GRI Research Ethics Checklist

Required Documents for IRB/Regulatory Submissions
Note: Requirements differ across IRBs and regulators. Some may ask for fewer documents, others for additional ones. Always check the specific IRB's guidelines.

1. Initial Application (New Study)

Typical requirements:

- IRB Application Form (board template)
- Full Study Protocol (background, objectives, methods, recruitment, risks/benefits, data plan)
- Informed Consent Forms (and assent for children/vulnerable populations) in relevant languages
- Recruitment Materials (scripts, flyers, social media ads, letters)
- Data Management Plan (DMP) – storage, sharing, deletion
- Survey/Interview Guides and Instruments
- Community Engagement Plan (if applicable)
- CVs of Principal Investigator and Key Researchers
- Proof of Training (e.g., CITI/ethics certifications)
- Local Approvals/Permits (government, community, institutional)
- Budget (if requested by IRB/funder)

2. Amendment (Changes During Study)

Typical requirements:

- Amendment Request Form (board template)
- Summary of Changes (what changed and why)
- Updated Protocol Sections
- Revised Consent/Assent Forms (if changes affect participants)
- Revised Data Collection Tools (if applicable)
- Supporting Documents (letters, new recruitment materials)

3. Renewal / Continuing Review (Ongoing Studies)

Typical requirements:

- Renewal/Continuing Review Form
- Study Progress Report (participants recruited, challenges, deviations)
- Safety Reports/Adverse Events (if any)
- Updated Timeline
- Updated Investigator CVs (if there are new staff)
- Any New Supporting Documents (updated permits, revised tools)

4. Study Closure

Typical requirements:

- Study Closure Form
- Final Study Report (summary of activities, participants, findings)
- Data Archiving/Deletion Plan (how data will be stored or destroyed)

- Evidence of Dissemination (community feedback, publications, reports)
- Exit/Community Engagement Report (where required)

Important Notes

- Each IRB has its own requirements.
- Some IRBs may ask for additional documents such as insurance certificates, conflict of interest statements, or translations.
- Missing documents can cause delays, rejections, or compliance risks.

How GRI Supports You

- Develop customized checklists based on specific IRB requirements.
- Draft and review protocols, consent forms, and DMPs.
- Manage amendments and renewals to avoid delays.
- Ensure compliance with international best practices and local regulations.
- Support ethical closure and dissemination of findings.