West Virginia University
Office of Human Research Protections

Research Roadmap:
Navigating the CIRB Process

Sarah Stutler, MBA, CCRP, CIP, CIM
WVU Senior IRB Coordinator
Objectives

1) Demonstrate knowledge of the Central Institutional Review Board (CIRB) Workflow for West Virginia University
2) Describe the options for CIRB use
3) Describe the requirements for CIRB use
4) Review the reporting requirements when using a CIRB
Overview

➢ Terms

▪ IRB of Record
▪ Central IRB (CIRB or External)
▪ IAA
  • Inter-Institutional Authorization Agreement
  • IRB Authorization Agreement
  • Reliance Agreement
▪ sIRB = Single IRB Review

➢ CIRB Workflow
➢ Reporting Requirements
➢ Summary and Reminders
➢ Q & A
Navigating CIRB Use At WVU

Who can submit?
Fees?
Funding?
Does my study qualify?

Where do I start?

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West Virginia University
PI identifies study through Sponsor outreach or other means.

➢ WVU IRB has standing agreements with WIRB-Copernicus, Advarra, and NCI CIRB.

➢ If determined that an IAA or sIRB is necessary, please contact the WVU IRB office for additional guidance.

➢ Prior to protocol or site submission to the IRB of Record, start a CIRB protocol type submission in WVU+kc to obtain an IRB protocol number. This number must be referenced in your submission to the external IRB.

➢ Ensure local context language and site specific information in Informed Consent.

➢ Once approval is obtained from the IRB of Record, complete the CIRB protocol in WVU+kc.

➢ Follow WVU IRB Reporting Requirements for CIRB protocols.

➢ WVU IRB Acknowledgment must be obtained prior to study enrollment.

➢ Include all study team members, locations of research, and required documentation.

➢ WVU IRB will send an acknowledgement letter to the PI.

➢ $1000 Administrative Review Fee to applicable Funding Source.
Starting Point
Does my study qualify?

Criteria for CIRB Use

- Multi-Center
- Phase II-IV
- Industry Sponsored
- Clinical Trial
“Check” Point
How do I choose?

Private/Industry Funding
➢ Advarra
   • Chesapeake
   • Schulman
   • Quorum – new acquisition
➢ WIRB-Copernicus Group (WCG)
   • WIRB, Copernicus, Aspire, Hummingbird, Midlands, New England

Federal Funding
➢ NCI CIRB
   • Separate HIPAA Consent
➢ sIRB
   • IAAs
   • SMART IRB
Along the Way...

What do I need to do?

**IRB of Record**
- Initial Approval
- Modifications
- Continuing Review
- Event Reporting
- Closure

**WVU IRB**
- Administrative Review
- Limited Event Reporting
- Closure

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WVU Administrative Review

- Begin a CIRB protocol prior to submission to IRB of Record to gain WVU IRB protocol number. Reference that number in your submission to the IRB of Record.
- Once approval is gained from the IRB of Record, complete your WVU+kc submission.

Registration

- IRB of Record Approval Letter
- Approved Sponsor Protocol
- Approved Informed Consent
- Drug/Device Information (i.e. Investigator Brochure)
- Ancillary Review Approval Letters

Attachments

- WVU IRB Acknowledgement Letter
- Fee of $1000 for Industry Sponsored protocols.

Acknowledged

Fee of $1000 for Industry Sponsored protocols.
Along the Way...

What and when do I report?

Limited Event Reporting

➢ Unanticipated, serious adverse events and/or side effect(s) encountered at WVU or an affiliate site that are found to be related to the research, must be reported to the WVU IRB within five (5) days, using the Notify IRB action in WVU+kc, following receipt of a determination from the IRB of Record.

➢ Any Unanticipated Problem or UPIRTSO or other research related event resulting in new or increased risk of harm to study subjects reported to the IRB of Record and occurring at WVU or an affiliate site, must be reported to the WVU IRB within five (5) days, using the Notify IRB action in WVU+kc, following receipt of a determination from the IRB of Record.
### Events

- IRB of Record’s Determination Letter
- Research Related Event Form
- Other applicable documents

### Closures

- IRB of Record’s Closure Approval Letter
- WVU Closure Form
End of the Road
You have arrived at your destination...

- Phase 1 – Reviewed by WVU IRB
- No Sponsor driven submissions on behalf of WVU.
  - Protocol Submission vs. Site Submission
- Considerations for Administrative Fee in budget.
- Local Context Considerations

Why?

Reminders...

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CIRB Workflow

Submission Information:
When an external IRB is determined to be the IRB of Record, the WVU IRB requires that an Administrative Review of the study, by the WVU IRB, is conducted following study and/or site approval by the IRB of Record. This serves as a registration of the study at WVU and allows for the appropriate signature signoffs as well as ensuring local considerations are accounted for in the Informed Consent and training requirements for study personnel are met.

WVU has standing agreements with NCI CIRB, WIRB-Copernicus, and Advarra. For other CIRBs or Institutions, an IAA or SMART IRB agreement will be required.

Private/Industry-sponsored clinical trials that are reviewed through private, for-profit IRBs, must pay an initial administrative fee of $1000 for each protocol to the WVU IRB.

Central IRB use applies only to Phase II through IV studies. Investigator-Initiated studies and single site studies must be reviewed by the WVU IRB.

At this time, no direct-sponsor submissions, on behalf of WVU, are permitted.

➢ PI identifies study through Sponsor outreach or other means.

➢ WVU IRB has standing agreements with WIRB-Copernicus, Advarra, Quorum, and NCI CIRB.

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Office of Human Research Protections
Staff Contact Information:

- **Gretchen McMasters**
  WVU OHRP Director

- **Rosemary Casteel**
  Continuous Improvement Manager

- **Sarah Stutler**
  Senior IRB Coordinator
  - Full Board, CIRBs, Research Related Events, Notify IRBs, Protocol Builder, Tissue/Data Repositories, DUAs, Prep to Research, Approval in Principle, Admin Reviews, HUDs, Emergency Use

- **Valerie Phillips**
  IRB Coordinator
  - Expedited, IAAs, sIRB, Notify IRBs

- **Lilo Ast**
  IRB Coordinator
  - Expedited, Exempt, CIRBs, Closures

- **Joseph Malcolm**
  IRB Coordinator
  - Tissue/Data Repositories, NHSRs, Flex, DUAs

- **Melissa Himes**
  IRB Coordinator
  - Expedited, IAAs, sIRB, Notify IRBs

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Questions and Answers