|  |
| --- |
| The purpose of this checklist is to fulfill the requirements of SOP HRP-043 IRB Meeting Minutes. |
|  |
| IRB Committee | [ ]  Committee A | [ ]  Committee B [ ]  Committee C |
| Meeting Date |       |
| Name of Person Completing Checklist |       |
| Name of Person Providing Response |       |
| Date Completed |       |
|  |
| 1. General Minutes Requirements
 |
| [ ]  Yes [ ]  No | Does the “Attendance List” record each IRB member (voting or non-voting) present at the meeting at any time? |
| [ ]  Yes [ ]  No [ ]  N/A | Does the “Attendance List” record for each alternate member the name of the IRB member for whom the alternate is substituting? (**“N/A”** if no alternate members substituted) |
| [ ]  Yes [ ]  No  | Do the minutes record that all members are present by teleconference and that they received all pertinent material before the meeting and were able to actively and equally participate in all discussions  |
| [ ]  Yes [ ]  No | Do the minutes record that a quorum was present? *(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* are *11 IRB members on the roster, then 11/2=5.5 and the next whole number is 6.)* |
| [ ]  Yes [ ]  No | Was a non-scientific member present for all committee votes? |
| [ ]  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 [ ]  N/A | Was a prisoner representative present? (**N/A** if no prisoner research was reviewed) |
|  |
| 1. Requirements for Each Protocol Reviewed
 |
| [ ]  Yes [ ]  No | Do the minutes record the type of review, protocol ID, protocol title, and an investigator’s name? |
| [ ]  Yes [ ]  No  | Do the minutes record the action taken by the IRB? |
| [ ]  Yes [ ]  No | Do the minutes record the number of votes for, against, and abstaining? |
| [ ]  Yes [ ]  No [ ]  N/A | Do the minutes list the names of voting IRB members who were recused? |
| [ ]  Yes [ ]  No [ ]  N/A | Do minutes document the basis for requiring changes in or disapproving research, if applicable? |
| [ ]  Yes [ ]  No [ ]  N/A | Do the minutes document a written summary of the discussion of controverted issues and their resolutions? (**“N/A”** if there were no controverted issues) |
| **3 Regulatory Determinations and Review Outcomes to be Recorded for Each Protocol Reviewed, When Applicable** |
| [ ]  Yes [ ]  No  | When issuing a new approval period for initial or continuing review, do the minutes record the period of approval for the motion?  |
| [ ]  Yes [ ]  No  | When applicable, do minutes document the level of risk determined by the convened IRB as either minimal risk or greater than minimal risk?  |
| [ ]  Yes [ ]  No  | When the IRB action is “Approved” do the minutes document the following: The criteria for approval have been met in accordance with HRP-314. |
| [ ]  Yes [ ]  No  | When the IRB action is “Modifications Required” do the minutes document the following: The regulatory criteria for approval and additional considerations, as outlined in HRP-314 will be met when the directive modifications described in the IRB determination letter have been confirmed. |
| [ ]  Yes [ ]  No  | When the IRB action is “Deferred” do the minutes document the following: The criteria for approval have not been met. Specific requirements are outlined in the IRB determination letter. |
| [ ]  Yes [ ]  No  | When a Conflict-of-Interest Management Plan has been accepted, do the minutes document the following: The Conflict of Interest Management Plan has been accepted as required by HRP-055. |
| [ ]  Yes [ ]  No  | When a waiver or alternation of the consent process has been issued, do the minute document the following: A waiver or alteration of the consent process has been issued in accordance with HRP-410. |
| [ ]  Yes [ ]  No  | When a waiver of written documentation of consent has been issued, do the minutes document that a waiver of written documentation of consent has been issued in accordance with HRP-411. |
| [ ]  Yes [ ]  No  | If the research involves an exception from informed consent requirements for emergency research, do the minutes document the following: An exception from informed consent requirements for emergency research has been issued in accordance with HRP-419. |
| [ ]  Yes [ ]  No  | When a waiver of HIPPA Authorization do the minutes document the following: A waiver of HIPAA Authorization has been issued in accordance with HRP-441.  |
| [ ]  Yes [ ]  No  | When children have been approved as participants do the minutes document the following: Children have been approved as participants in accordance with HRP-416. |
| [ ]  Yes [ ]  No  | When pregnant people, human fetuses, or neonates have been approved as participants do the minutes document the following: Pregnant people, human fetuses, or neonates have been approved as participants in accordance with HRP-412 or HRP-413, as applicable. |
| [ ]  Yes [ ]  No  | When prisoners have been approved as participants, do the minutes document that prisoners have been approved as participants in accordance with HRP-415. |
| [ ]  Yes [ ]  No  | When determinations of Unanticipated Problems, Serious or Continuing Noncompliance, Suspension or Termination of IRB Approval the minutes document the following: A determination of Unanticipated Problems, Serious or Continuing Noncompliance, or Suspension or Termination of IRB Approval has been made accordance with HRP-321. |
| [ ]  Yes [ ]  No  | When cognitively impaired adults have been approved as participants in a clinical trial do the minutes document the following: Cognitively impaired adults have been approved as participants when the study is a clinical trial in accordance with HRP-417. |
| [ ]  Yes [ ]  No  | When a Significant/Non-significant device determination has been made, do the minutes document the following: Significant/Non-significant device determination in accordance with HRP-418. (Not required if the FDA has already made a risk determination for a device study or the device is IDE exempt) |
|  |
| 1. Minutes Efficiency
 |
| Indicate the number of days between the meeting and the finalization of the minutes:       |