IRB Determinations and Meanings

A Tallahassee Memorial HealthCare IRB Guidance Document

Purpose

This document provides guidance on the decisions the Institutional Review Board (IRB) can make when reviewing a protocol at a convened meeting. Contact the IRB Office at IRBOffice@tmh.org if you have additional questions or need assistance.

DETERMINATION TYPE	FULL BOARD REVIEW DEFINITION	EXPEDITED LEVEL REVIEW DEFINITION
Approval	The Approval determination is made when all criteria are met, and there are no outstanding items.	The Approval determination is made when all criteria are met, and there are no outstanding items.
Modifications Required to Secure Approval	This determination is made when IRB members require specific modifications to a protocol before approval can be finalized. Examples include inserting required language into a consent document, providing CITI training for a study team member, or requiring language be removed from an advertisement/flyer. This determination does not require re-review by a convened committee, but rather the revisions can be reviewed at an expedited level.	Items that begin at the expedited level will not receive the Modifications Required to Secure Approval. Instead, specific stipulations will be sent back to the study team to achieve an approvable state. Items that were reviewed at the Full Board level and received this determination will be finalized at the Expedited level once the revisions have been received.
Tabled	The IRB will Table a study when the IRB cannot approve the research at a meeting for reasons unrelated to the protocol, such as loss of quorum. The IRB automatically schedules the protocol for review at the next meeting.	N/A
Deferred	This determination is made when the IRB is unable to approve a protocol and suggests modifications that may make the research approvable. When making this motion, the IRB describes its reasons for this decision, describes the modifications that may make the research approvable, and gives the investigator an opportunity to respond to the IRB in person or in writing. Examples of the modifications suggested in this type of determination include study design changes, major revisions to risks, or providing documentation for an otherwise incomplete submission. This determination requires re-review by a convened committee.	N/A
Disapproval	A disapproval determination is made when the IRB is unable to approve a protocol and the IRB cannot describe modifications that might make the research approval. When making this motion, the IRB describes its reasons for this decision and gives the investigator an opportunity to respond to the IRB in person or in writing.	N/A
Noted	This determination is made when an "approval" determination is not required. This acknowledges receipt of an item (i.e., non-reportable adverse event, publication, reports, or sponsor provided letter not requiring an approval).	This determination is made when an "approval" determination is not required. This acknowledges receipt of an item (i.e., non-reportable adverse event, publication, reports, or sponsor provided letter not requiring an approval).

Submission Type	Available Determination Type
Initial – Full Board	Approval, Mods Required, Tabled, Deferred, Disapproval
Amendment – Full Board	Approval, Mods Required, Tabled, Deferred, Disapproval
Continuing Review – Full Board	Approval, Mods Required, Tabled, Deferred, Disapproval
New Information (Adverse Event, Protocol Deviation, Miscellaneous, etc.)	Noted, Defer

The IRB may also make a Suspension or Termination determination in instances including (but not limited to) Unanticipated Problems, and Serious and/or Continuing Non-Compliance.

If the IRB has Approved the Human Subjects Research the project may commence once the IRB Letter of Approval and the IRB stamped Informed Consent form are received, and all other organizational approvals have been met. The approval period is noted in the approval letter.

If the IRB has determined Modifications Required to Secure Approval, Tabled, Deferred, or Disapproval of the project NO activities may begin until the IRB has Approved the study and the Letter of Approval and stamped Informed Consent have been received by the study team.