

KABARAK UNIVERSITY

Research Ethics Committee

Potential Risks & Protection Procedures

Risk-Benefit Ratio and Conflict of Interest

Dr. Michael Walekhwa

Research Ethics Workshop for ISERC Reviewers | 14th May 2026



MICHAEL N. WALEKHWA

CONTACT & CONNECT

MOBILE +254 705 290 520 | +254 713 050 548

EMAIL walekhwam@gmail.com

INSTITUTION mwalekhwa@kabarak.ac.ke

WEBSITE www.michaelwalekhwa.com

LINKEDIN dr-m-n-walekhwa-336489159

ORCID 0000-0003-1337-1284

LOCATION Nairobi / Nakuru, Kenya

SESSION OVERVIEW

This session addresses four core domains of protocol review



01

Potential Risks



Identification, classification and risk assessment frameworks

02

Protection Procedures



Safeguards, mitigation protocols and monitoring obligations

03

Risk-Benefit Ratio



Ethical calculus and reviewer decision-making criteria

04

Conflict of Interest



Types, disclosure obligations and management protocols

CATEGORIES OF POTENTIAL RESEARCH RISKS



PHYSICAL

Bodily harm, pain, injury or illness from study procedures



PSYCHOLOGICAL

Distress, trauma, anxiety or lasting emotional harm



SOCIAL

Stigma, reputation damage or social exclusion



ECONOMIC

Financial loss, lost income or undue material burden



LEGAL

Criminal exposure, civil liability or privacy breach



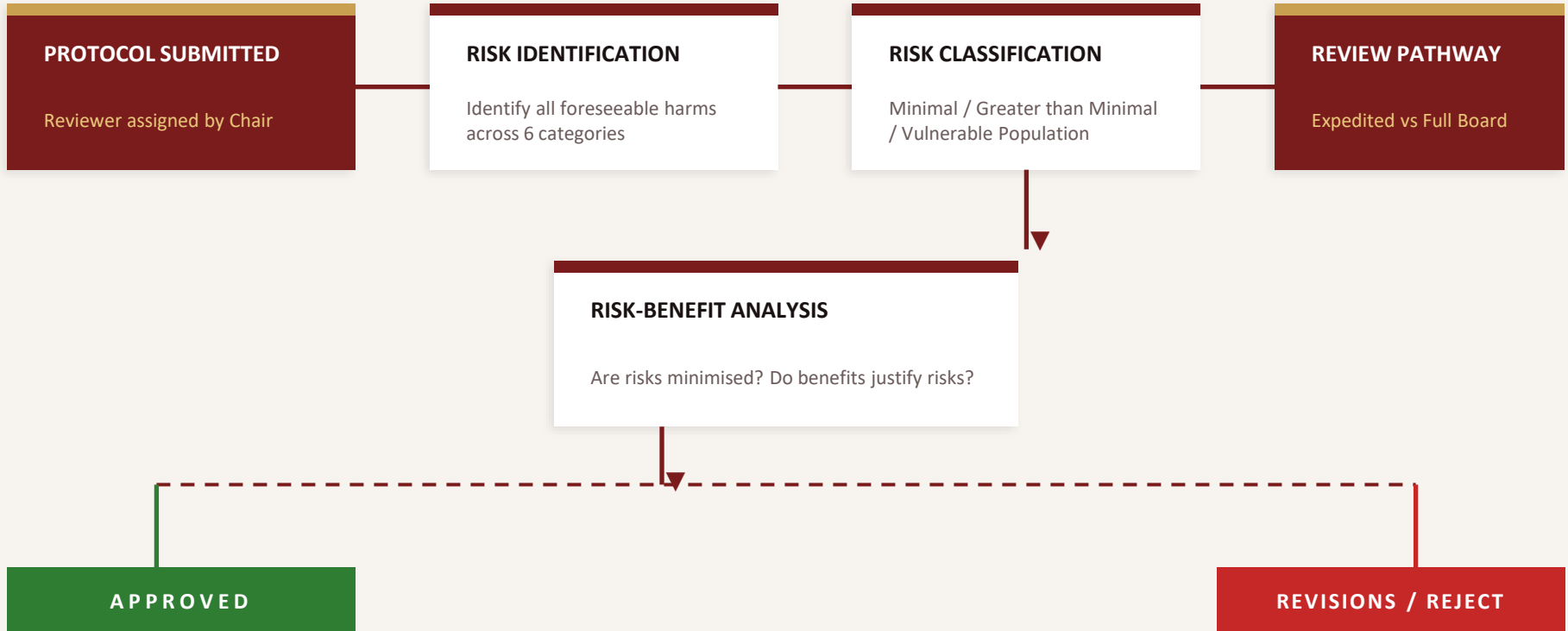
DIGNITY

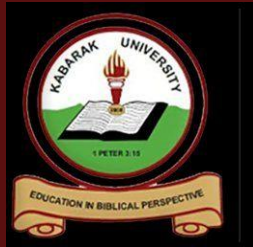
Violation of autonomy, culture or personal integrity

Scientific Integrity in Research

RISK ASSESSMENT FRAMEWORK

A structured review process for classifying and responding to research risk





KABARAK UNIVERSITY

Research Ethics Committee

REGULATORY BENCHMARKS

- The Belmont Report (1979)
- CIOMS Guidelines (2016)
- Kenya NACOSTI Framework
- ICH-GCP E6(R2)

01 MINIMAL RISK

EXPEDITED REVIEW
ELIGIBLE

Risks no greater than those in daily life or routine physical or psychological examinations. The researcher may apply for expedited review.

02 GREATER THAN MINIMAL RISK

FULL BOARD REVIEW
REQUIRED

Risk exceeds the standard threshold. Requires full committee deliberation, enhanced safeguards and robust consent documentation.

03 VULNERABLE POPULATIONS

HEIGHTENED
PROTECTION

Children, prisoners, pregnant women, cognitively impaired persons and economically disadvantaged groups require additional justification and enhanced protections.

PROTECTION PROCEDURES - CORE SAFEGUARDS

Protection procedures must be proportional to the nature and level of risk identified in the protocol.



PROCEDURAL

- Detailed inclusion and exclusion criteria
- Protocol adherence and monitoring
- Data Safety Monitoring Plan (DSMP)
- Standard Operating Procedures (SOPs)
- Independent safety board reviews



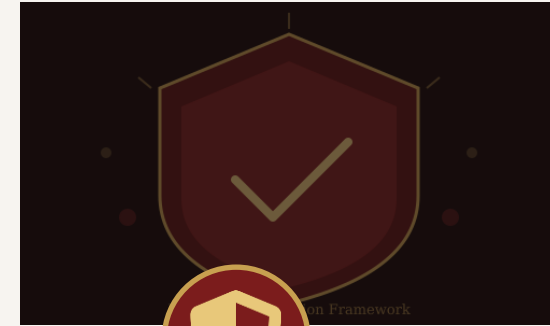
PARTICIPANT

- Free, prior and informed consent process
- Unrestricted right to withdraw
- Adequate compensation, no coercion
- Confidentiality and anonymisation
- Access to research results post-study



INSTITUTIONAL

- Ethics committee independent oversight
- Qualified, trained investigators
- Adequate facilities and equipment
- Insurance and indemnification cover
- Adverse event reporting systems



INFORMED CONSENT AS A PROTECTIVE MECHANISM

I

DISCLOSURE

Full information



All material risks, potential benefits, available alternatives, and the voluntary nature of participation must be communicated in plain, accessible language prior to enrolment.

II

COMPREHENSION

True understanding



The researcher must verify genuine comprehension, not mere signature. Special measures required for low-literacy populations, minors and cognitively impaired participants.

III

VOLUNTARINESS

Free from coercion



Consent must be free from undue influence, coercion or inducement. Power differentials between researcher and participant must be actively identified and mitigated.

RISK-BENEFIT RATIO — ETHICAL CALCULUS

Risks must be minimised and benefits maximised. No protocol is approvable where risks outweigh potential benefits.

RISKS TO PARTICIPANTS

Physical and psychological harm

Loss of privacy or confidentiality

Social stigma or discrimination

Economic burden or time loss

Therapeutic misconception

VS

BENEFITS OF RESEARCH

New knowledge for science and society

Direct therapeutic benefit to participants

Improved clinical or public health practice

Policy development and systemic change

Training and capacity building

The Reviewer's Seven-Point Checklist



- 1 Are all foreseeable risks identified and described with sufficient specificity in the protocol?
- 2 Are risks appropriately minimised through study design, procedures, and proposed safeguards?
- 3 Are the anticipated benefits realistic, specific, and not overstated or speculative?
- 4 Is the risk-benefit ratio favourable relative to the scientific or social value of the knowledge to be gained?
- 5 Are additional safeguards proposed and justified for any vulnerable participant groups?
- 6 Is there a robust plan for monitoring, documenting and responding to unexpected adverse events?
- 7 Have any anticipated risks been independently reviewed, piloted or otherwise empirically assessed?

CONFLICT OF INTEREST — DEFINITION AND SCOPE

DEFINITION

A conflict of interest arises when a researcher's, reviewer's or institution's secondary interests — financial, personal or professional — may compromise or appear to compromise the integrity of the research or its outcomes.



FINANCIAL

Equity in sponsor company, consultancy fees, sponsored travel, grants from parties with vested interests in outcomes



PERSONAL

Family relationships with participants or the PI, prior personal disputes, prior professional dependency



INTELLECTUAL

Prior public positions on study outcomes, competitive academic rivalry, reputational stakes in a particular result



INSTITUTIONAL

Institutional licensing deals, funding dependencies, reputational benefit to the university from specific outcomes

MANAGING CONFLICTS OF INTEREST — REVIEWER OBLIGATIONS

A four-step protocol for every reviewer, at every review meeting, without exception

1

IDENTIFY



Prior to each meeting, review your financial disclosures, personal relationships and professional positions relative to each protocol on the agenda.

2

DECLARE



Submit a written declaration to the committee chair before the meeting commences. Verbal-only declarations are not sufficient and are not recorded.

3

RECUSE



Absent yourself from all deliberations and voting on protocols where a conflict — real or perceived — exists. Do not merely abstain; physically leave the room.

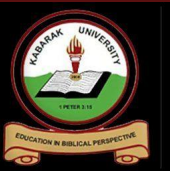
4

DOCUMENT



The committee secretary must record all declarations and recusals in the meeting minutes for transparency, regulatory compliance and audit purposes.

Ethics committee members bear an independent, non-delegable obligation to manage their own conflicts of interest.



KABARAK UNIVERSITY

Research Ethics Committee



MICHAEL N. WALEKHWA

Dr. Michael N. Walekhwa

PhD Medical Immunology | MBA Strategic Management

Senior Lecturer & HoD, Medical Laboratory Sciences
Kabarak University

+254 705 290 520 | +254 713 050 548

walekhwam@gmail.com

mwalekhwa@kabarak.ac.ke

www.michaelwalekhwa.com

ORCID: 0000-0003-1337-1284

EDUCATION IN BIBLICAL PERSPECTIVE

KEY TAKEAWAYS FOR REVIEWERS

Principles for Rigorous Ethical Review

ISERC Reviewer Workshop | 14th May 2026

01

Every protocol carries risks. Your duty is to assess them systematically, not assume they are negligible.

02

Protection procedures must be proportional to the level and nature of identified risk. Review critically.

03

The risk-benefit ratio must be independently and explicitly evaluated at every review. It cannot be assumed.

04

Informed consent is both an ethical obligation and a legal requirement. Assess substance, not paperwork.

05

Conflicts of interest, real or perceived, undermine public trust. Declare and recuse without exception.