Incoming Items (Intake)

Incoming Items Directed to the IRB (020)

Type of Information

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

Level of Review Needed

Committee Review:
- IRB Meeting Preparation (040)
- IRB Meeting (041)

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

Review Outcome

Approval or Determination

Other Information

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

Send correspondence

Suspensions or Terminations of IRB Approval (026)

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

Emergency Use Notification

Emergency Use of a Test Article in a Life Threatening Situation Review (023)

Emergency Use Notification

Await 5 day report or protocol submission

No further action

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

Finding that requires convened IRB review

Send correspondence

Investigations (025)

Committee Review:
- IRB Meeting Preparation (040)

Template Letter: External Report (520)

This is for suspensions or terminations by someone other than the convened IRB

TEMPLATE LETTER: Emergency Use (570-573)

Suspensions or Terminations of IRB Approval (026)

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

Emergency Use of a Test Article in a Life Threatening Situation Post-Review (027)

Await 5 day report or protocol submission

No further action

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

Finding that requires convened IRB review

Send correspondence

Send correspondence

New Information (024)

Review Outcome

Approval or Determination

Committee Review:
- IRB Meeting Preparation (040)

Investigations (025)

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

Emergency Use Notification

Emergency Use of a Test Article in a Life Threatening Situation Review (023)

Emergency Use Notification

Await 5 day report or protocol submission

No further action

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

Finding that requires convened IRB review

Send correspondence

Investigations (025)

Committee Review:
- IRB Meeting Preparation (040)
Non-Committee Review Preparation (031)

Non-Committee Review Conduct (032)

Post-Review (052)

Committee Review: IRB Meeting Preparation (040)

CHECKLIST: Non-Committee Review (402)
WORKSHEET: Review Materials (301)
WORKSHEET: Human Research Determination (310)
WORKSHEET: Engagement Determination (311)
WORKSHEET: Exemption Determination (312)
WORKSHEET: Eligibility for Review Using the Expedited Procedure (313)
WEMPLATE LETTER: Designated Reviewer Materials (540)

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 (418)
WORKSHEET: Criteria for Approval and Additional Considerations (314)
WORKSHEET: Advertisements (315)
WORKSHEET: Payments (316)
WORKSHEET: Short Form of Consent Documentation (317)
WORKSHEET: Additional Federal Agency Criteria (318)
WORKSHEET: Scientific or Scholarly Review (320)
WORKSHEET: Criteria for Approval and Additional Considerations for HUD (323)

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

Send correspondence
Await resubmission

Convened IRB review required
Review Outcome
Approved or determination granted
Modifications required to secure approval