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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RENEWAL
VALID UNTIL
28 MAR 2027
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P.O. BOX 7072, KAMPALA

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

Data analysis:

The use of a prospective cohort study design allows multiple subsequent analytic approaches. The three main methods of analysis will be (1) **analysis of the entire cohort**, (2) **analysis as case cohort studies**, (3) **analysis as nested case control studies**. As examples, for exposures (objective 1) or biomarkers/ultrasound findings (objective 2) available for all participants, analysis of the entire cohort will be used and logistic regression analyses will identify epidemiological, clinical, and laboratory parameters predictive of pre-eclampsia or other GOS. Associations will be estimated using risk ratios and 95% confidence intervals (CI).

In a case cohort design, all women experiencing the outcome of interest will be identified and a random sample of the cohort also obtained (Sharp, Poulaliou, Thompson, White, & Wood, 2014). All women who develop pre-eclampsia or any GOS will be compared to a random sample of the cohort who will have not developed that outcome of interest by the time of delivery. We shall assess the relationship between the sFLT1:PlGF ratio with and without serial ultrasound data, and the risk of GOS. Analysis will be performed using logistic regression as for objective 1, but the data from the comparison group will be statistically weighted by the inverse of the sampling fraction to allow calculation of screening statistics, such as positive predictive value, sensitivity and specificity.

The nested case control approach will be used where assays are expensive or laborious, such as in studies comparing the placenta in cases of stillbirth, and when using DNA sequencing-based approaches to detect pathogens (viral, bacterial or eukaryotic).

We will focus on AI techniques to extract and calibrate features, variables and risk factors from the socio-epidemiological data to be collected [5]. The data will then be used in training AI-based model(s) that integrate socio-demographic and clinical/pregnancy outcomes on the one hand, with GOS outcomes on the other to simultaneously ascribe their dynamic effect sizes in varying circumstances. That calibration could inform early interventions through helping optimize service delivery models to improve the prevention, tracking, management and treatment of women with GOS. This would not only help quantify the relative contributions of biological versus socio-demographic factors to GOS but also bolster the implementation of the problematic last mile in the mitigation of the GOS.

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