

Default Question Block**HRP-431 - CHECKLIST - Minutes Quality Assurance Assessment - Qualtrics Survey**

Welcome to the Audit Tool Checklist - Minutes Quality Improvement Assessment. The purpose of this online toolkit is to allow individuals to conduct a quality improvement assessment of IRB meeting minutes. If you have general questions about the Audit Tool Checklist, please discuss with your manager or contact the compliance team.

Choose the quarter in which the submission was reviewed and approved:

- Q1 (September - November)
- Q2 (December - February)
- Q3 (March - May)
- Q4 (June - August)

Please provide the following information about the minutes being reviewed:

Panel:

Meeting date:

Name of person that authored the meeting minutes

Date meeting minutes were finalized:

Name of person completing audit review:

Date audit review was completed:

General Minutes Requirements - Did the minutes include the following? **(Check if yes; all are required unless otherwise noted)**

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

- Yes
 No

Does the "Attendance Table" record each member's name?

- 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 an unaffiliated member or affiliated member?

- Yes

No

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

Yes

No

Does the "Attendance Table" record for each alternate member the name of IRB member for whom the alternate is substituting? (If an alternate member did not substitute for an IRB member, select N/A)

Yes

No

N/A

Does the "Attendance Table" record whether any members were present by teleconference and if so indicate them by name?

Yes

No

N/A

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

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 are 11 IRB members on the roster, then $11/2 = 5.5$ and the next whole number is 6.*)

- 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 submission that was discussed?

- Yes
- No

Comments: (include any noted trends, areas of concern, etc.)

Requirements for Each Protocol Reviewed - Do the minutes include the following? **(Check if yes; all are required unless otherwise noted)**

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

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

If the minutes record a consultant report, does it summarize the key information provided by the consultant?

- Yes
 No

Do the minutes record controverted issues (when the IRB members express a difference of opinion among themselves) and their resolution (or lack of a resolution)?

- Yes
- No

If the minutes record controverted issues does the "Controverted Issue/Resolution" section include a resolution or statement that there was no resolution?

- Yes
- No
- N/A

Do the minutes record a motion as one of the following: Approved, Approved with Modifications, Deferred, or Disapproved?

- Yes
- No

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

- Yes
- No

Do the minutes list the names of IRB members who were absent or recused during the vote?

- 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?

Yes

No

N/A

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"?

Yes

No

Do the minutes document the level of risk determined by the convened IRB as either minimal risk or more than minimal risk?

Yes

No

If the research involves waiver or alteration of consent, waiver of written documentation of consent, children, pregnant women, pregnant women, neonates, prisoners, or cognitively impaired adults do the minutes describe these study aspects?

Yes

No

N/A

If the minutes refer to a checklist is/are the corresponding completed checklist(s) in the IRB records?

- Yes
- No
- N/A

Do the minutes justify any deletion or substantive modification of information concerning risks or alternative procedures contained in the DHHS-approved sample consent document?

- Yes
- No
- N/A

Do the minutes document the rationale for a significant/non-significant device determination?

- Yes
- No
- N/A

Do the minutes document modifications required to secure approval?

- Yes
- No
- N/A

When minutes document modifications required to secure approval is there a reason (basis) for each modification?

- Yes
- No
- N/A

When minutes document modifications required to secure approval, are they written 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?

- Yes
- No
- N/A

If a protocol was deferred or disapproved, do the minutes indicate this and provide the reason for deferral / disapproval and the recommended changes?

- Yes
- No
- N/A

Comments: (include any noted trends, areas of concern, etc.)

Requirements for each RNI Reviewed

- Check this box if there were no problems reviewed at the meeting

Do the minutes describe the RNI reviewed

- Yes
- No

Do the minutes describe whether the problem was serious non-compliance, continuing non-compliance, an unanticipated problem involving risks to subjects or others, and/or a suspension or termination of IRB approval?

- Yes
- No

Do the minutes record a protocol ID?

- Yes
- No
- No

Do the minutes record a protocol title?

- Yes
- No
- N/A

Do the minutes record an investigator name?

- Yes
- No
- N/A

Do the minutes record controverted issues (when the IRB members express a difference of opinion among themselves) and their resolution or lack of a resolution? (If there were no controverted issues, select N/A)

- Yes
- No
- N/A

Do the minutes document the motion?

- Yes
- No

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

- Yes
- No

Do the minutes list the names of IRB members who were absent or recused?

- 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? (If both a regular IRB member and the alternate IRB member were not present at the meeting, select N/A)

- 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? (If both a regular IRB member and the alternate IRB member were not present at the meeting select N/A)

Yes

No

N/A

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?

Yes

No

Comments: (include any noted trends, areas of concern, etc.)

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