

Ecampus Research Ethics Committee

Comprehensive Guidelines for Applicants



Full
Lifecycle

Ethical
Oversight

Compliance
Standards

✓ SECTION 01

Introduction

All research involving human participants, identifiable data, or biological materials must receive **prior ethical approval**.



The Application Process Aligns **With:**



National Regulatory Frameworks



Institutional REC Standards



Full Research Lifecycle Oversight

Submission

Conduct

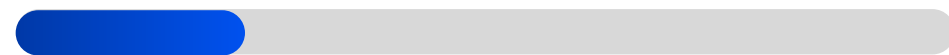
Closure

The Complete Research **Lifecycle**

Unlike basic guidance, eREC follows a full lifecycle model, meaning approval is not a one-time event.

01

Initial Application



02

Review And Approval



03

Study Implementation



04

Ongoing Monitoring
& Reporting



05

Amendments &
Compliance Reporting



06

Study Closure



 Approval is not a one-time event. Applicants must comply at every stage.

✓ STAGE 1

Initial Application

Before Starting Research



Initial Protocol Submission Form

Full

Expedited

Exempt

Important Note

Approval is typically valid for 1 year only and must be renewed if the study continues



This corresponds to the standard protocol submission structure **including:**

Investigator Details (PI, Co-Investigators, Supervisors)

Study Abstract And Methodology

Participant Numbers And Duration

Full Submission Checklist (Protocol, Consent Forms, Tools, Etc.)

Selecting the Correct Initial Review **Type**

Study Type	Form To Use	Description
High Risk / Vulnerable Populations	Full Review	Full REC Committee Review
Minimal Risk	Expedited Review	Chair/Designated Reviewers
Very Low Risk / Exempt Categories	Exemption Request	Administrative Determination

During the **Study**

Once approved, continuous compliance is required.



Form: Continuing Annual Review Application

- Must Be Submitted At Least 1 Month Before Expiry
- No Automatic Extensions Are Granted
- Failure Leads To Study Suspension Or Termination

Includes:

- Study Progress Summary
- Participant Enrollment Data
- Risk Updates
- Adverse Events And Deviations



Important Note

Review must be as rigorous as initial review



Form: **Progress Report**

Used for periodic updates on:

Recruitment Status

Study Implementation

Challenges

Outcomes And Dissemination

Safety Reporting

These are mandatory and time-bound obligations.



Serious Adverse Events (SAEs)

Form: Serious Adverse Event Reporting Form

🕒 3 days for SAEs

🕒 7 days for other adverse events

Includes:

- Nature Of Event (Death, Hospitalization, Disability, Etc.)
- Causality Assessment
- Impact On Study
- Required Protocol/Consent Changes



Protocol Deviations / Violations

Form: Protocol Deviation/Violation Report

🕒 Must be reported within 7 days of awareness

Includes:

- Description Of Deviation
- Impact On:
 - Participant Safety
 - Data Integrity
- Corrective And Preventive Actions

Amendments and Study **Changes**



Protocol Amendment / Modification

Form: Amendment Form

Required BEFORE implementing changes

**Exception: urgent safety changes
(must still be reported immediately)**

Examples:

- Change In Methodology
- New Study Sites
- Revised Consent Forms
- Change In Investigators



Proposal Re-Submission

Form: Re-Submission Form

Used when:

- Responding to REC review comments

Must Include:

- Response Table To Reviewer Comments
- Revised Protocol With Tracked Changes
- Updated Documents

✓ STAGE 5

Special Situations During **Study**



Extension Of Study Duration

Form: Extension Request

Required if study exceeds approved duration

Must include justification and new timeline



Study Re-Activation / Re-Opening

Form: Study Re-Opening Form

Used when:

- **Study approval was terminated or lapsed**

Requires:

- Explanation Of Termination
- Corrective Action Plan
- Confirmation Of Compliance Before Resuming

✓ STAGE 6

Study Closure

Final Report and Close-Out



Form: Study Close-Out Termination Form



Must be submitted when study is completed or terminated



Requirements: All Study Activities Must Cease



Summary Must Include:

Participants

Adverse Events

Findings And Dissemination

Decision Guide: Which Form Should You Use

These are mandatory and time-bound obligations.

Situation	Form to Use
• Starting a new study	Initial Application
• Responding to reviewer comments	Re-Submission
• Study ongoing (annual requirement)	Continuing Review
• Providing periodic updates	Progress Report
• Changing protocol	Amendment
• Study exceeding duration	Extension
• Study stopped and restarting	Re-Opening
• Adverse event occurs	SAE Report
• Protocol not followed	Deviation Report
• Study completed	Close-Out



Applicants **MUST**:

- 1 Not start research before approval
- 2 Submit annual review on time
- 3 Report SAEs within 3 days
- 4 Report deviations within 7 days
- 5 Obtain approval before amendments
- 6 Submit final report at closure

CRITICAL

Critical Rules

These are mandatory and time-bound obligations.



Failure May Result In:

- Suspension
- Termination
- Institutional sanctions

 AVOID THESE

Common Errors

These are mandatory and time-bound obligations.

01

Selecting Wrong Review Category

02

Missing Required Documents At Submission

03

Late Continuing Review Submission

04

Failure To Report Adverse Events

05

Implementing Changes Without Approval

06

Not Formally Closing The Study



Thank You

The eREC process is not just about approval
it is about continuous ethical oversight.

Think of your application as entering a regulated lifecycle, not a one-time submission.

 www.erec.ac.zm

 E3 Jubilee Hall Annex Pavilion Show
Grounds Great East Road Lusaka, Zambia