Obtaining Local IRB Approval for Community Readiness

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Learning Objectives

- Understand local IRB processes in your local setting
- Prepare complete ethics submissions
- Anticipate timelines and reviews
- Maintain compliance after approval

Why Ethics Matters

- PROTECT PARTICIPANTS

- RESPECT CULTURE AND COMMUNITY NORMS

- ENSURE INFORMED CONSENT

- MEET NATIONAL AND FUNDER REQUIREMENTS

- BUILD TRUST

Local Ethics Landscape

Understand your local ethics landscape

Examples:

- Nigeria: NHREC + Institutional HRECs
- Kenya: KEMRI/University ERCs
- Uganda: RECs + UNCST
- South Africa: University HRECs
- Always obtain approval from the institution where research occurs.
- Work with your mentors from your CRCs

IRB Workflow

1. Finalize your protocol
2. Mentor review
3. Prepare associated documents for submission
5. Submit to local IRB
6. Respond to queries
7. Approval
8. Begin recruitment (**DO NOT begin recruitment until you have IRB approval**)

Community Engagement Before Submission

Community engagement can occur before IRB submission

- Meet community leaders
- Engage Ministries of Health
- Consult community advisory boards
- Adapt outreach materials into local languages
- Adapt data collection tools
- Address literacy and cultural norms

Required Documents

- Your proposal (following mentor review)
- Consent/Assent forms
- Questionnaires
- Interview guides
- Recruitment materials
- CVs of your team members
- Human subjects certificates
- Budget
- Support letters
- Data management plan
- Timeline

Consent in Community Context

- Local language translations (optional)
- Low-literacy consent options (optional)
- Respect local decision-making while preserving autonomy
- Confidentiality protections
- **Ask your CRC mentors if they have templates you can use**

Data Security

- Password protection
- Encrypted storage
- REDCap
- Unique IDs
- Locked files
- Restricted access

Common Delays in IRB Approval

- Missing signatures
- Incomplete protocol
- Poor risk description
- No recruitment materials or data collection tools submitted
- Unclear data security

Responding to IRB

Use a point-by-point response matrix:

Respond respectfully and completely.

After Approval

Recruit only after written approval.

Submit amendments for protocol changes.

Report adverse events.

Maintain continuing review.

Suggested Timeline


Weeks 1–2 Protocol


Week 3 Documents


Week 4 Submission


Weeks 5–8 Review


Week 9 Responses


Week 10 Approval

Team Exercise

Complete:

- Lead institution or CRC
- IRB
- Submission date
- Documents completed
- Community engagement completed
- Expected approval

Key Takeaways

- Start early.
- Engage communities.
- Prepare complete submissions.
- Protect participants.
- Maintain ethics throughout the study.

References

- Declaration of Helsinki
- CIOMS Guidelines
- NIH Human Subjects
- Nigeria NHREC Code (For projects in Nigeria)
- 45 CFR 46