

Federal regulations and guidance require IRBs to maintain meeting minutes that reflect

- meeting attendance
- actions taken by the board
- votes on these actions, including the number of members voting for and against approval, as well as those abstaining
- the basis for requiring changes to a study or for deciding to disapprove the research
- a summary of board discussion of controverted issues and their resolution
- separate deliberations for each action
- alternate members voting on behalf of primary members
- approval periods for initial and continuing review applications
- all members who leave the meeting due to conflicts of interest
- determinations required by federal regulations, as well as justification for those determinations, for
 - waivers or alterations of consent or HIPAA Authorization
 - research involving pregnant women, fetuses, and neonates
 - research involving prisoners
 - research involving children
- when following Department of Health and Human Services regulations or guidance, justification for any removal of or substantive change to information about risks or alternative procedures in an HHS-approved sample consent document
- when following Food and Drug Administration regulations or guidance, rationale for significant and nonsignificant risk device determinations

IRB regulatory staff are responsible for recording minutes during each convened IRB meeting. After the meeting, staff check the information for accuracy and assemble a complete draft, which they then forward to the board for review. If the draft accurately reflects the actions, discussions, and votes of the meeting in question, the board votes to approve the minutes, and they become permanently part of the IRB record.

Meeting minutes provide critical information to oversight bodies, including both departments within the University and offices outside the institution. Federal agencies such as HHS, FDA, and the Office for Civil Rights review IRB meeting minutes when conducting institutional audits. Organizations like the Association for the Accreditation of Human Research Protections Programs (or AAHRPP) also request IRB meeting minutes as part of their accreditation reviews. Errors or inconsistencies in the minutes may result in citations in a federal audit and may influence an accrediting agency's decision whether to grant the IRB accreditation.

Checking meeting minutes for accuracy is an important part of IRB members' responsibilities. Members are expected to read minutes carefully before voting to approve them, particularly minutes relating to their own reviews, and especially when they reflect complex board discussion.

U-MIC TRANSCRIPT IRB Meeting Minutes

Contact the IRB for more information about board meeting minutes.

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