IBC Meeting Determinations

IBC Determination Process

Each study reviewed by a Site-Specific Sabai IBC will result in one of five possible determinations (outcomes). These outcomes are reached by a committee vote, reflecting the unique nature of both the individual study site and the diverse perspectives of the committee members. The determination to receive the majority vote will be officially recorded.

Study Approval Categories and Requirements

1. Full Approval

Full approval of the study is granted without any mandatory changes or conditions. The Approval Letter will be provided within 48 hours of the IBC meeting indicating the Review Decision.

- *Recommendations:* The Committee may offer non-binding recommendations (e.g., suggestions for best biosafety practices), but these are not required for Site approval.
- *Documentation:* These suggestions are documented in the meeting minutes' "Discussion" section but are not monitored for completion.

2. Full Approval with Stipulations

Full approval of the study is granted, but continuing approval is conditional upon the Site resolving the specific, required stipulation(s) within the time-frame set by the Committee (default is 30 days). The Approval Letter will be provided within 48 hours of the IBC meeting indicating the Review Decision.

- *Stipulation(s) Defined:* These are required action items concerning non-critical safety issues—issues less severe than those that would warrant Contingent Approval or Tabling.
- *Resolution Process:* Stipulations are tracked for completion and formally approved by the lead Associate Partner (AP) after reviewing the Site's resolution efforts.
- *Deadlines and Extensions:* APs will support the Site in meeting the required deadline. The IBC Chair may approve a time extension if the Site presents reasonable extenuating circumstances.
- *Consequences:* Failure to resolve the stipulations on time without adequate justification will trigger escalation. This requires the AP to coordinate with the Site and the IBC Chair to hold an Ad hoc IBC meeting to address the outstanding issue.

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3. Contingent Approval

Approval is withheld until the Site satisfactorily resolves all identified contingencies within the Committee's stated timeframe (default is 30 days). The Approval Letter will not be issued until the resolution of these contingencies is reviewed and formally approved. Once approved, the official Approval Letter, which will indicate the date the contingencies were resolved, will be provided to the Site within 48 hours.

- *Contingencies Defined:* These are required action items concerning critical safety, biosafety, and/or containment concerns.
- *Final Approval:* Full approval is only issued once the contingencies are met. The Committee determines, at the time of review, if resolving the contingencies requires a full Committee review or can be administratively granted by the Chair.
- *Deadlines and Extensions:* APs will assist the Site in meeting the deadline. The IBC Chair can grant a time extension if reasonable extenuating circumstances are provided.
- *Consequences:* Failure to resolve the contingencies on time without adequate justification will trigger escalation. This requires the AP to coordinate with the Site and the IBC Chair to hold an Ad hoc IBC meeting to address the outstanding issue.

4. Tabled

The study review is put on hold because the Site furnished insufficient information for the IBC to conduct a complete assessment of the study and site arrangements and issue a final determination.

- *Resolution:* The study may be tabled for up to 30 days. The Associate Partner (AP) will help the Site meet this deadline. If the Site provides the required information, a subsequent IBC meeting will be scheduled to complete the review.
- *Deadlines and Extensions:* The IBC Chair can grant a time extension ("grace period") if the Site presents reasonable extenuating circumstances for the delay.
- *Consequences:* Failure to submit the required information on time without adequate justification will result in the study being inactivated or closed.

5. Disapproved

The IBC denies approval for the study under review. This determination will be provided to the Site in writing within 48 hours of the IBC meeting indicating the Review Decision.