WORKSHEET: Minutes Quality Improvement Assessment

The purpose of this worksheet 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 Worksheet** | 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 member in attendance who did not vote 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? [[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, adults with impaired decision-making capacity)  |
| [ ]  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? |

1. Requirements for Each Protocol Reviewed

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| **Response** | **Requirement** |
| [ ]  Yes [ ]  No | 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 [ ]  NA | If the minutes record a consultant report, does it summarize the key information provided the consultant. (NA if there were no consultant reports) |
| [ ]  Yes [ ]  No | Do the minutes record controverted issues (when the IRB members express a difference of opinion among themselves) or indicate “None”? |
| [ ]  Yes [ ]  No [ ]  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) |
| [ ]  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 does the Controverted Issue include a resolution or a statement that there was no resolution? (NA if there were no controverted issues) |
| [ ]  Yes [ ]  No | Do the minutes record a 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 the period of approval for the motion? |
| [ ]  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 | 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 minutes document the level of risk determined by the convened IRB as either Minimal Risk or more than Minimal Risk? |
| [ ]  Yes [ ]  No [ ]  NA | If the research involves waiver or alteration of consent, waiver of written documentation of consent, children, pregnant women, neonates, prisoners, or adults with impaired decision-making capacity 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? (NA if no research requiring documented findings was reviewed) |
| [ ]  Yes [ ]  No [ ]  NA | If the minutes say “See IRB records for this protocol” is the corresponding completed worksheet(s) in the IRB records? (NA if no research requiring documented findings was reviewed) |
| [ ]  Yes [ ]  No [ ]  NA | If the minutes include one of more of the “Determination/Protocol Specific Findings” tables, is the table completed? (NA if no research requiring documented findings was reviewed) |
| [ ]  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 document the rationale for a significant/non-significant device determination? (NA if abbreviated IDE devices were not reviewed.) |
| [ ]  Yes [ ]  No [ ]  NA | Do minutes document modifications required to secure approval? (NA if there were no modifications required to secure approval) Otherwise, include the “Modifications Required to Secure Approval Table” in HRP-501 - TEMPLATE - MINUTES. |
| [ ]  Yes [ ]  No [ ]  NA | When minutes document modifications required to secure approval is the “Modifications Required to Secure Approval Table” included? (NA if there were no modifications required to secure approval) |
| [ ]  Yes [ ]  No [ ]  NA | When minutes document modifications required to secure approval does the “Modifications Required to Secure Approval Table” include a reason (basis) for each modification? (NA if there were no modifications required to secure approval) |
| [ ]  Yes [ ]  No [ ]  NA | 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? (NA if there were no modifications required to secure 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) |

1. Requirements for Each Problem Reviewed (☐ NA if no problems 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 ID? (NA if there was no specific protocol involved) |
| [ ]  Yes [ ]  No [ ]  NA | Do the minutes record a protocol title? (NA if there was no specific protocol involved) |
| [ ]  Yes [ ]  No [ ]  NA | Do the minutes record an investigator name? (NA if there was no specific investigator involved) |
| [ ]  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  | If the minutes record controverted issues, does what is recorded qualify as a “Controverted Issue” and “Resolution”?  |
| [ ]  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 does the “Controverted Issue” include a resolution or a statement that there was no resolution? (NA if there were no controverted issues) |
| [ ]  Yes [ ]  No | 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 [ ]  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. 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)