Research Ethics Policy

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1. Purpose

This policy establishes the framework for the ethical review and approval of all research conducted under the auspices of the Sudanese American Medical Association (SAMA). It ensures that research conducted in **clinical, humanitarian, and educational settings** upholds the highest ethical standards while respecting the specific challenges of **low-resource contexts** such as Sudan.

2. Scope

This policy applies to studies that fulfil the following criteria:

- All research proposals submitted by **SAMA-affiliated researchers**.
- Research involving **human participants**, their data, or biological specimens.
- Studies were conducted in **Sudan**

External researchers or partners may only be involved if formally affiliated with SAMA for the duration of the research.

3. Guiding Principles

The policy is informed by the **Council for International Organizations of Medical Sciences (CIOMS)** and the National Research Ethics Guidelines issued by the National Research Ethics Committee, and is in compliance with the research regulations, laws, and directives that were in effect at the time of the study.

Core principles:

- **Respect for Persons:** Voluntary and informed participation.
- **Beneficence & Non-Maleficence:** Minimize harm and maximize potential benefits.
- **Justice:** Equitable selection of participants and fair distribution of burdens and benefits.
- **Cultural Sensitivity:** Respect local norms and the Sudanese context.
- **Participant Safety:** Special attention to the vulnerabilities arising from conflict, displacement, and limited healthcare infrastructure.

4. Ethics Review Committee (ERC)

4.1 Composition

- **Size:** Minimum **3** and maximum **7** members.
- **Expertise:** Members must have prior **research experience** and understanding of the **Sudanese context**.
- **Diversity:** Whenever possible, include members from different disciplines relevant to SAMA's work.
- **External Members:** At least one external member (who is not serving on the board of directors, advisory board, or any other position within the organization) may serve to ensure impartiality.

4.2 Appointment & Tenure

- Members are selected by the BOD-appointed Convenor of the committee and serve **two-year renewable terms**.
  First term ends **12/31/2026**.
- The **Convenor**, appointed by the BOD, facilitates committee operations and may only exercise a **tie-breaking vote**. Final approval is determined by a **majority vote** of the ERC members.

5. Submission & Review Process

5.1 Submission

- All research proposals must be submitted via the **SAMA online research portal**.
- Submissions must include:
  - Research proposal
  - Consent forms and participant information sheets
  - Data collection tools
  - Research ethics training certificate for all research team members

5.2 Review

- **Single-level review** is the default to maintain process efficiency.
- Proposals will follow one of two paths based on **risk assessment**, following the **CIOMS model and the vulnerability-risk matrix**:

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Expedited Review *(minimal risk)*:
- Applied to studies involving minimal or no potential harm.
- Reviewed by a **subset of ERC members** for faster turnaround.
- All submissions will be thoroughly scanned and assessed for risk and vulnerability by the administrative member, to then either send for expedited review by 1 reviewer or full review.

- **Full Review** *(greater than minimal risk)*:
  - Required for studies but not limited to **clinical interventions, experimental treatments, or sensitive humanitarian contexts**.
  - Requires **deeper scrutiny by the full ERC** before approval.

- Each committee member assigned to the review has **two weeks** to respond via a secure online survey link.
- A **simple majority approval (i.e., half +1)** is required to proceed.
- Decisions and rationales are communicated **in writing by email** to applicants.

6. Ethical Standards

The following are the general ethical standards that need to be read and understood within the National Research Ethics Guidelines of Sudan, the relevant international guidelines, mainly the Declaration of Helsinki in its latest version, and the research regulating jurisdictions in Sudan at the time of the study.

6.1 Informed Consent

- Participation must be voluntary and based on **clear, understandable consent forms**.
- Consent must be obtained in the **participant's preferred language**.
- Researchers must document any instances where written consent cannot be obtained, using witnessed verbal consent instead.

6.2 Protection of Sensitive Data

- defined as (e.g., personally identifiable information, medical records, genetic information, financial details, or any data that could reasonably lead to identification or harm if disclosed)
- All research-related data must be stored in **SAMA's secure cloud storage**.

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- While **formal data protection laws** are not required, researchers must ensure:
  - Use of secure storage systems.
  - Avoidance of unnecessary identifiers.
  - Restricted access to datasets.

6.3 Participant Safety

- Researchers must identify potential risks, particularly in **conflict zones** and **low-resource settings**, and outline **risk mitigation strategies**.
- Studies that may expose participants and researchers to significant danger, including but not limited to, are **not permitted**.

7. Training Requirements

All principal investigators must complete **research ethics training** before submitting a proposal. SAMA will provide access to recommended training modules.

8. Post-Approval Process

- Once a study is approved, the ERC's role **concludes**.
- No ongoing monitoring or periodic reporting is required unless specifically mandated by the Convenor in exceptional cases.
- Researchers are required to submit a **brief final report** to the ERC upon completion of the study, within a 6-month period following the writing up of the final report of the approved study.
- The report must:
  - Confirm compliance with approved protocols.
  - Summarize any **ethical issues encountered** and how they were addressed.
- These reports will be archived by SAMA for institutional learning and accountability.---

9. Appeals Process

- Researchers may **resubmit** revised proposals if rejected, , no later than 2 weeks from receiving the ERC's decision about their application.

- Final decisions rest with the **ERC majority vote**, with the Convenor acting only as a tie-breaker if required.

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10. Policy Oversight and Review

- The **ERC** will review this policy annually to ensure continued alignment with CIOMS guidelines and evolving ethical standards.
- Updates require approval by the **SAMA Board of Directors**.

11. Composition of the ERC 2025-2026

Name	Role
Ghaiath Hussein	External Member - Reviewer
Elwaleed Elhassan	External Member - Reviewer
Salaheldin Abusin	BOD representative - Non reviewer
Um Salma Hassan Ahmed Eltayeb	rapporteur

Approved by the Ethics Review Committee on 9/27/2025

Salaheldin Abusin

Secretary General

October 4, 2025