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?