Welcome to the Audit Tool Checklist - Minutes Quality Improvement Assessment. The purpose of this online toolkit is to allow individuals to conduct a quality improvement assessment of IRB meeting minutes. If you have any questions about this online toolkit or if you encounter any errors, please contact Lisa Linn. If you have general questions about the Audit Tool Checklist, please discuss with your manager or contact the compliance team.

Choose the quarter in which the submission was reviewed and approved:

- Q1 (September – November)
- Q2 (December - February)
- Q3 (March - May)
- Q4 (June - August)

Please provide the following information about the minutes being reviewed:

Panel:

Meeting date:

Name of person that authored the meeting minutes

Date meeting minutes were finalized:
Name of person completing audit review:

Date audit review was completed:

General Minutes Requirements - Did the minutes include the following?

Do the minutes record the meeting start time?
- ☐ Yes
- ☐ No

Do the minutes record the meeting end time?
- ☐ Yes
- ☐ No

Do the minutes correctly record the total number of voting members on the roster?
- ☐ Yes
- ☐ No

Do the minutes correctly record the number of members required for a quorum?
- ☐ Yes
- ☐ No
Do the minutes correctly record the total number of voting members that attended the meeting?

☐ Yes
☐ No

Do the minutes correctly record the total number of non-voting alternates that attended the meeting?

☐ Yes
☐ No

Does the "Attendance Table" record the name of each member (regular members and alternates) present at the meeting at any time?

☐ 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?
Does the "Attendance Table" record each member's status as a scientific member or a non-scientific member?

- Yes
- No

Does the "Attendance Table" record each member's status as a voting member, voting alternate member or a non-voting alternate member?

- Yes
- No

Does the "Attendance Table" record for each voting alternate member the name of IRB member for whom the alternate is substituting? (If an alternate member did not substitute for an IRB member, select N/A)

- Yes
- No
- N/A

When a member is a representative of a vulnerable population during a specific meeting, does the "Attendance Table" record that member's representative capacity? (Prisoners, children, cognitively impaired persons; If a member did not act in that capacity check N/A)
Requirements for Each New Project and Modification Reviewed - Do the minutes include the following?

☐ Check this box if there were no new projects or modifications reviewed at the meeting

Do the recommended changes (i.e., Issues) include sufficient detail to show the basis for the required change and board motion? (if no issues and submission was approved, check yes)

☐ Yes

☐ No

For initial submissions, the discussion includes sufficient detail of protocol specific risk and how those risks are minimized?

☐ Yes

☐ No
For initial submissions, the discussion includes sufficient protocol details of the data and safety monitoring plan, if applicable?

- Yes
- No
- N/A

For initial submissions, the discussion includes sufficient detail of potential benefits to participants and/or society?

- Yes
- No
- N/A

For initial submissions, the minutes include a statement regarding the COI status of the investigators, and if applicable, any panel consideration of the COI?

- Yes
- No
- N/A

For initial submissions that received approval or pending approval, the minutes include the template 111 criteria statement and the bullet points are appropriate for that submission?

- Yes
- No
- N/A

For initial submissions that are deferred, the minutes include the required template statement and the reason for deferral?
If applicable, do the minutes justify the determination of a significant or non-significant risk device determination (including template language for NSR determination)?

- Yes
- No
- N/A

If applicable, the minutes include template language regarding the IND exemption status?

- Yes
- No
- N/A

If the minutes record a consultant report, does it summarize the key information provided by the consultant?

- Yes
- No
- N/A

Do the minutes include either a statement that no controverted issues were identified or a description of controverted issues that were identified?

- Yes
- No
If controverted issues occurred, do the minutes record the resolution or state that there was no resolution?

- Yes
- No
- N/A

Is the sum total of the number of members for, against, abstaining, absent, and/or recused constant among votes and equal to the number of voting members listed in the "Attendance Table"?

- Yes
- No

If applicable, does the vote table list the names of any alternate member that votes for a specific submission (not the full meetings, those are listed in the attendance table)?

- Yes
- No
- N/A

If applicable, does the vote table list the names of any members that abstained from the vote?

- Yes
- No
- N/A
If applicable, does the vote table list the names of any members that recused themselves from the vote?

- Yes
- No
- N/A

If applicable, does the vote table list the names of any members that were absent from the vote?

- Yes
- No
- N/A

If the research involves waiver or alteration of consent, waiver of written documentation of consent, waiver or alteration of HIPAA, children, pregnant women, or prisoners do the minutes include the appropriate checklist?

- Yes
- No
- N/A

Comments: (include any noted trends, areas of concern, etc.)
The following questions pertain to Continuing Reviews:

☐ Check this box if there were no continuing reviews reviewed at the meeting

Did the review include a summary of study & current status of the study?
☐ Yes
☐ No

Did the review include a summary of modifications over the past year?
☐ Yes
☐ No

Did the review include a summary of RNIs (i.e, reports of newly identified risks and/or non-compliance) over the past year?
☐ Yes
☐ No

Did the review include a statement that risks continue to be minimized and reasonable in relation to anticipated benefits?
☐ Yes
☐ No

Did the review include a statement of current COI status of the investigators and if applicable any COI management plan?
Did the review include a statement that the criteria for IRB approval of research continues to be met and includes the correct citation?

- Yes
- No

Did the review include a statement that there has been no changes over the past year that would impact previously made waiver determinations?

- Yes
- No
- N/A

Did the review include a statement that there has been no changes over the past year that would impact previously made subpart determinations?

- Yes
- No
- N/A

If the minutes record a consultant report, does it summarize the key information provided by the consultant?

- Yes
- No
- N/A
Do the minutes include either a statement that no controverted issues were identified or a description of controverted issues that were identified?

- Yes
- No

If controverted issues occurred, do the minutes record the resolution or state that there was no resolution?

- Yes
- No
- N/A

Is the sum total of the number of members for, against, abstaining, absent, and/or recused constant among votes and equal to the number of voting members listed in the "Attendance Table"?

- Yes
- No

If applicable, does the vote table list the names of any alternate member that votes for a specific submission (not the full meetings, those are listed in the attendance table)?

- Yes
- No
- N/A
If applicable, does the vote table list the names of any members that abstained from the vote?

- Yes
- No
- N/A

If applicable, does the vote table list the names of any members that recused themselves from the vote?

- Yes
- No
- N/A

If applicable, does the vote table list the names of any members that were absent from the vote?

- Yes
- No
- N/A

If the research involves waiver or alteration of consent, waiver of written documentation of consent, waiver or alteration of HIPAA, children, pregnant women, or prisoners do the minutes include the appropriate checklist?

- Yes
- No
- N/A
Requirements for Each Problem Reviewed (RNIs)

☐ Check this box if there were no problems reviewed at the meeting

Requirements for Each Problem Reviewed (RNIs) - Do the minutes document each problem reviewed at the meeting? (Check if yes; all are required unless otherwise noted)

Do the minutes describe the problem?

☐ Yes
☐ No

Do the minutes describe whether the problem was serious non-compliance, continuing non-compliance, an unanticipated problem involving risks to subjects or others, and/or a suspension or termination of IRB approval?

☐ Yes
☐ No

If applicable, do the minutes state that the corrective action plan was acceptable or describe what changes would be required to the corrective action plan.

☐ Yes
☐ No
☐ N/A
Do the minutes include either a statement that no controverted issues were identified or a description of controverted issues that were identified?

- Yes
- No

If controverted issues occurred, do the minutes record the resolution or state that there was no resolution?

- Yes
- No
- N/A

Is the sum total of the number of members for, against, abstaining, absent, and/or recused constant among votes and equal to the number of people listed in the "Attendance Table"?

- Yes
- No

If applicable, does the vote table list the names of any alternate member that votes for a specific submission (not the full meetings, those are listed in the attendance table)?
If applicable, does the vote table list the names of any members that abstained from the vote?

- Yes
- No
- N/A

If applicable, does the vote table list the names of any members that recused themselves from the vote?

- Yes
- No
- N/A

If applicable, does the vote table list the names of any members that were absent from the vote?

- Yes
- No
- N/A

Comments: (include any noted trends, areas of concern, etc.)