convened meeting. This IRB may choose to append a current IRB membership roster to the minutes to avoid having to repeat certain information (e.g., representative capacity for each IRB member).