Incoming Items (Intake)

Approval or Determination

This pathway is for all reviews that involve approval or a determination:
- Determination that an activity is not human research
- Exemption determination
- Initial review
- Continuing review
- Review of modifications
- Study closure
- Response to modifications required to secure approval
- Humanitarian Use Device (HUD)

Emergency Use Notification

Emergency Use Review (023)

Emergency Use Post-Review (027)

Await 5 day report or protocol submission

No further action

Other Information

This includes:
- Complaints
- Notifications
- Reports
- Non-compliance issues
- Adverse events

New Information (024)

Level of Review Needed

Committee Review: IRB Meeting Preparation (040)

Non-Committee Review: Non-Committee Review Preparation (031)

Study Closure: Post-Review (052)

Suspensions or Terminations of IRB Approval (026)

Committee Review: IRB Meeting Preparation (040)

Investigations (025)

Send correspondence

May require correspondence

No findings or non-serious/non-continuing non-compliance

Finding that requires convened IRB review

Committee Review: IRB Meeting Preparation (040)

Unanticipated problem involving risks to participants or others

Serious or continuing non-compliance

Suspension or termination of IRB approval

TEMPLATE LETTER: External Report (520)

Emergency Use Notification

Await 5 day report or protocol submission

No further action

SOP: IRB Records (070)

CHECKLIST: Pre-Review (401)

WORKSHEET: Drugs (306)

WORKSHEET: Devices (307)

Non-Committee reviews are all reviews that do not require review by a convened IRB:
- Determinations that an activity is not human research
- Exemption determinations
- Review using the expedited procedure

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Convened IRB Review

WORKSHEET: Evaluation of Quorum and Expertise (305)
WORKSHEET: Review Materials (301)
TEMPLATE LETTER: IRB Member Agenda Packet

IRB Meeting Preparation (040)

IRB Meeting Attendance Monitoring (042)

IRB Meeting Minutes (043)

IRB Meeting Conduct (041)

Post-Review (052)

Review Outcome

Approved

Send correspondence

Modifications required to secure approval, deferred, or disapproved

Await resubmission

CHECKLIST: Pre-Review (401)
CHECKLIST: Waiver or Alteration of the Consent Process (410)
CHECKLIST: Waiver of Written Documentation of the Consent Process (411)
CHECKLIST: Research Involving Pregnant Women (412)
CHECKLIST: Research Involving Non-Viable Neonates (413)
CHECKLIST: Research Involving Neonates of Uncertain Viability (414)
CHECKLIST: Research Involving Prisoners (415)
CHECKLIST: Research Involving Children (416)
CHECKLIST: Research Involving Cognitively Impaired Adults (417)
CHECKLIST: Non-significant Risk Device (317)
CHECKLIST: Waiver of the Consent Process for Emergency Research (419)
WORKSHEET: Evaluation of Quorum and Expertise (305)
WORKSHEET: Criteria for Approval and Additional Considerations for HUD (323)
WORKSHEET: Review of Information Items (321)
WORKSHEET: Calculation of Approval Intervals (302)
WORKSHEET: Communication of Review Results (303)
SOP: IRB Records (070)
TEMPLATE MINUTES (501)
SOP: IRB Records (070)

Consultation to the IRB (051)
Conflicting Interest of IRB Members (050)