



## CHECKLIST: Minutes Quality Improvement Assessment

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

<b>IRB Number</b>	
<b>Meeting Date</b>	
<b>Name of Person Completing Checklist</b>	
<b>Date Completed</b>	

### 1 General Minutes Requirements

<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" 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 or vice chairs?
<input type="checkbox"/> Yes	<input type="checkbox"/> No	Does the "Attendance Table" record each member's status as an unaffiliated member or affiliated member? 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 vulnerable population, does the "Attendance Table" record that member's representative capacity? ( <i>Prisoners, children, cognitively impaired adults</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 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 any members were present by teleconference and if so indicate them by name?
<input type="checkbox"/> Yes	<input type="checkbox"/> No	Do the minutes record the total number of 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? ( <i>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.</i> )
<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A 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? ("N/A" if no members were present by teleconference)
<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

<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	<input type="checkbox"/> N/A 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	If the minutes record a consultant report, does it summarize the key information provided the consultant. ("N/A" if there were no consultant reports)
<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) and their resolution or indicate "None" or record using the "Controverted Issue/Resolution" table. If there was no resolution, indicate this.
<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A If the minutes record controverted issues is there a "Controverted Issue/Resolution" table? ("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 does the "Controverted Issue/Resolution" table summarize the controverted issue? ("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 does the "Controverted Issue/Resolution" table include a resolution or a statement that there was no resolution? ("N/A" 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, Approved with Modifications, Deferred, Disapproved?



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<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, absent, or recused?	
<input type="checkbox"/> Yes	<input type="checkbox"/> No	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"/> 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 more 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 say “See IRB Records” or include one of more of the “Determination/Protocol Specific Findings” tables in HRP-501 - TEMPLATE - MINUTES? (“N/A” if no research requiring documented findings was reviewed)
<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A	If the minutes say “See IRB records for this protocol” is the corresponding completed checklist(s) in the IRB records? (“N/A” if no research requiring documented findings was reviewed)
<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A	If the minutes include one of more of the “Determination/Protocol Specific Findings” tables, is the table completed? (“N/A” if no research requiring documented findings was reviewed)
<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 DHHS-approved sample consent document? (“N/A” if a DHHS-approved sample 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	Do minutes document modifications required to secure approval? (“N/A” if there were no modifications required to secure approval) Otherwise, include the “Modifications Required to Secure Approval Table” in HRP-501 - TEMPLATE - MINUTES.
<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A	When minutes document modifications required to secure approval is the “Modifications Required to Secure Approval Table” included? (“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 does the “Modifications Required to Secure Approval Table” 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 does the “Modifications Required to Secure Approval Table” 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)
<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 minute 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 minute document recommended changes? (“N/A” if there were no deferred or disapproved protocols)

**3 Requirements for Each Problem Reviewed (  N/A if no problems were reviewed )**

<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 <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) and their resolution or indicate “None” or record using the “Controverted Issue/Resolution” table. If there was no resolution, indicate this.
<input type="checkbox"/> Yes	<input type="checkbox"/> No		If the minutes record controverted issues is there a “Controverted Issue/Resolution” table? (“N/A” if there were no controverted issues)



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<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	If the minutes record controverted issues does the "Controverted Issue/Resolution" table summarize the controverted issue? ("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 does the "Controverted Issue/Resolution" table include a resolution or a statement that there was no resolution? ("N/A" 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, abstaining, absent, or recused?
<input type="checkbox"/> Yes <input type="checkbox"/> No	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"/> 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?

**4 Minutes Efficiency**

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