



INITIAL REVIEW

INVESTIGATOR submits duly-accomplished forms [**Review Checklist (2A)**, **Application Form (2B)**, **Study Protocol Assessment Form (2C)**, **Informed Consent Assessment Form (2D)** and other protocol-related documents as enumerated in the checklist] to the Secretariat who forwards it to the Chair (**2 days**)

Chair classifies type of submission: exempted, full board, expedited (**2 days**)

EXEMPTED: finalized at the level of the Chair

IERC notifies investigator of exemption (**2 days**)

FULL BOARD: IERC *en banc* deliberates on full board action and decision during the monthly full board meeting

Approval: IERC notifies investigator
Minor Modification: IERC notifies investigator; resubmission is processed by expedited review
Major Modification: IERC notifies investigator; resubmission is processed by full board review
Disapproval: IERC notifies investigator
(**7 days after full board meeting**)

EXPEDITED: Primary Reviewers recommend action; finalized at the level of the Chair (**7 days**)

Approval: IERC notifies investigator
Minor or Major Modification: IERC notifies investigator; resubmission is processed by expedited review
Disapproval: IERC notifies investigator
(**3 days after Primary Reviewers make a recommendation**)

POST-APPROVAL REVIEW

INVESTIGATOR submits duly-accomplished forms for **Study Protocol Amendments (3A)**, **Continuing Review Applications (3B)**, **Final Reports (3C)**, **Non-compliance/Deviation/Violation Reports (3D)**, **Early Study Termination Application (3E)**, **Participant Queries and Complaints (3F)**, **Serious Adverse Events Report (3G)**, and **Progress Reports (3L)**, along with other protocol-related documents to the Secretariat who forwards it to the Chair (**2 days**)

Chair classifies type of submission: exempted, full board, expedited (**2 days**)

FULL BOARD: IERC *en banc* deliberates on full board action and decision during the monthly full board meeting

EXPEDITED: Primary Reviewers recommend action; finalized at the level of the Chair (**7 days**)

AMENDMENT

Approval: IERC notifies investigator

Minor Modification: IERC notifies investigator; resubmission is processed by expedited review

Major Modification: IERC notifies investigator; resubmission is processed by full board review

Disapproval: IERC notifies investigator

(7 days after full board meeting)

OTHER POST-APPROVAL SUBMISSIONS

Uphold original approval

Request information

Recommend further action

Full board: **7 days** after full board meeting

Expedited: **3 days** after Primary Reviewers make a recommendation

AMENDMENT

Approval: IERC notifies investigator

Minor or Major Modification: IERC notifies investigator; resubmission is processed by expedited review

Disapproval: IERC notifies investigator

(3 days after Primary Reviewers make a recommendation)