Human research approval process

Important Notes

In order to conduct research with human subjects at MCW, including data and specimens, Principal Investigators (PIs) must obtain approval from the Institutional Review Board (IRB). For more information, visit Working with Human Subjects or email IRBOffice@mcw.edu

Median time from submission to approval for new protocols: Expedited Review = 28 days; Full Committee = 64 days

Index of Process Maps

Glossary

C2 – IRB Coordinator II
C3 – IRB Coordinator III
eBridge – online system for routing approvals
FP – Funding Proposal in eBridge
IRB – Institutional Review Board
PI – Principal Investigator
PRO – human research protocol in eBridge
RSS – Research Support Specialist
Human research approval process

Overview

Start

- Obtain funding approval
  - Work on IRB protocol (PRO) in eBridge
  - Submit PRO
  - IRB reviews & approves study
    - PRO Approved
      - Ancillary committee(s) review & approve study
      - If needed, obtain ancillary committee approval(s)

For example, safety committee approval for biologics; hazardous chemicals; radiation; MRI. View Master List of Process Maps (PDF) to see steps needed for these approvals.

eBridge is MCW’s online system for routing approvals
Human research approval process

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For Profit Sponsor?

- No
  - Wait until validated
  - Contract comparison validated

- Yes
  - Contract comparison must be validated

Obtain ancillary committee approval(s)

Wait for approval(s)

Obtain ancillary committee approval(s)

Ancillary committee approvals needed?

- No
  - Wait until training complete
  - Training completed

- Yes
  - Apply for ancillary committee approval(s)

Work on Funding Proposal (FP) in eBridge

Wait for FP to attain state of Awarded Pending IRB Approval

FP in state of Awarded Pending IRB Approval

Median wait time for new PROs:
- Exp = 28 days
- Full = 64 days

Submit PRO

PRO ready for submission

Work on IRB protocol (PRO) in eBridge

eBridge is MCW’s online system for routing approvals

Obtain required training: CITI, DOD, Banking

Wait until training complete

Training completed

IRB reviews & approves study

PRO Approved

End

Start
Human research approval process

From Phase 1

Review PRO for basic administrative requirements

Change(s) needed? No → Assign PRO to a committee → Forward PRO to C2 → To Phase 3

Yes → Request change(s)

Receive change(s)

Submit change(s)

Make requested change(s)

Receive request for change(s)

Refer to New Project Checklist

Phase 2

Revised 9.20.18
Expedited review is an option for certain kinds of research involving no more than minimal risk and for minor changes in approved research.

From Phase 2

Receive PRO

Review PRO

Change(s) needed?

Yes

Request change(s)

No

Full Committee or Expedited Review?

Full

Submit to Full Committee for review

To Phase 4 Full

Expedited

Submit for Expedited Review

To Phase 4 Expedited

Make requested change(s)

Receive request for change(s)

Submit change(s)
Human research approval process

From Phase 3

Receive PRO

Review PRO

Request change(s)

Change(s) needed?

Federal regulatory criteria not met

PRO tabled

To Phase 5

Request change(s)

New

Receive change(s)

Change(s) approved?

No

Receive request for change(s)

Receive PRO

Revise PRO to fulfill Federal regulatory criteria

Resubmit to Full Committee

Back to Guide
Human research approval process

IRB Expedited Committee

From Phase 3

Receive PRO

Review PRO

Receive change(s)

Request change(s)

Submit change(s)

Make requested change(s)

Receive request for change(s)

Send to Full Committee

Full Committee review needed

Change(s) needed?

Yes

No

To Phase 4

To Phase 5

Phase 4 Exp

Revised 9.20.18

Back to Guide
Human research approval process

Phase 5

Revised 9.20.18

IRB Committee

From Phase 4
Expedited

From Phase 4
Full

PRO approval pending

Wait for ancillary committee approval(s)

Yes

Approved by ancillary committee(s)

End

No

Ancillary committee approval needed?

Wait for Funding Proposal (FP) to be awarded

FP state is Awarded Pending IRB Review

Is FP Sponsor For Profit?

Yes

Forward to C2 to initiate contract comparison

Complete the subprocess for Contract Comparison

No

Receive PRO

Back to Guide

IRB Coordinator 2
(C2)
Only for studies with **For Profit** Sponsors

- **Start**
  - Receive PRO
  - Notify C3 contract comparison is needed
  - Receive notification
  - Compare contract with consent form
  - Comparison valid?
    - Yes: PRO Approved
    - No: Notify C2 change(s) needed
  - Notify C2 contract needed
  - Send PRO to study team to correct consent language

- **PRO Approved**
  - End

- **Submit to C2**
  - Make correction
  - Receive request for correction