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The purpose of this worksheet is to provide support for OIA staff performing quality assessment of minutes. This worksheet, or equivalent, must be used. It does not need to be completed or retained.

IRB	<input type="checkbox"/> IRB A <input type="checkbox"/> IRB B <input type="checkbox"/> IRB C <input type="checkbox"/> IRB D <input type="checkbox"/> IRB O/P <input type="checkbox"/> IRB S
Meeting Date	
Name of Person Completing Worksheet	
Name of Person Providing Response	
Date Completed	

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 <input type="checkbox"/> N/A	Was a prisoner representative present? (If no <u>research</u> involving <u>prisoners</u> was reviewed, check N/A)
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	Does the "attendance table" record non-voting members under "attendance table?"
<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?
<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?
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	Does the "attendance table" record for each alternate member the name of IRB member for whom alternate is substituting, if applicable?
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	Does the "attendance table" record whether any members were present by teleconference and if so indicate them by name, if applicable?
<input type="checkbox"/> Yes <input type="checkbox"/> No	Do the minutes record the total number of members present on the current IRB roster, or equivalent, 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, or equivalent, then 10/2 = 5 and the next whole number is 6, so quorum requires 6 members. If there are 11 IRB members on the roster, or equivalent, then 11/2=5.5 and the next whole number is 6, and quorum requires 6 members.</i>)
<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 <input type="checkbox"/> N/A	Do the minutes record a summary of each business item that was discussed?
<input type="checkbox"/> Yes <input type="checkbox"/> No	Are the minutes written for an audience (e.g. inspector/auditor) reviewing for understanding after a meeting has taken place?

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's 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 <u>research</u> ?
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> 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)
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	Do the minutes record <u>controverted issues</u> (when the IRB members express a difference of opinion among themselves) and their resolution? Section should indicate "none" or record using the " <u>controverted issue/resolution</u> section." ("N/A" if there were no <u>controverted issues</u>)
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	If the minutes record <u>controverted issues</u> , is there a " <u>controverted issue/resolution</u> section?" ("N/A" if there were no <u>controverted issues</u>)
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	If the minutes record <u>controverted issues</u> , does the " <u>controverted issue/resolution</u> section" summarize the <u>controverted issue</u> ? ("N/A" if there were no <u>controverted issues</u>)
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	If the minutes record <u>controverted issues</u> , does the " <u>controverted issue/resolution</u> section" include a resolution or a statement that there was no resolution? ("N/A" if there were no <u>controverted issues</u>)
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	For initial, continuing, or modification submissions, do the minutes record a motion as one of the following: approved, approved pending modifications, deferred, disapproved, or no motion was put forward and the

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<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	submission was tabled? For reportable event submissions, do the minutes record a motion as one of the following: Acknowledged, <u>non-compliance</u> , <u>serious and/or continuing non-compliance</u> , <u>unanticipated problem involving risks to subjects or others/unanticipated problem report (UPR)</u> , accept corrective and preventive action (CAPA) plan, <u>non-compliance</u> with no basis in fact, deferred, or no motion was put forward and the submission was tabled?
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	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, other, or recused?
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	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 IRB members were recused due to a <u>conflicting interest</u> , do the minutes state that the recusal was due to a <u>conflicting interest</u> ?
<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 who 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, other, or recused constant among votes and equal to the number of people listed as voting 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 greater than <u>minimal risk</u> ? (Deferred or tabled studies may list the level of risk as "to be determined" if the convened IRB is unable to make a risk determination.)
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	Do the minutes document whether the criteria for approval have been met? (" N/A " if the submission is a reportable event and/or the protocol was deferred)
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	If the PI discloses a <u>related financial interest</u> , do the minutes document whether the <u>conflict of interest</u> committee <u>management plan</u> was reviewed and accepted? (" N/A " if the submission is a reportable event, the <u>COI</u> committee <u>management plan</u> was previously reviewed and accepted, and/or the protocol was deferred)
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	If the <u>research</u> involves waiver or alteration of consent, full or partial waiver of <u>HIPAA</u> authorization, waiver of written documentation of consent, <u>children</u> , pregnant subjects, neonates, <u>prisoners</u> , or cognitively impaired adults, do the minutes or the checklist(s) indicate the criteria are met and the reasons they are met (i.e., there must be documentation explaining the reasons for the determination)?
<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 Department of Health and Human Services (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 an Investigational Device Exemption (IDE) exempt, significant/non-significant risk device, IND exempt determination? (" N/A " if abbreviated IDE, IDE exempt devices, or IND exempt drugs/biologics were not reviewed)
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	When the minutes document modifications required to secure approval, does the "modifications required to secure approval section" 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 the minutes document modifications required to secure approval, does the "modifications required to secure approval section" describe the required modifications in such a way that an OIA 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 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)
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	If a protocol was previously reviewed by the IRB and/or <u>designated reviewer</u> and returned for review by the full board, does the narrative make the review history clear?

3 Minutes Efficiency

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