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| The purpose of this Checklist is to allow individuals to summarize and document findings for quality improvement assessment of IRB minutes. |
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| IRB Number/Letter |       |
| Meeting Date |       |
| Name of Person Completing Checklist |       |
| Date Completed |       |
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| 1. General Minutes Requirements
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| [ ]  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” not record non-voting members under “Attendance Table” |
| [ ]  Yes [ ]  No | Does the “Attendance Table” record each member’s name? |
| [ ]  Yes [ ]  No | Does the “Attendance Table” record which members were Chairs or Acting Chairs? |
| [ ]  Yes [ ]  No | Does the “Attendance Table” record each member’s status as an Affiliated or Nonaffiliated member?  |
| [ ]  Yes [ ]  No | Does the “Attendance Table” record each member’s status as a scientific 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 [ ]  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) |
| [ ]  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 [ ]  N/A | Do the minutes record whether members reported any conflicting interests with items on the agenda in the cover sheet? |
| [ ]  Yes [ ]  No | 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 | 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? |
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| 1. Requirements for Each Protocol Reviewed
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| [ ]  Yes [ ]  No | Do the minutes record an IRB Number? |
| [ ]  Yes [ ]  No | Do the minutes record a title? |
| [ ]  Yes [ ]  No | Do the minutes record an investigator name and responsible party (if RNI)? |
| [ ]  Yes [ ]  No | Do the minutes record the study funding source and award number or indicate there is no study funding? |
| [ ]  Yes [ ]  No [ ]  N/A | Do the minutes record a type of review as Initial Review, Modification, Continuing Review, Report of New Information, Response to Modifications Required, Response to Deferral, or Reactivation? |
| [ ]  Yes [ ]  No [ ]  N/A | Do the minutes record the study safety monitoring plan for initial study submissions? |
| [ ]  Yes [ ]  No [ ]  N/A | If the minutes record a consultant report, is the consultant report available in the ETHOS record? |
| [ ]  Yes [ ]  No [ ]  N/A | Do the minutes record the type of Scientific Review required? |
| [ ]  Yes [ ]  No [ ]  N/A | If there was a Scientific Review requirement, do the minutes record whether the IRB accepted the review? |
| [ ]  Yes [ ]  No [ ]  N/A | 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 [ ]  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. |
| [ ]  Yes [ ]  No [ ]  N/A | If the minutes record controverted issues does the “Controverted Issue/Resolution” table summarize the controverted issue? |
| [ ]  Yes [ ]  No [ ]  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? |
| [ ]  Yes [ ]  No [ ]  N/A | Do the minutes record the study level of risk? For RNI submissions, the minutes include "N/A." 'Unable to Assess Risk' should only be used when an initial study submission is deferred. |
| [ ]  Yes [ ]  No [ ]  N/A | Do the minutes record any determinations and findings that require documentation? |
| [ ]  Yes [ ]  No [ ]  N/A | For any determinations and findings that require documentation, are the appropriate Checklists included with the minutes? |
| [ ]  Yes [ ]  No [ ]  N/A | 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? |
| [ ]  Yes [ ]  No [ ]  N/A | Do the minutes record the rationale for a significant/non-significant device risk device determination? |
| [ ]  Yes [ ]  No [ ]  N/A | For a significant/non-significant risk device determination, is the appropriate Checklist included with the minutes? |
| [ ]  Yes [ ]  No [ ]  N/A | Do the minutes record the last day of the approval period? |
| [ ]  Yes [ ]  No [ ]  N/A | Do the minutes record the motion for Initial Review, Modification, or Continuing Review? |
| [ ]  Yes [ ]  No [ ]  N/A | Do the minutes record modifications required to secure approval or that there are no recommended changes for this submission? |
| [ ]  Yes [ ]  No [ ]  N/A | Do the minutes record deferral/disapproval reasons and recommended changes? |
| [ ]  Yes [ ]  No [ ]  N/A | Do the minutes record RNI determination(s) |
| [ ]  Yes [ ]  No [ ]  N/A | Do the minutes record RNI action(s) required? |
| [ ]  Yes [ ]  No [ ]  N/A | Do the minutes record suspension/termination reasons and recommended changes? |
| [ ]  Yes [ ]  No [ ]  N/A | Do the minutes record the reason the submission was tabled, if applicable? |
| [ ]  Yes [ ]  No [ ]  N/A | Do the minutes record a high-level summary/narrative of any key discussions related to the criteria for approval? |
| [ ]  Yes [ ]  No [ ]  N/A | The minutes do not include any issues that should have precluded IRB approval, per the *Guidelines for Assessing Convened IRB Decisions* document |
| [ ]  Yes [ ]  No [ ]  N/A  | Do the minutes record the vote as the number of members for, against, abstaining, absent, or recused? (“**N/A**” if the submission was tabled) |
| [ ]  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? (“**N/A**” if the submission was tabled) |
| [ ]  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? (“**N/A**” if the submission was tabled) |
| [ ]  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? (“**N/A**” if the submission was tabled) |
| [ ]  Yes [ ]  No [ ]  N/A | Do the minutes record submission-specific substitutions? (“**N/A**” if the submission was tabled) |
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| 1. Key Findings
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| Summarize key findings and, when appropriate, recommended corrective action plan(s):       |
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| 1. Minutes Efficiency
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| Indicate the number of days between the meeting and the finalization of the minutes:       |
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