IRBMED: Ceding IRB Review to an External IRB

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TERMINOLOGY

For the purposes of this presentation:

• IRB of Record
• External IRB
• Reviewing IRB
• Central IRB

• Ceding IRB
• Relying IRB
• IRBMED

Not covered in this presentation – Agreements, SMART IRB, IREx (IRB Exchange). Contact IRBMED for assistance.
Required IRBMED Submissions

Why, when there is another IRB of record?

• Tracking of PI/Institutional activities related to U-M patients/subjects
• External IRB review is limited to IRB regulatory requirements
• Local context/informed consent
• Obligation to verify training
• Obligation to consider Conflicts of Interest
• Verify that local policies will be followed
• Ancillary reviews
TYPES OF EXTERNAL IRBs

Commercial IRBs
Advarra, Quorum, Western IRB, etc.
• Industry-sponsored, multisite clinical trials
• sIRB for NIH-sponsored trial
• Consortium research

NCI-CIRB
• NCI-sponsored clinical trials

Outside Institution IRBs
Universities, hospitals, etc.
• sIRB for NIH-sponsored trial
• Consortium research
• Other collaborative research
Ceded Study Submissions

• Initial Reviews
• Amendments
• Continuing Reviews
• Adverse Event (ADV) and ORIO Reports

Need IRB of Record approval letters before IRBMED acknowledgement.

Exceptions: Certain ADV/ORIOs and study team updates if the Informed Consent Form is not affected.
Working with Central (External) IRBs

https://research.medicine.umich.edu/office-research/institutional-review-boards-irbmed/central-irb-information

• Guidance on the overall process
• Direct contact information for specific commercial IRBs
• Guidance regarding what to submit to IRBMED at initial review and afterwards
IRBMED Intake Process for Ceding IRB Review

Commercial IRB
• If a Master Reliance Agreement is in place - complete only the ceding application
  • Advarra (formerly Chesapeake/Schulman)
  • Quorum
  • Western IRB (WIRB)

Consortium
• If a Master Reliance Agreement is place – complete only the ceding application
  • ‘XYZ’ Net

Others
• Complete an Intake Form (found on the IRBMED website to be updated by 4/13)
  • SMART IRB participant
  • Any other academic partner
Ceding Application: Initial Reviews

• In eResearch, Section 1-1.1 – Requesting review by non-UM IRB
• All appropriate ancillary reviews are still required
• IRBMED will acknowledge that external IRB will be the IRB of Record

Generally, IRBMED considers the following for a ceded submission:
• Institutional risk
• Conflicts of interest
• Institutional policies
• Whether project meets IRBMED criteria for ceding
Ceding Application: Initial Reviews

Items confirmed by IRBMED:

• PEERRS training for U-M study personnel
• Current CV’s (within 2 years)
• Appropriate Informed Consent/Assent Forms
• IRB approval for the study from the external IRB
• Institutional Cover Page (Advarra (formerly Chesapeake/Schulman), Quorum, etc.)

Approved consent documents should be posted as correspondence by the study team after receiving approval from the IRB of Record.
Ceding Application: Initial Reviews

Must have the following before beginning research-related activities:

- IRBMED acknowledgement
- External IRB approval
- Required U-M ancillary approvals
Ceding Application: Amendments

When to submit:
Any changes to the study that impact U-M ancillary committees:

- **Research Pharmacy (IDS or Investigational Drug Service):** Changes in dosing, addition of medication, prescribers
- **RDRC/SHUR (Radioactive Drug Research Committee/Subcommittee on the Human Use of Radioisotopes):** Changes in radiation dosing
- **CRAO (Clinical Research Calendar Review & Analysis Office):** Billing calendar updates, changes that impact subject injury language in consent
- **COI (Conflict of Interest):** Addition or removal of study team members
Ceding Application: Amendments

What to submit:

• Revised or new documents that prompt submitting an amendment
• External IRB approval letter
Ceding Application: Continuing Reviews

• Submit prior to expiration date
• Include current External IRB Approval Letter

If terminating (closing) the study, include the External IRB letter reflecting termination of the study.
Ceding Application: Reporting Requirements

Report events involving local subjects to IRBMED*: 

- Serious Adverse Events related to the research per IRBMED guidance
- Unanticipated Problems
- Protocol deviations that may represent a systematic problem requiring local evaluation by IRBMED to determine that sufficient local resources are available for the safe conduct of the study
- Reports of Continuing and/or Serious Non-Compliance
- Study holds or suspensions that are not built into the study design from External IRB or Sponsor (e.g. interim analysis or enrollment completion need not be reported)

*May require dual reporting – to IRBMED and External IRB
Common Mistakes to Avoid

• IRB approval letter from external IRB missing from application
• Uploading the incorrect version of the Informed Consent Document
• CV older than 2 years
• COI management plan not followed
New Challenges and Responsibilities

• Tracking multiple different IRB procedures for AE/ORIO reporting
• Use of different consent templates and needing familiarity with each of them for discussions with subjects
• Remembering to submit necessary amendments to IRBMED
Questions?