How to Submit a Research Study for Ethical Review at MRCZ

Before You Begin

If your study is a clinical trial, you are required to submit your application to both the **Medical Research Council of Zimbabwe (MRCZ)** and the **Medicines Control Authority of Zimbabwe (MCAZ)** simultaneously. A clinical trial is defined in the Medicines and Allied Substances Control Act [Chapter 15:03] as:

"A systematic study in human beings or animals in order to establish the efficacy of, or to discover or verify the effects or adverse reactions of medicines, and includes a study of the absorption, distribution, metabolism and excretion of medicines"

The National Biotechnology Authority must approve any research involving genetically modified organisms or regulated biotechnology materials. This step only applies when Genetically Modified Organisms (GMOs) are part of the study

Researchers are encouraged to familiarize themselves with all submission requirements before preparing their application package.

Information for foreign researchers

- The Research Council of Zimbabwe (RCZ) is mandated to register foreign researchers.
- A foreign researcher is defined in Section 27 of the Research Act as:
  (1) Any person—
    (a) who wishes to conduct research in Zimbabwe on behalf of a foreign institution, foreign organization, or other foreign person, whether as an employee or otherwise
    (b) other than citizen of or a person ordinarily resident in Zimbabwe, who wishes to conduct research in Zimbabwe
- All foreign researchers should follow the registration guidelines outlined on the Council's website
- Full regulatory approval and commencement of participant recruitment is contingent upon issuance of a foreign researcher permit and unconditional approval by the RCZ and MRCZ, respectively.

Material Transfer

- Investigators wishing to ship biospecimens outside Zimbabwe for research purposes, will be required to seek clearance from the RCZ in line with Council guidelines and applicable data protection. Applicable fees are available on the RCZ website

Making a Submission

Stage 1: Download the Application Form

Download the **MRCZ New Study Application Form** from the MRCZ website.

The first page of the application form contains a comprehensive checklist of all documents required for submission.

Stage 2: Prepare Your Application Package

Before submission, ensure that the following documents are included:

Application Form

- Completed MRCZ Form 101.
- Signed and dated by the Principal and any Co-investigators.

Research Proposal

- Proposal summary (maximum 4 pages). Use the guidelines provided in MRCZ Form 101
- Full research proposal.
- All documents should be clearly labelled, paginated, and version-controlled.

Informed Consent Documents

- Informed Consent Forms to be used for recruitment of participants in Zimbabwe (ICFs) must be aligned with the MRCZ informed consent form template.
- ICFs should be on your institutional letterhead.
- Where applicable, consent forms must be translated into the appropriate local language by a qualified professional.
- Consent forms must be appropriately titled, paginated, and version-controlled.

Assent Forms

- Studies involving participants under 18 years of age must include assent forms.
- Assent forms should be developed in simple language appropriate for the age of participants.
- Refer to the assent form template provided by MRCZ

Data Collection Tools

- Questionnaires, interview guides, case report forms, and other study tools.
- Local language versions should be provided where applicable.

Permission Letters

- Letters from institutions, facilities, communities, schools, hospitals, or organizations where data will be collected.
- These letters should demonstrate authorization and authenticity.

Investigator Documentation

- Curriculum Vitae (CVs) of all Principal Investigators.
- Valid Good Clinical Practice (GCP) certificates for all Principal Investigators.

- ICH GCP training can be facilitated by MRCZ upon request

Acceptable Free GCP training and certification can be obtained from:

- NIDA Clinical Trials Network (https://gcp.nidatraining.org/)
- TRREE (https://elearning.trree.org/)
- WHO Training Platforms (https://whoacademy.org/)

Funding Documentation

- Proof of funding on the funder's official letterhead.

Ethics Approval

- Submit approval or clearance from your Institutional Review Board (IRB), where one is available to you.
- Additionally, for international researchers, where applicable, a support letter from a local institution of affiliation is required
- Local IRB approval is required, where necessary.

Stage 3: Pay the Relevant Application Fee

The following review categories are available (see explanations...):

Fee structure

No.	Submission Type	Standard Fee	Expedited Fee
1	Individual Researcher	$500	$1 000
	Students PhD MSc Undergraduate/Diploma Students registered with local universities can pay using the local currency equivalent at the intermarket rate.	$200 $50 $10	
	Exemption from full ethics review (Researchers are not supposed to exempt themselves from ethics review)	$200	
2	Study Extension	$100	$200
3	Amendment	$100	$200
4	Annual Renewal	$100	$200
5	Study Reopening/Reactivation	$400	
6	Training	$40/day/person	
7	Search fee	$20	
8	Late Submission Penalties	$200/30 days $1 200/year	
9	Non-Research Specimen Shipment Request	$20	
10	Late SAE Submission	$20/day	
11	Research Levy (Diplomas, Undergraduate, Masters and Exemptions are waived to pay)	1% of Total Budget Flat fee of $100 for studies with budgets <10 000	

Submission type	**Description**	**Regular Review Fee/US$**	**Expedited Review Fee/US$**
Individual researcher	New research application (individuals and institutions) Turn-around-time— Regular review: 4-6 weeks Expedited review: 10 business days	**500**	**1,000**
Annual Renewal	Renewal of ethics clearance which is done annually as part of ongoing monitoring and assessment of approved research Turn-around-time— Regular review: 4-6 weeks Expedited review: 10 business days	**100**	**200**
Protocol Amendment	Request to modify an approved study protocol Turn-around-time— Regular review: 4-6 weeks	**100**	**200**

	Expedited review: 10 business days		
Study Extension	Request to extend study timelines from the initially approved duration Turn-around-time— Regular review: 4-6 weeks Expedited review: 10 business days	**100**	**200**
Study Reopening	Application to re-open previously terminated research Turn-around-time: 4-6 weeks	**400**	**N/A**
Exemption from Full ethics Review	Application for exemption from full ethical review of research, which, at the discretion of the NREC and in line with exemption criteria, does not pose greater than minimal risk Turn-around-time: 10 business days	**200**	**N/A**

Research Levy

- Monitoring and administration fee, amounting to 1% of the total study budget, paid to MRCZ after the study receives full regulatory approval

ICH-GCP E6(R3) and Research Ethics Training

- Fee levied for the facilitation of synchronous in-person training in Research Ethics and ICH-GCP

Non-research Material Transfer Request

- Application to ship human biospecimens to a foreign territory for non-research purposes, such as external quality assurance programs (EQA)

Search Fee

- Administration fee for the reproduction of previously issued hard copy correspondence

SAE Late Submission Fee

- Punitive fee levied against investigators for reporting AEs and SAEs outside of the stipulated reporting windows

Late Renewal Penalty

- Punitive fee levied against researchers for late renewal of ethical clearance.

Payment details can be obtained from the MRCZ Finance Department.

Stage 4: Submit Your Application

Submit the complete application package electronically to mrcz@mrcz.org.zw

Incomplete applications will **not** be accepted.

Review Process

Stage 5: Application Acknowledgement

Once your submission has been received:

- MRCZ will acknowledge receipt of your application.
- A unique study reference number will be assigned.
- All future correspondence should quote this reference number.

Stage 6: Ethical Review

- Your application will undergo ethical review by the relevant MRCZ review committee.
- Researchers are advised to submit applications well in advance of their intended study start date.
- Submission deadlines and committee meeting dates are available on the MRCZ calendar.

Stage 7: Receive Reviewer Feedback

Following review, MRCZ will send comments, recommendations, and feedback via email.

Researchers should carefully address all reviewer comments.

- Applicants may be invited to an *ad hoc* meeting with members of the National Health Research and Development Committee, where necessary, to assist with the review process. This primarily helps with reducing the query loops and ultimately shorten lead times, thus improving efficiency.

Stage 8: Submit Responses to Comments

Researchers are expected to:

- Respond to reviewer comments within two weeks.
- Submit revised documents with tracked changes.
- Complete and submit the MRCZ Responses to comments Form.

Stage 9: Final Review and Decision

Response to reviewers' comments should be sent back to the MRCZ secretariat at mrcz@mrcz.org.zw. Once responses have been received, the application will undergo further review. Once the review is completed, the committee's decision will be communicated to the applicant.

Local Researchers

Full regulatory approval is issued when all queries have been adequately addressed.

Foreign Researchers

Foreign researchers will receive a Conditional Approval Letter.

Before final approval can be granted, researchers must:

1. Register the study with the Research Council of Zimbabwe (RCZ).
2. Present the required documents to MRCZ for official stamping and signature before RCZ submission.

Stage 10: Foreign Researcher Registration

- Pursuant to the requirements of the Research Act, foreign researchers are required to obtain clearance from RCZ before full ethical approval documentation can be issued.
- Once RCZ clearance has been received, researchers should collect the research permits from MRCZ

Post-Approval Compliance

Stage 11: Research Levy Payment

Before an unconditional letter of approval can be issued, applicants must settle the MRCZ Research levy.

Research Levy

- 1% of the total approved study budget.
- An invoice can be obtained from the MRCZ Finance Office.

Stage 12: Collection of Approval Documents

Once the research levy has been paid:

- The MRCZ Approval Letter will be issued.
- Researchers should bring clean final copies of:
    - The approved research proposal.
    - Informed Consent Forms.

- Assent Forms (where applicable).
- Data collection tools.

These documents will be stamped and endorsed by MRCZ.

Researchers may then collect their approval letter, documents, and commence the study in accordance with all approval conditions.

Research Execution

Stage 13: Research Implementation and Continued Monitoring

Approved studies must be conducted with the highest level of ethical and regulatory compliance and integrity. In keeping with MRCZ policy, ongoing approved research must be continuously monitored to ensure that the safety, rights, and welfare of study participants are upheld.

Annual Renewal

- Ethical clearance issued by MRCZ is valid for one year, and must be renewed without exception.
- The Principal Investigator is responsible for the timely submission of an annual renewal application (at least 3 months before the expiry of the approval date).
- While MRCZ may issue a reminder of the need to renew ethics approval, it is the responsibility of the Principal Investigator to apply for renewal before its expiration. Failure to do so will result in the accrual of punitive late renewal fees, study suspension, and possible termination.
- Before submitting your Protocol for Continuing Review (Annual Renewal), check that your submission package is aligned with MRCZ requirements as outlined in the checklist found in the MRCZ Annual Renewal Form
- Valid MRCZ approval must be held during the study round-up and data analysis as well.
- An up-to-date SAE Report Log must be completed and submitted as part of the annual renewal documentation, where applicable, to provide a comprehensive record of all reported Serious Adverse Events.

Protocol Amendment

- No deviations from or changes to the approved protocol should be initiated without prior documented MRCZ approval of an appropriate protocol amendment, except when necessary to eliminate immediate hazards to study participants.
- Before submitting your amendment application, check that your submission package is aligned with MRCZ requirements and that the standard MRCZ Amendment application form is completed

Protocol Deviation

- Any unplanned departure from the study's approved protocol should be documented and reported to MRCZ for review within 7 calendar days. The deviation is to be reported using the MRCZ Deviation form.
- An up-to-date Protocol Deviations Log must be completed and submitted as part of the annual renewal documentation, where applicable, to provide a comprehensive record of

all protocol deviations that occurred during the reporting period, including corrective and preventive actions taken

Adverse Event

- This is any unfavourable occurrence in a research participant. The adverse event does not necessarily have a causal relationship with the study. A serious adverse event (SAE) is any untoward medical occurrence in a research participant that results in death, is life-threatening, requires or prolongs hospitalization, or causes persistent or significant disability or incapacity, or leads to a congenital anomaly/birth defect. MRCZ requires that SAEs be reported within 3 calendar days of site awareness using the MRCZ SAE form. Adverse events (AEs) should be reported within 7 calendar days of the site becoming aware.

Study extension

- Should a study be projected to go beyond the initially proposed timeline, a study duration extension application must be submitted to MRCZ for review and approval. Before submitting your protocol for study extension, check that you have also completed the MRCZ Study Extension Form.

Study Termination

- Study termination is the process of the formal closure of the study after completion of research activities.
- The Principal Investigator is required to inform the RCZ and MRCZ of study closure by submitting the standard study termination form and aligning with the requirements outlined in the form checklists

Study Reopening

- Study re-opening is the process of seeking approval from the Medical Research Council of Zimbabwe (MRCZ) to resume a research study that was previously terminated.
- The Principal Investigator is required to submit the standard study re-opening application form together with all supporting documentation as outlined in the form checklist for review by MRCZ.
- No research activities may resume until formal written approval for study re-opening has been granted by MRCZ.
- Upon receipt of approval, the Principal Investigator is responsible for notifying all study personnel that the study has been re-opened and that research activities may recommence under MRCZ oversight.