eREC Ecampus Research Ethics Committee

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

SECTION 02

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.)

SECTION 03

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

STAGE 2

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

STAGE 3 - CRITICAL

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

STAGE 4

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

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

CRITICAL

Critical **Rules**

These are mandatory and time-bound obligations.

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

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

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