# SAHARA MEDICAL COLLEGE NAROWAL

## Research Ethics Evaluation Proforma

This proforma is designed to evaluate the ethical aspects of research proposals at Sahara Medical College

1. **Basic Information**

   - **Title of Research Project:** _____
   - **Principal Investigator (PI):** _____
   - **Co-Investigators:** _____
   - **Department:** _____
   - **Contact Information (PI):** _____
   - **Date of Submission:** _____

2. **Research Proposal Overview**

   - **Objective(S) of the Study:** _____
   - **Research Hypothesis:** _____

     _____
   - **Study Design:** _____
   - **Inclusion and exclusion criteria:** _____

     _____
   - **Sample Size:** _____
   - **Duration of Study:** _____
   - **Funding Source (if any):** _____

3. **Research Design and Methodology**

   - Is the research design appropriate to answer the research question? ☐ Yes ☐ No
   - Are the research methods adequately described? ☐ Yes ☐ No
   - Are data collection and analysis methods appropriate? ☐ Yes ☐ No
   - Is there a clear timeline for the study? ☐ Yes ☐ No

## 4. Subject Profile

**Age Range**

- 0-7 (Include parental consent form ☐ 8-17 (Include child's assent form and parental consent form)

18-64 ☐ 65 and older Exact ages to be included: ☐

**Vulnerable Populations:**

- Does the study involve vulnerable populations (e.g. children, pregnant women, prisoners, patients with sensitive medical Conditions e.g. HIV/AIDS, drug addiction)? ☐ Yes No ☐

**Location of subjects**

- Location of subjects during research activity or location of records to be accessed for research

**Sahara Medical College** ☐ **Sughra Shafi Medical Complex** ☐ **other specify** ☐

- Will the subjects be chosen from records? ☐
- If yes who gave approval for use of the records?

_____

## 5. Risks and Benefits

- Are there any potential risks to participants? ☐ Yes No ☐
- If yes, describe the risks:

_____

- What measures are taken to minimize these risks?

_____

- What are the potential benefits to participants or society?
- _____

## 6. Ethical Considerations

**Informed Consent:**

- Is informed consent required? ☐ Yes ☐ No
- Is the informed consent form attached? ☐ Yes ☐ No
- Is the consent process clearly explained in the proposal? ☐ Yes ☐ No

**Confidentiality:**

- How will participant confidentiality be maintained?_____
- Are data protection measures described? ☐ Yes ☐ No

**Participant Rights**

- For studies involving surveys or questionnaires, do participants have the right to questions and maintain their anonymity? Yes ☐ No ☐ N/A ☐

**Animal Research:**

- Does the study involve animal research? Yes ☐ No ☐
- If yes, is there an animal ethics committee approval? ☐ Yes No ☐

## 7. Potential Biohazards

- Does this study involve the handling, transportation, or storage of infections agents, toxins, or chemicals that are hazardous to humans, animals, or plants? Yes ☐ No ☐
- If so, have appropriate biosafety measures been put in place, including contamination control, spill response, waste management, protective apparel usage, and inventory management, to ensure the safe conduct of the project. Yes ☐ No ☐

## 8. Legal and Regulatory Compliance

Does the study comply with applicable local, national, and international regulations regarding human research, including data protection and confidentiality laws? ☐

9. **Declaration by Principal Investigator** I, the undersigned, declare that the information provided in this form is accurate and complete to the best of my knowledge.

**Signature of Principal Investigator:**

**Date of Submission to ERB/IRB:**

## 10. Ethical Review Committee Evaluation

**Ethical Review Committee Decision:**

- ☐ Approved
- ☐ Conditionally Approved
- ☐ Revisions Required
- ☐ Rejected

**Comments:**

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**Signature of Director Research Cell**

**Signature of Chairperson, Ethical Review Committee/Institutional Review Board:**

**Date:**