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| The purpose of this checklist is to support HSPP Audit Team efforts to conduct quality assurance audits of IRB minutes. | | |
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| IRB Number | |  |
| Meeting Date | |  |
| Name of Audit Analyst Completing Checklist | |  |
| Date Completed | |  |
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| 1. General Minutes Requirements: | | |
| Yes  No | Does “Attendance” Table record each voting member (regular members and alternates) and all other attendees present at the meeting at any time? | |
| Yes  No | Does the “Attendance Table” record each member’s name and all other attendees? | |
| 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 a scientific member or non-scientific member? | |
| Yes  No | Does the “Attendance Table” record the presence of a non-scientific member to satisfy quorum? | |
| Yes  No | When a member is a representative of a vulnerable population, does the “Attendance Table” record that member’s representative capacity *(e.g. Prisoners, children, cognitively impaired adults, other) [*This information is captured in the Member Profile, and can be verified there.] | |
| Yes  No  N/A | Does the “Attendance Table” record for each alternate member the name of IRB member for whom alternate is substituting. (“**N/A**” if no alternate members are substituting for an IRB member) | |
| Yes  No | Does the “Attendance Table” record whether any members were present by tele- or video-conference and if so indicate them by name? | |
| Yes  No | Do the minutes record the total number of members present on the current IRB roster? | |
| 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.)* | |
| Attendance info to be listed  Yes  No  N/A | Do the minutes indicate whether members present by tele- or video-conference 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 tele- or video-conference) [45 CFR 46.108b] | |
| 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? | |
| Yes  No | Do the minutes reflect IRB member comments in ways that do not reveal individual member’s identities. | |
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| 1. Requirements for Each Protocol Reviewed: | | |
| 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  N/A | Do the minutes record a type of review as either initial review, continuing review, or review of modifications to previously approved research? | |
| Yes  No  N/A | Do the minutes list the names of IRB members who were excused or recused? (“**N/A**” if no members were excused or recused. | |
| Yes  No | Does the “Attendance Table” record each member’s status as a non-affiliated member or affiliated member? | |
| Yes  No  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) | |
| Yes  No  N/A | Do the minutes record controverted issues (when the IRB members express a difference of opinion among themselves)? (“**N/A**” if there were no controverted issues.) | |
| Yes  No  N/A | If the minutes record controverted issues, do the minutes summarize the controverted issues and their resolution? (**“N/A”** if there were no controverted issues) [45 CFR 46.115(a)(2); 21 CFR 56.115(a)(2)] | |
| Yes  No | Do the minutes record a motion as one of the following: Approved, Approved with Conditions or Stipulations, Deferred/Tabled, Disapproved? | |
| Yes  No | For initial or continuing review do the minutes record the period of approval for the motion? | |
| Yes  No | Do the minutes record the vote as the number of members for, against, abstaining, excused, or recused? | |
| Yes  No | When an alternate member substitutes for a primary member, do the minutes identify the name of the primary member for whom the alternate member is substituting? | |
| 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 both a regular IRB member and the alternate IRB member were not present at the meeting) | |
| 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 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 Minor Increase of Minimal Risk or Greater than Minimal Risk? | |
| Yes  No  N/A | If the research involves waiver or alteration of consent, waiver of written documentation of consent, children, pregnant women, neonates, prisoners, or cognitively impaired adults do the minutes either state the applicable checklist determinations or state that the completed applicable checklist(s) is found in e-IRB. (**“N/A”** if the research did not involve completion of checklist(s)) | |
| Yes  No | Do the minutes reflect that the criteria for approval were reviewed? | |
| Yes  No  N/A | Are applicable completed checklist(s) found in the appropriate e-IRB workspace? (**“N/A”** if the research did not require completion of a checklist(s.) | |
| Yes  No  N/A | Do minutes justify any deletion or substantive modification of information concerning risks or alternative procedures contained in the proposed informed consent form? (**“N/A”** if deletion/modification of information to required informational elements in the consent document were proposed or if a consent form was not reviewed) | |
| Yes  No  N/A | Do minutes document the rationale for a significant/non-significant device determination? (**“N/A”** if abbreviated IDE devices were not reviewed.) | |
| Yes  No  N/A | When minutes document modifications required to secure approval do the minutes include a reason (basis) for each modification (**“N/A”** if there were no modifications required to secure approval.) | |
| Yes  No  N/A | When minutes document modifications required to secure approval, do the minutes 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? (**“N/A”** if there were no modifications required to secure approval or when IRB required convened board re-review). | |
| Yes  No  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) | |
| Yes  No  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) | |
| Yes  No  N/A | If a protocol was deferred do the minutes document recommended changes? (**“N/A”** if there were no deferred or disapproved protocols) | |
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| 1. Requirements for Each Reportable Event (Reportable New Information) Reviewed ( N/A if no problems were reviewed) | | |
| Yes  No | Do the minutes describe the Reportable Event? | |
| Yes  No | Do the minutes describe whether the Reportable Event 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  N/A | Do the minutes record a protocol ID? (**“N/A”** if there were no specific protocol involved) | |
| Yes  No  N/A | Do the minutes record a protocol title? (**“N/A”** if there were no specific protocol involved) | |
| Yes  No  N/A | Do the minutes record an investigator name? (**“N/A”** if there were no specific investigator involved) | |
| Yes  No  N/A | Do the minutes record controverted issues (when the IRB members express a difference of opinion among themselves)? (Indicate “**N/A**” if there were no controverted issues.) | |
| Yes  No  N/A | If the minutes record controverted issues do the minutes summarize each controverted issue and their resolution? (**“N/A”** 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, excused, or recused? | |
| Yes  No | When an alternate member substitutes for a primary member, do the minutes identify the name of the primary member for whom the alternate member is substituting? | |
| 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 both a regular IRB member and the alternate IRB member were not present at the meeting) | |
| 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 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? | |
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| 1. Minutes Efficiency | | |
| Indicate the number of days between the meeting and the finalization of the minutes: | | |