

Please complete one checklist for the meeting minutes for one IRB Meeting

IRB Panel Name	
Date of Meeting	
Name of Person Completing Checklist	
Date Completed	
Length of Meeting:	Time Meeting Started:
	Time Meeting Ended:

General Minutes Requirements

OHRP & FDA

1.	<input type="checkbox"/> Yes <input type="checkbox"/> No	Do the minutes record the names of IRB members present?
2.	<input type="checkbox"/> Yes <input type="checkbox"/> No	Do the minutes record the names of IRB members absent from the meeting?
3.	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	Do the minutes record the names of consultants and visitors present?
4.	<input type="checkbox"/> Yes <input type="checkbox"/> No	Does the IRB approve the minutes from the prior meeting?

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5.	<input type="checkbox"/> Yes <input type="checkbox"/> No	Do the minutes record which member was chair?
6.	<input type="checkbox"/> Yes <input type="checkbox"/> No	Do the minutes record each member's status as an unaffiliated member or affiliated member?
7.	<input type="checkbox"/> Yes <input type="checkbox"/> No	Do the minutes record each member's status as a scientific member or non-scientific member?
8.	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	Do the minutes record the voting status (voting or non-voting) of each member present?
9.	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	For each alternate member, do the minutes record the name of IRB member for whom the alternate is substituting?
10.	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	Do the minutes record whether any members were present by teleconference and if so indicate them by name?
11.	<input type="checkbox"/> Yes <input type="checkbox"/> No	Do the minutes record the total number of members present on the current IRB roster excluding alternate IRB members?
12.	<input type="checkbox"/> Yes <input type="checkbox"/> No	Do the minutes correctly record the number of members required for a quorum? (<i>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.</i>)
13.	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	Do the minutes record a summary/list of each business item (e.g. educational items, announcements, etc.) that was discussed?
14.	<input type="checkbox"/> Yes <input type="checkbox"/> No	Do the minutes record acknowledgement of expedited actions (including approvals, continuing reviews and amendments) carried out since the last meeting? If not, how are these approvals communicated to IRB members?

IRB Minutes Quality Improvement Assessment

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15.	<input type="checkbox"/> Yes <input type="checkbox"/> No	Do the minutes record the chair's conflict of interest (COI) reminder?
16.	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	For protocols undergoing continuing review by full committee, does the convened IRB (with quorum) review, deliberate, and vote for each study?
17.	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	Do the minutes document IRB review of adverse events and unanticipated problems?
18.	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	Do the minutes include IRB review of protocol violations or deviations?

INSTITUTIONAL REQUIREMENTS (Please include policies specific to your institution that should be included in your minutes)

19.	<input type="checkbox"/> Yes <input type="checkbox"/> No	
20.	<input type="checkbox"/> Yes <input type="checkbox"/> No	
21.	<input type="checkbox"/> Yes <input type="checkbox"/> No	

Requirements for Each Protocol or Report Reviewed

OHRP & FDA

22.	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	For each protocol reviewed by the IRB, do the minutes include written documentation of any discussion of controverted issues and their resolution?
23.	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	For protocols in which the IRB waived the requirement of informed consent, was the justification for waiver documented in the minutes in accordance with 45 CFR 46.116(d)?
24.	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	For research involving pregnant women and/or fetuses, do the minutes document IRB findings required under Subpart B of 45 CFR 46?
25.	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	For research involving prisoners, does the composition of the IRB include a prisoner or a prisoner representative with appropriate background and experience?
26.	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	For research involving prisoners, do the minutes document IRB findings as required under 45 CFR 46.305(a)?
27.	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	For research involving children, do the minutes document IRB findings in accordance with Subpart D of 45 CFR 46?
28.	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	Do the minutes document consideration of additional safeguards for vulnerable subjects when appropriate?
29.	<input type="checkbox"/> Yes <input type="checkbox"/> No	Do the minutes document that a quorum was present for all IRB actions requiring a vote?
30.	<input type="checkbox"/> Yes <input type="checkbox"/> No	Do the minutes document that at least a majority of the IRB members present voted on all actions requiring a vote?
31.	<input type="checkbox"/> Yes <input type="checkbox"/> No	Do the minutes document that all IRB actions included at least one scientist in the review and vote?
32.	<input type="checkbox"/> Yes <input type="checkbox"/> No	Do the minutes document that all IRB actions included at least one non-scientist in the review and vote?
33.	<input type="checkbox"/> Yes <input type="checkbox"/> No	Do the minutes document that all IRB actions included at least one non-institutional member in the review and vote? If not, how frequently has the absence of this member occurred in the past 3 months?

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34.	<input type="checkbox"/> Yes <input type="checkbox"/> No	Do the minutes of the IRB meetings include sufficient detail to show the vote on the IRB's actions including the number of members voting for, against, and abstaining?
35.	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	Do the minutes record the name of IRB members who abstained from a vote and provide the reason for abstention?
36.	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/> Yes <input type="checkbox"/> No	Do the minutes record the name of IRB members who recused themselves from the discussion and vote due to a conflict of interest? If yes, was the reason for the conflict documented in the minutes?
37.	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	When specific minor modifications are required to approve a study, do the IRB minutes state who (e.g., chair, reviewers, full committee) will review and confirm that the investigator has completed the modifications requested by the IRB?
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38.	<input type="checkbox"/> Yes <input type="checkbox"/> No	Do the minutes record a protocol number? (May not be applicable for Reportable New Information with no specific protocol involved.)
39.	<input type="checkbox"/> Yes <input type="checkbox"/> No	Do the minutes record a study title? (May not be applicable for Reportable New Information with no specific protocol involved.)
40.	<input type="checkbox"/> Yes <input type="checkbox"/> No	Do the minutes record the principal investigator's name? (May not be applicable for Reportable New Information with no specific protocol involved.)
41.	<input type="checkbox"/> Yes <input type="checkbox"/> No	Do the minutes record a type of review as initial review, continuing review, review of modifications to previously approved research, or reportable new information?
42.	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	If the minutes record a consultant report, does it summarize the key information provided the consultant. ("N/A" if there were no consultant reports)
43.	<input type="checkbox"/> Yes <input type="checkbox"/> No	Do the minutes record a motion as one of the following: Approved, Requires Modifications, Deferred, or Disapproved. (May not be applicable for Reportable New Information.)
44.	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	For initial or continuing review, do the minutes record the period of approval for the motion?
45.	<input type="checkbox"/> Yes <input type="checkbox"/> No	Do the minutes record the number of members for, against, abstaining, absent, or recused for each vote?
46.	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	Do the minutes list the names of IRB members who were absent or recused for each vote?
47.	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	Do minutes document the level of risk determined by the convened IRB as either minimal risk or greater than minimal risk?
48.	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	If the research involves waiver or alteration of consent, waiver of written documentation of consent, inclusion children, pregnant women, neonates, fetuses, prisoners, do the minutes either say "See IRB Records" or include documentation that the criteria were met? ("N/A" if no research requiring documented findings was reviewed)
49.	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	Do minutes justify any deletion or substantive modification of information concerning risks or alternative procedures contained in the DHHS-approved sample consent document? ("N/A" if a DHHS-approved sample consent form was not reviewed)
50.	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	Do the minutes document the determination of need for an Investigational New Drug Application (IND)

IRB Minutes Quality Improvement Assessment

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51.	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	Do minutes document the rationale for a significant/non-significant device determination? ("N/A" if abbreviated IDE devices were not reviewed.)
52.	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	Do minutes document modifications required to secure approval? ("N/A" if there were no modifications required to secure approval)
53.	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	When minutes document modifications required to secure approval is a reason (basis) for each modification included? ("N/A" if there were no modifications required to secure approval)
54.	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> 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)
55.	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	If a protocol was deferred do the minutes document recommended changes? ("N/A" if there were no deferred or disapproved protocols)
56.	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	If both a regular IRB member and the alternate IRB member are present at the meeting, do the minutes indicate which voted and 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.)
57.	<input type="checkbox"/> Yes <input type="checkbox"/> 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 meeting attendance roster?
58.	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	For each Reportable New Information (RNI) reviewed, do the minutes describe the new information? ("N/A" if no RNIs were reviewed)
59.	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	For each Reportable New Information (RNI) reviewed, do the minutes describe whether the new information was serious or continuing non-compliance, an unanticipated problem involving risks to subjects or others, or a suspension or termination of IRB approval? ("N/A" if no RNIs were reviewed)
60.	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	For each Reportable New Information (RNI) reviewed, do the minutes describe whether the IRB members considered termination of IRB approval? ("N/A" if no RNIs were reviewed)
61.	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	For each Reportable New Information (RNI) reviewed, do the minutes document the required action(s) of the Investigator and/or IRB? ("N/A" if no RNIs were reviewed)
62.	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	For each Reportable New Information (RNI) reviewed, do the minutes document the motion? ("N/A" if no RNIs were reviewed)
63.	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	If the minutes record controverted issues, is there a "Controverted Issue/Resolution" table? ("N/A" if there were no controverted issues)
64.	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	If the "Controverted Issue/Resolution" table was used, does it summarize the controverted issue? ("N/A" if there were no controverted issues)
65.	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	If the "Controverted Issue/Resolution" table was used, does it include a resolution or a statement that there was no resolution? ("N/A" if there were no controverted issues)
66.	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	If appropriate, do the minutes record research data security issues and resolutions?
67.		
68.		
69.		

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Optional Questions

***These questions were taken from the OHRP QA Self-Assessment Tool**

Estimated amount of time for full committee protocols/meeting:	
Estimated amount of time for modifications requiring full committee review/meeting:	
Estimated amount of time for review of adverse reactions/unanticipated events reported/meeting:	
Estimated amount of time for continuing review protocols requiring full committee review/meeting:	