KABARAK UNIVERSITY

OFFICE OF THE DIRECTOR, RESEARCH, INNOVATION AND OUTREACH

RESEARCH ETHICS COMMITTEE

REQUEST FORM FOR THE INCLUSION OF VULNERABLE POPULATIONS IN RESEARCH

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

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This form is to be completed for any research study targeting or reasonably anticipating enrolling vulnerable individuals (as referenced in the Reviewer Guideline form, section III).

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

- ☐ **Cognitively Impaired**
- ☐ **Children**
- ☐ **Economically/Educationally/Politically Disadvantaged (including refugees and IDPs)**
- ☐ **Pregnant Women, Human Fetuses, or Fetal Material or Neonates**
- ☐ **Prisoners**
- ☐ **Students**

For populations that are ticked complete the appropriate pages for each group and submit only those pages with this form:
Please type only in the gray boxes. To mark a box as checked, double-click the box, select "checked", and click "OK".

Cognitively Impaired: Section A
Children: Section B

Economically/Educationally/Politically Disadvantaged: Section C
Pregnant Women, Human Fetuses, Fetal Material or Neonates: Section D
Prisoners: Section E
Students: Section F

SECTION A: COGNITIVELY IMPAIRED INDIVIDUALS

1. Explain why it is necessary to involve cognitively impaired populations as participants for this research.

2. Explain how the participants' mental status will be evaluated to determine whether they are capable of consenting or assenting. Tests or evaluation instruments used must be included with the submission.

3. Is it reasonable to expect that during the course of the study, participants may lose their capacity to consent or assent or their ability to withdraw (e.g. research involving administration of or withdrawal from psychotropic agents)?
   ☐ No
   ☐ Yes. Please explain what provisions have been made to protect the participants' rights (e.g. legal guardianship, consenting a caregiver as well as the subject, etc.).

4. Explain how persons authorized to give legally valid consent on behalf of any individual(s) judged incapable of consenting on their own behalf will be identified and how they will be adequately informed of their roles and obligations for protecting the participant.

5. Will the patient's physician or another health care provider be consulted before any individual is invited to participate in the research?
   ☐ No
   ☐ Yes. Please explain.

6. In your opinion, is the research likely to interfere with ongoing therapy or regimens?
   ☐ No
   ☐ Yes. Please explain.

7. Are institutionalized individuals going to be involved in the research?
   ☐ No
   ☐ Yes. Please provide justification for the use of that population and explain why non-institutionalized subjects are not appropriate for this research and why they may not be reasonably available.

8. 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 participant does not agree to participate in the study.
- ☐ The information provided during the consent/assent process will be presented in a balanced way with equal emphasis on all elements of consent/assent (e.g. there will not be over-emphasis of benefits and under-emphasis of risks).
- ☐ Other (specify):

SECTION B: CHILDREN

1. State the necessity for involving children in the research:

IREC must determine which of the four categories of research apply to the study. As such, identify in which category it is believed the study falls and respond to the additional questions.

☐ **Category 1**: Research not involving greater than minimal risk to children.

Explain how adequate provisions are made for soliciting the assent of the children and the permission (parental/guardian informed consent) of each parent or guardian and provide justification if permission from only one parent or guardian will be solicited.

☐ **Category 2**: Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual child. The anticipated benefit must justify the risk and the relation of the anticipated benefit to the risk must be at least as favorable as that of alternative approaches**.**

Explain why the risk is justified by the anticipated benefit to the child.

Explain why the relation of the anticipated benefit to the risk is at least as favorable to the participants as that presented by available alternative approaches.

Explain how adequate provisions are made for soliciting the assent of the children and the permission (parental/guardian informed consent) of each parent or guardian and provide justification if permission from only one parent or guardian will be solicited.

☐ **Category 3**: Research involving greater than minimal risk and no prospect of direct benefit to the individual child, but likely to yield generalizable knowledge about the child's disorder or condition. The risk must represent only a minor increase over minimal risk, the intervention or procedure must present experiences to the children that are reasonably commensurate with those inherent in their actual, or expected medical, dental, psychological, social, or educational situations, and the intervention or procedure must be likely to yield generalizable knowledge about the children's disorder or condition which is a vital importance for understanding or amelioration of the disorder or condition.

Explain why the risk represents a minor increase over minimal risk.

Explain why the intervention or procedure presents experiences to the participant that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations.

Explain why the intervention or procedure is likely to yield generalizable knowledge about the participants' disorder or condition, which is of vital importance for the understanding or amelioration of the subjects' disorder or condition.

Explain how adequate provisions are made for soliciting the assent of the children and the permission (parental/guardian informed consent) of both parents and guardians unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.

☐ **Category 4** Research not otherwise approvable under one of the above categories, which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children.

Explain why the proposed research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children.

Explain how adequate provisions are made for soliciting the assent of the children and the permission (parental/guardian informed consent) of both parents and guardians unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.

NOTE. When research is covered by categories **§46.406** and **§46.407,** the informed consent must be obtained from both parents unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.

WAIVER OF CHILD ASSENT

☐ **I am not requesting a waiver of child assent. I will be obtaining assent from all children.**

I am requesting a waiver of assent:
☐ **For all children.**
☐ **For some children.**

Please indicate the type(s) of child assent waiver(s) you are requesting:
☐ Assent from children is not possible because the capability of the child(ren) is so limited the child(ren) cannot reasonably be consulted. Please explain.
☐ Assent from children is not possible because the intervention(s) or procedure(s) holds out the prospect of direct benefit that is important to the health or well-being of the child(ren) and is available only in the context of the research. Please explain.
☐ Assent from children will not be obtained because the study meets the adult criteria for waiving consent pursuant to 45 CFR 46.116(d). Please address how the following criteria are satisfied.

1. The research involves not more than minimal risks to the subjects. Please explain.

2. The waiver will not adversely affect the rights and welfare of the subjects. Please explain.

3. The research could not practicably be carried out without the waiver. Please explain.

4. Whenever appropriate, the subjects will be provided with additional pertinent information after participation. Please explain.

5. The research is not FDA-regulated.

NOTE: If the IERC grants a waiver of assent, the investigator will be required to make an accounting of the number of waivers employed, including the justification for the waivers, at the time of continuing review.

Although a waiver of child assent has been requested, <u>parental/guardian permission must still be obtained</u> (unless you are requesting a waiver of parental/guardian permission); thus, please explain the consent process for parents/guardians:

☐ **N/A. I am also requesting a waiver of parental/guardian permission. Continue to the Waiver of Parental/Guardian Permission (Consent) section below.**

1. **When (in what timeframe) and where (what setting) will parental/guardian permission (consent) take place?** Indicate any waiting period between informing the parent/guardian and obtaining their consent. The timeframe and any waiting should ensure the parent/guardian is provided sufficient opportunity to consider whether or not their child should participate in the study.

2. **Who will be responsible for obtaining initial and ongoing parental/guardian consent?** (check all that apply)
   - ☐ Principal Investigator
   - ☐ Co-Investigator
   - ☐ Research Coordinator
   - ☐ Other (specify): ☐

   a. Explain how these individuals will be adequately trained to conduct the consent interview and answer subject's or parent's/guardian's questions:

   b. Indicate in what language(s) the consent interview will be conducted (tick all that apply):
      - ☐ English
      - ☐ Kiswahili
      - ☐ Other (specify):

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

      NOTE: Ensure that language-appropriate parental/guardian consent documents are submitted with the application.

3. **Explain how subjects' and parents'/guardians' privacy will be protected during the consent process**. This refers to how access to subjects and parents/guardians 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/parent/guardian 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):

WAIVER OF DOCUMENTATION OF CHILD ASSENT

☐ **I am not requesting a waiver of documentation of child assent.**

I am requesting a waiver of documentation of child assent:
☐ **For <u>all</u> children.**
☐ **For <u>some</u> children.**

Check which of the following criterion is met:
☐ The only record linking the subject and the research would be the assent document and the principal risk would be potential harm resulting from a breach of confidentiality, and the research is not FDA-regulated. Each subject will be asked whether he/she wants documentation linking him/her with the research and the subject's wishes will govern.
Please explain:

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

WAIVER OF PARENTAL/GUARDIAN PERMISSION (CONSENT)

☐ **I am not requesting a waiver of parental/guardian permission (consent).**

☐ Parental/guardian permission (consent) will not be obtained because the study meets the criteria for waiving consent pursuant to 45 CFR 46.116(d). Please address how the following criteria are satisfied.

   ☐ Check here if the criteria have already been explained in the Waiver of Child Assent section above.

   1. The research involves not more than minimal risks to the subjects. Please explain.

   2. The waiver will not adversely affect the rights and welfare of the subjects. Please explain.

   3. The research could not practicably be carried out without the waiver. Please explain.

4. Whenever appropriate, the subjects will be provided with additional pertinent information after participation. Please explain.

5. The research is not FDA-regulated.

☐ Parental/guardian permission (consent) will not be obtained because the research is designed for conditions or for a participant population for which parental or guardian permission (consent) is not a reasonable requirement to protect the participants (for example, neglected or abused children), and **the research is not FDA-regulated**. Please explain.

1. An appropriate mechanism for protecting the children who will participate as subjects in the research must be used. The choice of an appropriate mechanism would depend upon the nature and purpose of the activities described in the protocol, the risk and anticipated benefit to the research participants, and their age, maturity, status, and condition. Please explain.

SECTION C: ECONOMICALLY/EDUCATIONALLY/POLITICALLY DISADVANTAGED

1. Explain why the proposed research must include economically, educationally or politically disadvantaged persons.

2. Does the research involve any monetary benefits or material goods that will be provided to the participants?
   ☐ **Yes. Explain:**
   ☐ **No**

3. If Yes, will these monetary benefits or goods constitute coercion or unfair inducement for participation in the study by participants who might otherwise refuse? Please explain:

4. What measures will be taken to ensure that participants fully understand the risks and benefits of the study and can make an informed voluntary decision for participation?

SECTION D: PREGNANT WOMEN, HUMAN FETUSES, FETAL MATERIAL OR NEONATES

State the necessity for involving pregnant women, human fetuses, and neonates in the research:

Indicate below the category that best fits your proposed research and answer the questions that immediately follow.

1. ☐ **<u>Research Involving Pregnant Women or Fetuses</u>**

Explain why the proposed research is scientifically appropriate, including descriptions of any pre-clinical studies on pregnant animals and any clinical studies conducted on non-pregnant women that have been conducted and provided data for assessing potential risks to pregnant women and fetuses.

a. Place a check in the appropriate box that best describes the anticipated risk to the <u>foetus</u>:

☒ not greater than minimal; or
☐ greater than minimal risk and the risk to the fetus is caused solely by interventions or procedures that hold out the prospect of direct benefit for the woman or the fetus.

Provide justification for the above anticipated risk selection:

b. Explain why any risk is the least possible for achieving the objectives of the research:
The blood that will be drawn from the participants of the study will be the same volume that is drawn as part of their routine prenatal visit.

c. Place a check in the appropriate box as it applies to this research:

☐No ☒Yes The research holds out the prospect of a direct benefit to the pregnant woman.

☐No ☒Yes The research holds out the prospect of a direct benefit **both** to the pregnant woman and to the fetus.

☐No ☐Yes The research does not hold out the prospect of a direct benefit for the woman or the fetus, but the risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge that cannot be obtained by any other means.

Note: If you answered "Yes" to any of the above, informed consent must be obtained from the pregnant woman or her legally authorized representative as required in 45 CFR 46.116 and 117. The informed consent process should include a clear explanation regarding the reasonably foreseeable impact of the research on the fetus.

☐No ☐Yes The research holds out the prospect of a direct benefit solely to the fetus.

Note: If you answered "Yes" to the above, informed consent must be obtained from the pregnant woman and the father as required in 45 CFR 46.116 and 117. The informed consent process should include a clear explanation regarding the reasonably foreseeable impact of the research on the fetus. The father's informed consent need not be obtained if he is unable to consent because of unavailability, incompetence, or temporary incapacity or the pregnancy resulted from rape or incest.

☐No ☐Yes The research will involve participants who are pregnant and meet the definition of "children" as defined in 45 CFR 46.402.

Note: If you answered "Yes" to the above, assent from the pregnant child and permission from her parent or legal guardian must be obtained in accordance with the provisions of 45 CFR 46, Subpart D.

d. Will there be any inducements, monetary or otherwise, offered to terminate a pregnancy?
☒No ☐Yes

e. Will individuals engaged in the research have any part in any decisions as to the timing, method, or procedures used to terminate a pregnancy?
☒No ☐Yes

f. Will individuals engaged in the research have any part in determining the viability of a fetus?

☒No ☐Yes

Describe the protections in place to protect the rights and welfare of the pregnant woman/fetus:

2. ☐ **Research Involving Neonates**

Until it has been ascertained whether or not a neonate is viable, a neonate may not be involved in research covered by Subpart B unless the following conditions are met:

a. Explain why the proposed research is scientifically appropriate and provide a description of any pre-clinical and clinical studies that have been conducted which provide data for assessing potential risks to neonates:

b. Will individuals engaged in the research have any part in determining the viability of a neonate?
☐No ☐Yes

☐ **Neonates of Uncertain Viability - Additional Requirements**

c. Place a check in the appropriate box below as it applies to this research:

☐ The research holds out the prospect of enhancing the probability of survival of the neonate to the point of viability, **AND** any risk is the least possible for achieving that objective, or

☐ The research has the main purpose of the development of important biomedical knowledge, which cannot be obtained by other means **AND** there will be no added risk to the neonate resulting from the research.

d. Explain the procedures that will be used to obtain legally effective informed consent of either parent of the neonate or, if neither parent is able to consent because of unavailability, incompetence, or temporary incapacity, the legally effective informed consent of either parent's legally authorized representative will be obtained as required by 45 CFR 46.116 & 117:

Note: These procedures must assure that each individual providing informed consent will be fully informed regarding the reasonably foreseeable impact of the research on the neonate. The father's informed consent need not be obtained if he is unable to consent because of unavailability, incompetence, or temporary incapacity or the pregnancy resulted from rape or incest.

☐ **Nonviable Neonates – Additional Requirements**

After delivery, a nonviable neonate may not be involved in research covered by Subpart B unless all of the following additional conditions are met:

e. Will the vital functions of the neonate be artificially maintained?
☐No ☐Yes

If "Yes", please describe:

f. Does the research include procedures to terminate the heartbeat or respiration of the neonate?
☐No ☐Yes

If "Yes," please describe:

g. Will there be any added risk to the neonate resulting from this research?
☐No ☐Yes

If "Yes," please describe:

h. Is the sole purpose of the research for the development of important biomedical knowledge that cannot be obtained by other means?
☐No ☐ Yes

If "Yes," please describe:

i. Explain the procedures that will be used to obtain legally effective informed consent of both parents of the neonate, or if either parent is unable to consent because of unavailability, incompetence, or temporary incapacity, the informed consent of one parent of a nonviable neonate will suffice except that the consent of the father need not be obtained if the pregnancy resulted from rape or incest. The consent of a legally authorized representative of either or both of the parents of a nonviable neonate will not suffice.

NOTE: These procedures must assure that each individual providing informed consent will be fully informed regarding the reasonably foreseeable impact of the research on the neonate.

☐ **Viable Neonates**
A neonate, after delivery, that has been determined to be viable may be included in research only to the extent permitted by and in accordance with the requirements of subparts A and D of 45 CFR 46 for the involvement of children as subjects in research. Please indicate "children" as a subject population involved in the research and respond to the appropriate additional requirements in Section III of the summary safeguard statement.

3. ☐ **<u>Research Involving, After Delivery, The Placenta, The Dead Foetus, Or Foetal Material</u>**

This research proposes to use the following: (Check all that apply)

☐ placenta	☐ the dead fetus	☐ macerated fetal material
☐ cells excised from dead fetus	☐ tissue excised from dead fetus	☐ organs excised from dead fetus

NOTE: The use of any of the above must be conducted in accordance with any applicable Federal, State, or local laws, regulations, and institutional policies regarding such activities.

a. Will any information associated with the material identified above be recorded for research purposes in such a manner that living individuals can be identified, directly or through identifiers linked to those individuals?
☐No ☐Yes

Provide a rationale for the above response:

NOTE: If you answered "Yes", those individuals are considered to be research subjects and all pertinent human subject regulations are applicable to their participation.

4. ☐ **Research Not Otherwise Approvable Which Presents an Opportunity to Understand, Prevent, or Alleviate a Serious Problem Affecting the Health or Welfare of Pregnant Women, Human Fetuses, or Neonates.**
This requires review by the Secretary of the Department of Health and Human Services (DHHS) and posting in the Federal Register for public comments and review.

SECTION E: PRISONERS

1. Explain the necessity for involving prisoners in this research:

2. Explain how the possibility of coercion or undue influence will be minimized when informed consent is being sought:
3. Will individual records from this research be available to prison authorities?
   a. If Yes, please explain the rationale for allowing prison authorities to view individual participant records:
4. Is it likely that prisoners involved in this research could suffer legal consequences or a change in the terms of their incarceration as a result of their participation?
   a. If Yes, please explain how this risk will be minimized:

SECTION F: STUDENTS

1. Clarify the necessity for involving students in the research:

2. Explain how the possibility of coercion or undue influence will be minimized when informed consent is being sought:

3. Explain what genuinely equivalent alternatives are available for students who wish not to participate: