HRP-431 | 3/29/2024

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

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| **Minutes Information** | **Response** |
| **IRB Number** | Click or tap here to enter text. |
| **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

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| **Response** | **Requirement** |
| [ ]  Yes [ ]  No | 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 any individual in attendance who did not vote at any time (under “Other Attendees”)? |
| [ ]  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?[[1]](#endnote-2)  |
| [ ]  Yes [ ]  No | Does the “Attendance Table” record each member’s status as a scientific member or non-scientific member?  |
| [ ]  Yes [ ]  No | When a member is a representative of vulnerable population, does the “Attendance Table” record that member’s representative capacity? (Prisoners, children, cognitively impaired adults) |
| [ ]  Yes [ ]  No | Is there an *HRP-305-Quorum and Expertise* worksheet on file for this meeting confirming there was appropriate expertise on the panel for each submission? |
| [ ]  Yes [ ]  No | Does the “Attendance Table” record for each alternate member the name of IRB member for whom alternate is substituting. |
| [ ]  Yes [ ]  No | Does the “Attendance Table” record whether any members were present by teleconference and if so indicate them by name? |
| [ ]  Yes [ ]  No | 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 11 IRB members on the roster, then 11/2=5.5 and the next whole number is 6.) |
| [ ]  Yes [ ]  No [ ]  NA | 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? (NA if no members were present by teleconference) |
| [ ]  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 as appropriate (See Minutes Template for potential items that may be included)? |
| [ ]  Yes [ ]  No [ ]  NA | Do the minutes record whether members reported any conflicting interests with items on the agenda in the cover sheet? |
| [ ]  Yes [ ]  No [ ]  NA | If a member has a conflict of interest, do the minutes record which study the member recused from, and that the member was not present for the item discussion or vote in the cover sheet? |
| [ ]  Yes [ ]  No [ ]  NA | If a member stepped out of the convened meeting, do the minutes record the absence and what, if any, actions were taken during that time? |
| [ ]  Yes [ ]  No | Do the minutes indicate that a non-scientist member was in attendance during the discussion and voted on all action items on the convened IRB agenda? |

1. Requirements for Each Protocol Reviewed

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| **Response** | **Requirement** |
| [ ]  Yes [ ]  No | Do the minutes record a submission ID? |
| [ ]  Yes [ ]  No | Do the minutes record a submission title? |
| [ ]  Yes [ ]  No | Do the minutes record an investigator name?  |
| [ ]  Yes [ ]  No | Do the minutes record the study funding source and award number or indicate there is no study funding? |
| [ ]  Yes [ ]  No | Do the minutes record a type of review as either initial review, continuing review, report of new information, or review of modifications to previously approved research? |
| [ ]  Yes [ ]  No | Do the minutes record the study safety monitoring plan for initial study and continuing review submissions? |
| [ ]  Yes [ ]  No [ ]  NA | If the minutes record a consultant report, is the consultant report available in the ETHOS record?  |
| [ ]  Yes [ ]  No [ ]  NA | Do the minutes record the type of Scientific Review required for initial studies? |
| [ ]  Yes [ ]  No [ ]  NA | If there was a Scientific Review requirement, do the minutes record whether the IRB accepted the review (see “Notes” section of the Minutes)? |
| [ ]  Yes [ ]  No [ ]  NA | The IRB Analyst documented in the IRB meeting minutes whether a conflict of interest exists, if a management plan was provided, and the committee's discussion as to whether the investigator's relationship to the research could create a bias that might affect the rights and welfare of the human participant or the reliability of the data. This should also be re-assessed at the time of continuing review.  |
| [ ]  Yes [ ]  No [ ]  NA | Do the minutes record controverted issues (when the IRB members express a difference of opinion among themselves)?  |
| [ ]  Yes [ ]  No [ ]  NA | If the minutes record controverted issues does the information sufficiently describe the controverted issue? (NA if there were no controverted issues) |
| [ ]  Yes [ ]  No [ ]  NA | If the minutes record controverted issues do they record a resolution or a statement that there was no resolution? (NA if there were no controverted issues) |
| [ ]  Yes [ ]  No [ ]  NA | Do the minutes record any determinations and findings that require documentation for initial review, or reaffirm for continuing reviews? |
| [ ]  Yes [ ]  No [ ]  NA | For any determinations and findings that require documentation, are the appropriate Checklists included with the minutes or previously uploaded? |
| [ ]  Yes [ ]  No [ ]  NA | For any studies including a vulnerable population, was at least one IRB member present who was knowledgeable about or experienced in working with such participants, or was consultation obtained? |
| [ ]  Yes [ ]  No [ ]  NA | Do the minutes record the last day of the approval period? |
| [ ]  Yes [ ]  No [ ]  NA | Do the minutes record the motion as one of the following: Approved, Modifications Required to Secure Approval, Deferred, Disapproved? |
| [ ]  Yes [ ]  No [ ]  NA | For initial or continuing review do the minutes record rationale for a period of approval that is less than a year? |
| [ ]  Yes [ ]  No [ ]  NA | Do the minutes record RNI determination(s)? |
| [ ]  Yes [ ]  No [ ]  NA | Do the minutes record RNI action(s) required? |
| [ ]  Yes [ ]  No [ ]  NA | Do the minutes record suspension/termination reasons and recommended changes? |
| [ ]  Yes [ ]  No [ ]  NA | Do the minutes record the vote as the number of members for, against, abstaining, absent, or recused? |
| [ ]  Yes [ ]  No [ ]  NA | Do the minutes list the names of IRB members who were absent or recused? |
| [ ]  Yes [ ]  No [ ]  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) |
| [ ]  Yes [ ]  No [ ]  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) |
| [ ]  Yes [ ]  No [ ]  NA | 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 [ ]  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) |
| [ ]  Yes [ ]  No [ ]  NA | Do minutes record the significant/non-significant device determination? (NA if abbreviated IDE devices were not reviewed.) |
| [ ]  Yes [ ]  No [ ]  NA | Do minutes document modifications required to secure approval or that there are no recommended changes for this submission?  |
| [ ]  Yes [ ]  No [ ]  NA | When minutes document modifications required to secure approval, do the minutes identify who will review the study team’s response? |
| [ ]  Yes [ ]  No [ ]  NA | When minutes document modifications required to secure approval do they include a reason for the change? |
| [ ]  Yes [ ]  No [ ]  NA | When minutes document modifications required to secure approval, the minutes do not include any issues that should have precluded IRB approval, per the Guidelines for Assessing Convened IRB Decisions as found in HRP-314-WORKSHEET-Criteria for Approval. |
| [ ]  Yes [ ]  No [ ]  NA | If a protocol was tabled, do the minutes indicate this and provide the reason for tabling? (NA if there were no tabled protocols) |
| [ ]  Yes [ ]  No [ ]  NA | If a protocol was deferred or disapproved do the minute document the reasons? (NA if there were no deferred or disapproved protocols) |
| [ ]  Yes [ ]  No [ ]  NA | If a protocol was deferred do the minute document recommended changes? (NA if there were no deferred or disapproved protocols) |
| [ ]  Yes [ ]  No [ ]  NA | Do the minutes record submission-specific substitutions? (NA if the submission was tabled) |

1. Requirements for Each Report of New Information Reviewed ([ ]  NA if no RNIs were reviewed)

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| **Response** | **Requirement** |
| [ ]  Yes [ ]  No | Do the minutes describe the problem? |
| [ ]  Yes [ ]  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? |
| [ ]  Yes [ ]  No [ ]  NA | Do the minutes record a protocol and submission ID?  |
| [ ]  Yes [ ]  No [ ]  NA | Do the minutes record a protocol and submission title?  |
| [ ]  Yes [ ]  No  | Do the minutes record an investigator name?  |
| [ ]  Yes [ ]  No | Do the minutes record controverted issues (when the IRB members express a difference of opinion among themselves) and their resolution or indicate “None”?  |
| [ ]  Yes [ ]  No [ ]  NA | If the minutes record controverted issues does the information sufficiently describe the controverted issue? (NA if there were no controverted issues) |
| [ ]  Yes [ ]  No [ ]  NA | If the minutes record controverted issues do they include a resolution or a statement that there was no resolution? (NA if there were no controverted issues) |
| [ ]  Yes [ ]  No | Do the minutes record the determination? |
| [ ]  Yes [ ]  No | Do the minutes record the vote as the number of members for, against, abstaining, absent, or recused? |
| [ ]  Yes [ ]  No [ ]  NA | Do the minutes list the names of IRB members who were absent or recused? |
| [ ]  Yes [ ]  No [ ]  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) |
| [ ]  Yes [ ]  No [ ]  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) |
| [ ]  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? |

1. Key Findings

Summarize key findings and, when appropriate, recommended corrective action plan(s): Click or tap here to enter text.

1. Minutes Efficiency

Indicate the number of days between the meeting and the finalization of the minutes: Click or tap here to enter text.

1. 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). [↑](#endnote-ref-2)