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

INFORMED CONSENT FOR STORAGE OF BIOLOGICAL SPECIMENS FOR FUTURE USE

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

INFORMATION TO PARTICIPANTS

Thank you for accepting to participate in the research study aimed at developing improved methods for predicting which women are most likely to experience adverse pregnancy outcomes. We would now like seek permission from you to store some of your samples for use in future studies. Before you make up your mind it is important that you understand why we need to store your samples for future use 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.

Quantities of samples to be stored

As we have already explained, at enrolment in the study we will ask you to give a 15ml blood sample –three tea spoon full - taken through a needle from a vein in your arm. Seven (7) 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 adverse pregnancy outcomes and to develop improved methods for predicting which women are most likely to these pregnancy complications. We would

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like to store a 2mls serum sample and 2mls plasma for future analysis of biomarkers important in pre-eclampsia and other pregnancy complications.

We plan to follow you up at three time points in pregnancy (at 20, 28 and 36 weeks of gestation). At each visit 10ml of blood will be taken off for serum and plasma to be used for analysis of 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. DNA can be used in future to investigate the genes that predispose someone to getting pre-eclampsia and its complications. We request for storage of this whole blood and the remaining serum and plasma (after the initial analysis), such that they can be used for future studies. This is expected to amount to 3 mls of plasma and 3 mls of serum.

Delivery is the last point of contact with the study. At delivery, we will take samples of the umbilical cord for DNA (a 2cm 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 of serum for future studies. We request for storage of all these samples, such that they can be used for future studies.

In summary, we request to store the following samples in total; 21 mls of serum, 21 mls of plasma, 3mls of whole blood, 2cm piece of umbilical cord, 10mls of cord blood serum and four $2cm^3$ placental cubes and membranes.

Purpose of sample storage

Due to insufficient resources, we are unable to do these lab tests now but this could be possible in future. Additionally, the purpose of this work is to alleviate the problem of pre-eclampsia and other pregnancy complications. If the research were successful there would undoubtedly be further questions that may need to be further investigated. It is therefore important to store some samples in a secure and anonymous way to allow the research to continue without necessarily collecting samples from new volunteers.

Subject Study ID

Place where samples will be stored

The samples will be stored in the biorepositories located at Makerere University College of Health sciences.

Measures to protect confidentiality

The information collected from you will be kept with maximum confidentiality. All information concerning your stored samples will be kept anonymous so you cannot be recognized from it.

Policies that will govern use of the samples in future research

Any future studies using these stored samples would be concerned with addressing the problem of pre-eclampsia and other pregnancy complications related to placental dysfunction (preterm birth, intrauterine growth restriction, stillbirth). There would be no selling of samples to commercial organisations for profit. Only studies approved by the Research and Ethics Committees of the College of Health Sciences Makerere University would be undertaken. A Ugandan scientist shall be included as co-investigator in all future studies using these samples.

Potential risks and benefits of storing samples for future research

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. All information concerning your stored samples will be kept anonymous so you cannot be recognized from it. There are no obvious benefits for storage of these samples for future use. You will however have participated in widening the frontiers of scientific knowledge.

Voluntarism

You shall not be penalized for your refusal to store the samples. You reserve the right to withdraw your samples from storage if the samples are linked or without giving a reason.

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Refusal to have your samples stored would not affect your medical care received from this hospital.

WHOM SHOULD I CONTACT IF I HAVE ANY QUESTIONS OR PROBLEMS?

If you have any questions about your storage of samples for use in future studies 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

If you have any problems, concerns, or complaints concerning the storage of your samples please contact the following people:

1. Assoc Prof Ponciano 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 to use records and samples for future studies

---------- has asked me for permission to use my records and samples for future studies concerning pre-eclampsia and other pregnancy complications related to placental dysfunction. I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction. I consent voluntarily to have my records and samples stored for use in future studies.

_____	_____	_____
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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