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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 | | | |
| 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 | | | |
| 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 | | | |
| Summarize key findings and, when appropriate, recommended corrective action plan(s): | | | |
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| 1. Minutes Efficiency | | | |
| Indicate the number of days between the meeting and the finalization of the minutes: | | | |
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