MAKERERE UNIVERSITY

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COLLEGE OF HEALTH SCIENCES
SCHOOL OF MEDICINE

RESEARCH ETHICS COMMITTEE

March 27, 2026

Assoc. Prof. Nakimuli Annettee Olivia
Department of Obstetrics and Gynecology

Category of review
[ ] Initial review
[X] Continuing review
[ ] Amendment
[ ] Termination of study
[ ] SAEs

Dear Assoc. Prof. Nakimuli,

RE: REC REF No. 2022-300

Title: "Enhancing prediction of adverse pregnancy outcomes in Africa through partnerships and innovation"

Renewal Approval Date: 27th March, 2026
Project Expiration Date: 28th March, 2027

On behalf of the committee, I write to inform you that the **proposed extension has been approved.**

The Makerere University School of Medicine Research and Ethics Committee (REC) initially reviewed and approved the above-referenced protocol on 28th March, 2022. Previous approval of this protocol expires on 28th March, 2026.

The review by the committee has found that your renewal is consistent with the continued protection of the rights and welfare of human subjects which protection of human subjects is a partnership between the Research and Ethics Committee (REC) and the investigators. We look forward to working with you as we both fulfill our responsibilities.

Renewals: REC approval is valid until the expiration date given above. If you are continuing your project, you must submit an application for renewal at least six (6) to eight (8) weeks before the lapse date. If the project is completed, please submit an application for permanent closure.

Amendments: The REC must review any changes in the project, prior to initiation of the change. Please submit an Application for Amendments to have your changes reviewed and summarize the proposed change and the rationale for it in a letter to the School of Medicine Research and Ethics Committee. If changes are made at the time of renewal, please include an application for amendments with the renewal application.
In addition, submit three (3) copies of an updated version of your original protocol application- one showing all proposed changes in bold or 'track changes,' and the other without bold or track changes.

Adverse Events: If issues should arise during the conduct of the research, such as unanticipated problems, severe adverse events or any other problem that may increase the risk to the human subjects, notify the REC Chairman promptly. The forms are available to report these issues.

Please use the REC REF number listed above on any forms submitted which relate to this project/study.

Good luck in your research. If we can be of further assistance, please contact us at (+256) 0414 -533541 or via email at research@chs.mak.ac.ug/rresearch9@gmail.com. Thank you for your cooperation.

Yours sincerely,

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Dr. Aloysius Gonzaga Mubuuke
Vice Chairperson School of Medicine Research and Ethics Committee

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Enhancing prediction of adverse pregnancy outcomes in Africa through partnerships and innovation

By

Nakimuli Annettee Olivia, MBChB, MMed (obs/gyn), PhD

Associate Professor, Department of Obstetrics and Gynaecology

School of Medicine, College of Health Sciences

Makerere University

Calestous Juma Science Leadership Fellow of the Bill and Melinda Gates Foundation

FUNDER:

This research proposal is funded under Calestous Juma Science Leadership Fellowship Programme of the Bill and Melinda Gates Foundation.

MARCH 2022

Version 2.0

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Subject Study ID

ENGLISH CONSENT FORM

STUDY TITLE: ENHANCING PREDICTION OF ADVERSE PREGNANCY OUTCOMES IN AFRICA THROUGH PARTNERSHIPS AND INNOVATION

INVESTIGATORS

Dr Nakimuli Annettee Olivia, MBChB, MMed (Obs/gyn),PhD

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SPONSORSHIP AND FUNDING

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INFORMATION TO PARTICIPANTS

We would like to invite you to take part in a research study. Before you make up your mind it is important that you understand why the study is being done and what it would involve if you were to take part. Please read or listen to this information carefully and ask us if there is anything you don't understand or if you would like more information. You will be given as much time as you want to make a decision.

Background and rationale for the study:

The number of women and newborns dying during pregnancy and childbirth remains unacceptably high especially in Sub Saharan Africa (SSA). Pre-eclampsia, which is a fatal complication of pregnancy that is characterized by increase in a woman's blood pressure, is a major contributor to these deaths. There are also other contributors to these deaths that are a bit related in aetiology to pre-eclampsia and these include preterm labour, intrauterine growth restriction and stillbirth. They are collected called "the Great Obstetrical Syndromes (GOS)."

Efforts to identify women at high risk of pregnancy complications (such as pre-eclampsia) have been futile because current tests perform poorly. To address this, pregnancy follow-up studies have been conducted in high-income-countries (HIC) to develop better screening approaches but these studies poorly represent the biological and socio-economic conditions in SSA. Therefore, follow up studies of pregnancy women in SSA are needed to address this challenge.

Purpose:

We aim to conduct a follow-up study of Ugandan women, getting them immediately after conception. We shall perform repeated ultrasound scans and blood sampling throughout pregnancy and at the time of birth. We want to analyse the blood samples and ultrasound information to better understand what might cause adverse pregnancy outcomes and to develop improved methods for predicting which women are most likely to experience these complications. This study will also facilitate conducting more research in future.

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We are requesting you to participate in this study because you are attending Kawempe National Referral Hospital or Mulago Specialised Women and Neonatal Hospital for antenatal care, you are pregnant and you have not had any previous births (you may have had previous abortions or tubal pregnancies). You will receive your antenatal care as expected but in addition the study will have some experimentation. The experimentation will be the repeated ultrasound scans and blood sampling throughout pregnancy and at the time of birth. We plan to recruit 4000 women in this study. We plan to follow up each research participant up to the time of delivery.

Procedures:

Participation in the study will allow the research team to collect the information and samples which are required to study what causes the adverse pregnancy outcomes of interest and to develop better methods of predicting them. Hence, visits will include obtaining information through questions, making measurements during an ultrasound scan or obtaining blood samples. Specifically, participation in the study involves the following:

1. When you show willingness to participate in this study we shall perform an ultrasound scan on you to determine the gestational age of your pregnancy and the viability of the fetus. To be eligible the gestational age should be before 18 weeks of gestation and the fetus has to be alive.
2. At enrolment, some of your sociodemographic data (age, marital status, religion, your ethnicity and that of your parents, the ethnicity of your spouse and his parents, address, and educational level) will be collected using an interviewer-administered questionnaire. We shall collect some clinical details about you as well as perform some physical examination.
3. We shall ask for your mobile phone number and that of your next of kin or friend and this is for purposes of easily contacting you in case there is need. These phone contacts will be only known to the researchers closely working on this study. For

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example, we shall call you between the visits so as to keep updated on how you are doing and to remind you of upcoming visits.

4. At enrolment we will ask you to give a 15ml blood sample –three tea spoon full - taken through a needle from a vein in your arm. This would cause no more discomfort than any of the other routine blood tests that you might have had before. Seven mls of the blood drawn will be used to carry out tests that should be routinely done for all pregnant women and these include; check the amount of blood that you have and the status of some of your blood cells, functioning of your kidneys and liver, HIV status, syphilis status. In addition to these routine tests, some of the blood will be used specifically for experiments of this study and as follows; 8 mls will be used to test for substances in your blood called biomarkers that could make us better understand what might cause pre-eclampsia and to develop improved methods for predicting which women are most likely to experience pre-eclampsia and its severe complications.
5. We shall also do additional routine tests on you. We shall prick one of your fingers to get a drop of blood that will be used to check whether you have malaria or not. After the prick, you will feel some pain at the site for about 2 minutes but this should be bearable. We shall also take off about 10 mls of your urine –two tea spoon full and this will be used to measure the amount of protein in your urine using a dipstick and check for cells, casts and glucose.
6. We plan to follow you up at three time points in pregnancy (at 20, 28 and 36 weeks of gestation) and at the time of delivery. We shall try to make these visits to coincide with your regular antenatal care visits for your convenience. You will still be expected to attend any other visits scheduled by the hospital team that cares for you, outside the research related visits.
7. At each antenatal follow up visit, more clinical information and a physical examination will be performed (in particular blood pressure and urine protein measurement). You will also have further scans and blood sample collection of 10 mls which will be used to get serum and plasma to be used for analysis of

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biomarkers that predict pre-eclampsia. At the 20 weeks visit an additional 3mls of blood will be taken off and stored for DNA extraction in future. Separate consent will be sought for storage of this whole blood and the remaining serum and plasma (after the initial analysis), such that it can be used for future studies.

8. The scan at around 20 weeks will take place as normally and is routinely done to assess the fetal anatomy (how the baby has formed/developed). Any findings from that scan will result in the same care as if you were not participating in the study. We will obtain some further measurements at the time of the scan but this will not affect your care.
9. You will have research scans at around 28 and 36 weeks. These are scans that you would not normally have as part of routine care. We will let you know if these scans demonstrate any serious problem with the baby. Otherwise, we will simply use the information for the purposes of research.
10. At delivery, we will record details of labour, delivery and pregnancy outcome including data on duration of labour, mode of delivery and intrapartum complications. Routine data from the baby (weight, sex, Apgar score) will also be collected. We will take samples of the umbilical cord for DNA (a 2 cm piece), 10mls of maternal blood for serum and plasma samples for a viral screen and samples of the placenta to make formalin-fixed blocks for histology of placentas and membranes. 10 mls of cord blood will be taken for isolation serum for future studies. Study participants and their babies will be reviewed 6 weeks after delivery as a routine and not for research purposes. From your perspective, delivery is the last point of contact with the study and there is nothing else we will be asking you to do. However, it is possible that we may contact you at some point in the future to see if you are interested in taking part in follow up studies. We would involve a separate consenting process and you would not be under any obligation to agree.

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Risks/Discomforts:

This is a minimal risk study. Drawing blood from you would cause no more discomfort than any of the other routine blood tests that you might have had before. The amount of blood to be taken off at the different time points will not make you anaemic if you regularly take your tablets of iron and folic acid as is recommended for all pregnant women. The process involved in using the ultrasound scan is painless and non-invasive. Some of the information collected may be sensitive but privacy and confidentiality will be ensured to minimize risk of this information getting to other parties.

Benefits:

It is recommended that ultrasound scan is performed in early pregnancy for accurate estimation of gestational age of the pregnancy but ultrasound is not currently available on a routine basis in Kawempe Hospital (and indeed in most hospitals in SSA) and when requested for it is done at a fee. The benefit of this study is that you will be able to get the dating scan and extra scans at no cost. The main benefit is the possibility that the extra ultrasound scans might provide useful information that may help the doctors attending to you. These are the five things we will tell you from these extra scans.

1. We will let you know if the placenta is low at the time of the research scans at 28 and 36 weeks of gestation.
2. We will inform you if we found that your baby had an abnormality at the time of the research scans at 28 and 36 weeks of gestation. However, both of these can usually be seen at the 20 week scan and it is uncommon to see abnormalities for the first time in later pregnancy.
3. We will let you know whether your baby is presenting head first or bottom first. At 28 weeks, this is for interest only. But this is useful to know at 36 weeks.
4. We will tell you if the fluid around the baby is severely reduced at the time of the research scans at 28 and 36 weeks of gestation.
5. We will tell you if the baby is dead at the time of the research scans at 20, 28 and 36 weeks of gestation.

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In the event of any of the above, we will refer you to a doctor within Kawempe or Mulago Hospital, as appropriate.

Confidentiality:

Doctors or research nurses/midwives will review your medical records. The information collected will be kept with maximum confidentiality in locked up cupboards or filing cabinets. All information will be kept anonymous so you cannot be recognized from it. Only staff employed to work on this project will access your study-related information. The results of the routine tests performed on your urine, blood and ultrasound scan will be revealed to you as soon as possible and if there is need for treatment you will be informed immediately and linked to the appropriate clinics. The local Research Ethics Committee; Makerere University School of Medicine Research Ethics Committee (SOMREC) and Uganda National Council for Science and Technology (UNCST) as entities may have access to private information that identifies the research participants by name.

Alternatives:

Participation in the study is not mandatory and if you choose not to participate this would not affect your medical care received from this hospital.

Cost:

The cost of the four study related ultrasound scans (at booking, 20 weeks, 28 weeks and 36 weeks) and the baseline routine antenatal tests will be met by the research project.

Reimbursement and compensation for participation in the study:

At each of the follow up visits, a modest transport refund of 30,000/= will be given to you. Refreshments and snacks worth 5,000/= will be provided during each follow up visit. This being a minimal risk study therefore no major injuries anticipated. If you are injured during the course of participation, you will be offered emergency care which is freely available at Kawempe Hospital. If there is need to refer you, this will be done by the study research team.

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Statement of voluntariness:

You are entirely free to choose if you want to take part or not. If you would prefer not to do so you would not need to give a reason. You can also withdraw from the study at any time if you feel you need to stop. This would not affect your medical care received from this hospital. We cannot guarantee to discover anything that would directly benefit you or your family.

Dissemination of results:

You will get feedback on findings and progress of the study and any new information that affects the study or data that has clinical relevance to you (including incidental findings) will be made available to you and/or your health care providers.

Ethical approval:

This study has been approved by the School of Medicine Research and Ethics Committee (SOMREC) and the Uganda National Council for Science and Technology.

QUESTIONS ABOUT THE STUDY

If you have any questions related to this study you may ask them now or later. The questions can be directed to the following people:

1. **Associate Professor Annettee Nakimuli** Tel: 0772 471618

2. Study coordinator or Nurse Tel: 0784022693 or 0709891405 or 0780524451 or 0707008546

QUESTIONS ABOUT PARTICIPANTS' RIGHTS

If you have any problems, concerns, or complaints concerning the study please contact the following people:

1. **Assoc Prof Ponsiano Ocama** (Chairman of the School of Medicine Research and Ethics Committee at the College of Health Sciences, Makerere University)

Tel: +256-772421190 Email: rresearch9@gmail.com

2. **Uganda National Council for Science and Technology** Tel: +256-414750500

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Statement of Consent

---------- has described to me what is going to be done, the risks, the benefits involved and my rights regarding this study. I understand that my decision to participate in this study will not alter my usual medical care. In the use of this information, my identity will be concealed. I am aware that I may withdraw at any time. I understand that by signing this form, I do not waive any of my legal rights but merely indicate that I have been informed about the research study in which I am voluntarily agreeing to participate. A copy of this form will be provided to me.

_____	_____	_____
Date	Signature/thumbprint	Name of participant

In case of illiterate participants

_____	_____	_____
Date	Signature/thumbprint	Name of Witness

_____	_____	_____
Date	Signature of Researcher	Name of Researcher

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