KABARAK UNIVERSITY

OFFICE OF THE DIRECTOR, RESEARCH, INNOVATION AND OUTREACH

RESEARCH ETHICS COMMITTEE

APPLICATION FOR FULL ETHICAL REVIEW

THIS FORM MUST BE NEATLY TYPED. (DO NOT TYPE ON THE REVERSE SIDE OF ANY FORMS). **Note: To check a box on this form, double-click the box and select "Checked" under "Default Value."**

Principal Investigator Name (print)	**Date**
Study Title	**Application Number** **(KUREC office only)**
Principal Investigator's Signature	

Please type only in the gray boxes. To mark a box as checked, double-click the box, select "checked", and click "OK".

Using non-technical language, describe the general purpose and nature of the study. Include a description of the study methods used to measure the objectives.

SECTION I: STUDY DESCRIPTION

Specify the locations for the proposed study

SECTION II: PERFORMANCE SITE

☐ Kabarak University Facility: ☐ Other Institution: ☐ Other Health Study Site:
☐ Other: Specify:

Please list other facilities not under the direct supervision of the investigator where research-related procedures will be performed (e.g. Health facility pathology, nursing, pharmacy, radiology, and

counseling etc.). ***You must ensure these persons/facilities are kept adequately informed about the study and their research-related duties and functions as they relate to the protection of human participants.***

SECTION III: PARTICIPANT POPULATION

A. State the Target Population for this study:

B. Use of Vulnerable Populations. *Check all participant population categories below for which there is a reasonable expectation of enrollment into this research study:*

- ☐ **Children** (Complete the Request Form for the Inclusion of Children in Research)
- ☐ **Cognitively Impaired** (Complete the Request Form for the Inclusion of Cognitively Impaired Individuals in Research)
- ☐ **Economically/Educationally/Politically Disadvantaged (including refugees and IDPs)**
- ☐ **Pregnant Women, Human Foetuses, or Foetal Material** (Complete the Request Form for the Inclusion of Pregnant Women, Human Foetuses, and Neonates in Research)
- ☐ **Prisoners** (Complete the Request Form for the Inclusion of Prisoners in Research)
- ☐ **Students** (When there is a teacher-student relationship dynamic, complete the following questions)

If any of the above populations will be recruited, you must submit the separate Request Form for the Inclusion of Vulnerable Populations in Research with this application.

C. ***Inclusion/Exclusion.*** *List specific eligibility requirements for participants, including those criteria which would exclude otherwise acceptable participants (e.g. inclusion/exclusion criteria), Data and safety monitoring plan and reporting on protocol violations.*

D. ***Number of Participants:*** *State the number of participants to be recruited both locally and nationally (if a multi-center studies). List total as a single number, rather than a range.*

SECTION IV: RECRUITMENT

1. Describe how potential participants will be initially identified (include specific source, e.g. databases, medical records, advertisements, newsletters, self-referral, physician referral, from clinics, etc.):

2. Describe how potential participants who are identified will be contacted (e.g. letter, phone call, face-to-face) and who will be contacting them (e.g. their physician, research coordinator, nurse, etc.). Include a copy of all information to be shared with or intended to be seen by potential participants.

Note: If your study includes recruitment incentives, explain such arrangements in Section XI.

SECTION V: STUDY PROCEDURES

List all methods by which information or data about or from participants will be obtained, including any drugs or devices to be used on human participants and all procedures/interventions that are being performed that would not otherwise be performed outside of the research study [e.g. an investigational drug, a blood draw that is taken purely for research (not treatment purposes) or a standardized survey that is being completed solely for the purposes of this research].

SECTION VI: POTENTIAL RISKS

State the potential risks – for example, physical, psychological, social, legal, loss of confidentiality or other – connected with the proposed procedures.

SECTION VII: PROTECTION PROCEDURES

1. Describe procedures for protecting against, or minimizing, the potential risks described in Section VI, including using procedures that are already being performed on subjects for diagnostic, treatment, or standard purposes, when appropriate.

2. Explain provisions to protect privacy interests of participants. This refers to how access to participants will be controlled (e.g. time, place, etc. of research procedures).

SECTION VIII: DATA SAFETY MONITORING PLAN

For all intervention studies that are **greater than minimal risk** a Data Safety Monitoring Plan must be developed. This is a plan to assure the research includes a system for appropriate oversight and monitoring of the conduct of the study to ensure the safety of subjects and the validity and integrity of the data. Names of all the individuals in the data safety monitoring board be submitted to IREC

☐ N/A. The intervention is minimal risk
☐ The DSMP is contained in the protocol. State where in the protocol the description is located: _____

NOTE: Ensure that all points outlined below are addressed in the description in the protocol. If any points are not addressed, within the protocol, they should be addressed below.

☐ The DSMP is NOT contained in the protocol; however, this is a repository/database protocol and the primary risk is that of loss of confidentiality; thus, I do not need to complete this section. Please see Section IX for confidentiality safeguards.
☐ The DSMP is NOT contained in the protocol. Complete the questions below

1. **Who will be responsible for the data and safety monitoring?** (Examples include: a DSMC or DSMB, medical monitor, investigator, independent physician) **Clarify if this individual or committee is independent from the sponsor and/or investigator.**

_____

2. **What will be monitored?** (Examples include: data quality, subject recruitment, accrual, and retention, outcome and adverse event data, assessment of scientific reports or therapeutic development, results of related studies that impact subject safety, procedures designed to protect the privacy of subjects)

_____

3. What are the procedures for analysis and interpretation of data, the actions to be taken upon specific events or endpoints, the procedures for communication from the data monitor to the IRB and site, and other reporting mechanisms?

4. **What is the frequency of monitoring?** (The appropriate frequency of data and safety monitoring will be dependent on the nature and progress of the research; however, monitoring must be performed on a regular basis (e.g, at least annually).

5. **What information will be reported to the IREC?** (Minimally, the IREC requires the following information at the time of continuing review: 1) frequency and date(s) of monitoring; 2) summary of cumulative adverse events; 3) assessment of external factors (i.e. scientific reports, therapeutic developments, results of related studies) that impacted the safety of subjects; 4) summary of subject privacy and research data confidentiality outcomes; and 5) any changes to the risk-benefit ratio.

SECTION IX: CONFIDENTIALITY & SAFEGUARDS

A. Check the items below to explain how confidentiality and privacy of data collected for the purpose of the research study will be protected

1. Data Source (Please check all that apply)

a. ☒ Treatment or Test Results, Medical and/or Dental Records, etc.:
- ☐ Paper
- ☐ Film
- ☐ Electronic

b. ☐ Interviews

c. ☐ Survey or Questionnaire
- ☐ Paper
- ☐ Electronic

d ☐ Video

e. ☐ Audio

f. ☐ Photographs

g. ☐ Other (Please describe): _____

2. Data Recording / Collection Method (Please check all that apply)

a. ☐ Computer:

b ☐ PDA (Personal Digital Assistant)

c. ☐ Paper (e.g. Notes, Case Report Form, etc.)

d. ☐ Video

e. ☐ Audio

f. ☐ Other (Please describe): _____

Please describe how you will safeguard data for all the Data Recording/Collection Methods described in Section IX.A.2. by completing #3, #4 and #5 below. Please check all that apply

3. Secure Storage

a. Who will have access to the individually identifiable information/data?

☐ Principal Investigator ☐ Research Coordinator ☒ Co-Investigators
☐ Governmental Agencies ☐ IREC or its designee
☐ Research Sponsor, Monitor, Other Research Organizations
☐ Other: _____

b Please describe the measures you are taking to safeguard the information/data:
☐ Locking cabinets and doors
☐ Information is located in an area with limited public access
☐ Computers and/or files will be password-protected
☐ PDAs and removable media (such as CDs, diskettes, etc…) will kept in a secure location
☐ Regular back-ups of electronic data.
☐ Describe any other measures you are using to safeguard the data: _____

4. Secure Disposal

a. How long will you retain the data before discarding?

☐ Minimum of 3 years for non-health data
☐ Minimum of 7 years for health data (if required by a governing body)
☐ Per sponsor requirements
☐ Indefinitely
☐ Other (Please describe): _____

b. How will you discard the data?
☐ Paper will be shredded ☐ Delete files from or destroy diskettes and CDs
☐ Permanently delete data from computers and PDAs ☐ Other (Please describe) _____

5. Sharing Data

For purposes of conducting this research, sharing may include releasing, transmitting or providing access to research and health data within the research team, outside the university, to research sponsors, etc. You must use reasonable safeguards when sharing any form of research data, health or non-health.

a. Will you share data in any of the following formats?
☐ Non-Health Data only.
☐ De-identified Data.
☐ Identifiable Data (i.e. includes patient identifiers, names, initials, Subject ID numbers, etc. - Please answer items 1. and 2. below.)
1. Indicate which secure method(s) of transmission will be used? Check all that apply:
☐ Secured web site
☐ Encrypted email
☐ Postal Service or other trackable courier services
☐ Fax in a secured area
☐ Shared drive with password protection
☐ Personal delivery by authorized research personnel
☐ Private telephone conversation to authorized personnel
☐ Other: (describe)

2. Will you share identifiable health data with anyone not listed on the Reviewer Guideline Form or the Authorization?
   1. ☒ No – Proceed to Section X.
   2. ☐ Yes – These people must be added to the Reviewer Guideline Form:

☐ Data will not be shared – Please explain: _____

SECTION X: STUDY BENEFITS

A. What, if any, benefit is to be gained by the **PARTICIPANTS**?

B. What information may accrue to **SCIENCE** or **SOCIETY**, in general, as a result of this work

SECTION XI: PAYMENT FOR PARTICIPATION

A. Will participants be paid for participation in the study (e.g. monetary, free services, gifts, course credit, including extra credit)?
☒ No. Proceed to Section XII.
☐ Yes. Complete items B., C., and D. below.

B. Explain the payment arrangements (e.g. amount and timing of payment and the proposed method of disbursement), including reimbursement of expenses. Note: Payments must accrue and not be contingent upon completion of the study. However, a small payment (bonus) for completion of the study may be approved by the IREC if it is found to not be persuasive for the participants to remain in the study.

C. Justify the proposed payment arrangements described in section B. (e.g., how this proposed payment arrangement is not considered to be coercive).

D. Explain if there will be any partial payment if theparticipant withdraws prior to completion of the study (e.g. prorated). Note: This payment may be paid at the end of the subject's participation or at the end of the study.

SECTION XII: RISK-BENEFIT RATIO

Describe how risks to subjects are reasonable in relation to anticipated benefits.

SECTION XIV: INFORMED CONSENT PROCESS

☐ Check here if this study will only enroll children and the parental/guardian permission (consent) process has already been explained on the Request Form for the Inclusion of Vulnerable Populations in Research. You do not need to complete section A below.

☐ **A. I WILL be obtaining informed consent from all participants.**

1. **When (in what timeframe) and where (what setting) will consent take place?**

2. **Who will be responsible for obtaining initial and ongoing consent? (check all that apply)**
   ☐ Principal Investigator

☐ Co-Investigator
☐ Other (specify):

NOTE: Individuals who will be obtaining consent must be listed in Section XVII of this document.

a. Explain how these individuals will be adequately trained to conduct the consent interview and answer subject's questions (check all that apply):

☐ **Passed the human participants protection test**
☐ **Received study-specific training**
☐ **Other (specify):**

b. Indicate in what language(s) the consent interview will be conducted.

☐ English
☐ Swahili
☐ Other (specify):

c. If the consent interview will be conducted in a language other than English/Swahili, state how the interview will be conducted (e.g. use of a translator):

NOTE: Ensure that language-appropriate consent documents are submitted with this application.

3. **Explain how participants' privacy will be protected during the consent process.** This refers to how access to subjects will be controlled (e.g. time, place, etc. of consent procedures).

4. **Describe steps taken to minimize the possibility of coercion or undue influence. (check all that apply)**
   ☐ There will not be any threat of harm or adverse consequences if the subject does not agree to participate in the study.
   ☐ The information provided during the consent process will be presented in a balanced way with equal emphasis on all elements of consent (e.g. there will not be over-emphasis of benefits and under-emphasis of risks).
   ☐ Other (specify):

☐ **B. I am requesting a <u>waiver of the informed consent process (i.e. no consent document)</u> for: (check all that apply):**
☐ **The entire study**
☐ **Recruitment only**
☐ **A specific minimal risk research activity or procedure that is part of the study. Specify:**

For the IERC to grant a waiver of informed consent, the below criteria must be satisfied. Please provide a response to each criterion.

1. The research involves no more than minimal risk to the subject. If you are requesting a waiver of informed consent for part of the study (e.g. recruitment or a specific minimal risk

activity or procedure), please state to which activity/procedure the waiver request applies and explain how this criterion is satisfied.

2. Explain how the waiver will not adversely affect the rights and welfare of the subjects.

3. Explain how the research could not be practicably carried out without the waiver.

4. Explain how, if appropriate, subjects will be informed of pertinent results at the conclusion of the study.

☐ **C. I am requesting a <u>waiver of *written documentation* of informed consent</u> (i.e. a consent process will occur verbally, but no signature will be obtained from the subject).**

NOTE: You must submit a written statement regarding the research, which must be provided to subjects upon their request.

For the IERC to grant a waiver of written documentation of informed consent, EITHER of the following criteria must be met. Please indicate which criterion is met and provide an appropriate response below.

☐ 1. The only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality, and the research is not regulated (e.g FDA). Each participant will be asked whether the subject wants documentation linking the participant with the research and the subject's wishes will govern. Please explain:

OR

☐ 2. The research presents no more than minimal risk of harm to participants and involves no procedures for which written consent is normally required outside of the research context. Please explain:

SECTION XV:

A. Has a proposal for funding been submitted to or is this study funded?
☐ No. Proceed to Section XVI.
☒ Yes.

B. Is this study a multicenter clinical trial that includes a centrally approved sample informed consent?
☒ No.
☐ Yes. Provide a copy of the centrally approved sample consent document.

SECTION XVI: INVESTIGATIONAL DRUGS/DEVICES

☒ N/A. No drugs or devices are being studied in this research.

If you are studying a drug or device, approval from Pharmacy and Poisons Board (PPB) is required.

INVESTIGATIONAL DRUGS

A. Name of Drug Sponsor:_____
Name of Drug: _____

B. Study Phase: ☐ I ☐ I/II ☐ II ☐ II/III ☐ III ☐ III/IV ☐ IV

INVESTIGATIONAL DEVICES

A. Name of Device Manufacturer:_____ Name of Device:_____

B. The IREC is required to determine whether or not the device is significant risk. To help in this determination, please provide the sponsor's documentation on the risk assessment and the rationale used in making the risk determination. ***Please provide the investigator's assessment of the device risk below***:

☐ Significant Risk (SR) Device ☐ Non Significant Risk (NSR) Device

Risk assessment and rationale for above risk determination:

SECTION XVII: INVESTIGATORS

List the principal investigator and any co-investigators and their respective departments. (If there are multiple investigators, please indicate only one person as the principal investigator; others should be designated as co-investigators).

A. **Principal Investigator**: Department/Designation (faculty /student)

B. **Co-Prinicipal Investigator** (or Faculty Supervisor in the case of Student Research)
Name Department

C. **Co-investigators**: Provide the name and department of other individual(s) assisting with the study who 1) will be responsible for the design, conduct, or reporting of the study, 2) have access to subjects (i.e. will consent subjects, conduct parts of the study), 3) will be making independent decisions about the inclusion or exclusion of participants, or 4) have access to identifying and confidential information.

1. List individuals from affiliated institutions who are directly interacting or intervening with subjects:
   Name Department

2. List individuals from affiliated institutions who are **not** directly interacting or intervening with subjects:
   Name Department

SECTION XVIII: CONFLICT OF INTEREST

1. Do any of the investigators listed in Section XVII (or their immediate family members) have a (potential) financial interest which relates to this research?

   Potential financial interests could include: stock ownership in the sponsor or manufacturer of the investigational item, compensation from the sponsor or manufacturer of the investigational item (excluding payments for conducting as outlined in the clinical trials agreement), patent or proprietary interest in the investigational item, employment relationship with the sponsor or manufacturer or the investigational item, and/or any other interest which may be perceived to interfere with the investigator's ability to protect subjects.

   ☐ No.
   ☐ Yes. The following investigators have a financial interest in this research:

   If any of the investigators listed in Section XVII have a financial interest in this research, the informed consent document must include the financial interest statement. Please see the Informed Consent Template for more information.

2. As per the Standard Operating Procedures of IERC, all investigators **MUST** declare their conflicts of interest .