Change in Research/ Emergency Use Workflow

Use this chart to track the Current State (i.e., “Researcher Prep”) of your Change in Research or Emergency Use Application from submission to IRB approval.

Researcher Prep
Application is being prepared by study team and has never been submitted for IRB review.

PRA Review
Prospective Reimbursement Analysis Review. All New Applications (and Change in Research Applications previously marked as “PRA Required”) will transition to the “PRA Review” current status.

Legend:
CFS – Consent Form Specialist Blue Box – Pre IRB Review
RSS – Research Subjects Specialist Purple Box – Post IRB Review
Orange Box – Decision

Application complete/ready for IRB review?

NO

Yes

RSS Review – Pre IRB
Application is assigned to a pre-team RSS for pre-IRB meeting review.

PI Response – Pre IRB
Pre-IRB meeting reviewer notes (from pre-team RSS and compliance team) have been sent to study team; Application requires the study team to respond and resubmit within 60 days.

CFS Review – Pre IRB
Application is assigned to CFS team for pre meeting review/processing.

CFS Review?

NO

YES

RSS Review – Post IRB
Application is assigned to RSS team for post meeting review/processing.

CFS Review – Post IRB
Application is assigned to CFS team for post meeting review/processing.

CFS Review?

NO

YES

Waiting Outcome
Application has been assigned to a meeting and is waiting for post team to record meeting outcome.

IRB Review Complete?

NO

YES

RSS Review – Post IRB
Meeting outcome has been recorded by post team. Post team performs all post meeting responsibilities.

PI Response – Post IRB
Post-IRB meeting reviewer notes have been sent to the study team; Application requires the study team to respond and resubmit within 60 days.

PI Response – Post IRB

Disapproved
Application is disapproved. A new application must be submitted to pursue this study.

Approved
Application is approved and research may begin.

Approved?

NO

YES