STANDARD CONSENT FORM TEMPLATE

TITLE: The impact of molecular diagnosis of malaria with LAMP on maternal and fetal outcomes: A pilot prospective diagnostic study.

SPONSOR: Grand Challenges Canada.

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This consent form is only part of the process of informed consent. It should give you the basic idea of what the research is about and what your participation will involve. If you would like more detail about something mentioned here, or information not included here, please ask. Take the time to read this carefully and to understand any accompanying information. You will receive a copy of this form.

BACKGROUND

1) Background & Rationale
Malaria is a major killer of pregnant mothers and neonates. Diagnostics rely on microscopy and rapid tests at present which lack sensitivity leading to undiagnosed cases.
(2) Research Question & Objectives
A new malaria test called LAMP is more sensitive and in pilot data was superior to microscopy and rapid tests. We predict that a better malaria test like LAMP will reduce maternal and infant morbidity and mortality.
(3) Methods
We will randomize mothers to standard testing versus enhanced testing with standard of care plus LAMP to see if LAMP detects additional cases. We will follow the mothers out to delivery and measure the following outcomes:
a. maternal/infant mortality
b. maternal/infant anemia
c. infant birth weight

WHAT IS THE PURPOSE OF THE STUDY?

To determine the effect of LAMP testing for malaria in pregnant mothers in NW Ethiopia

WHAT WOULD I HAVE TO DO?

For this study blood samples will be collected and examined for the presence Plasmodium (Malaria) species as is customary at the antenatal clinic. You are selected as one of the study participants. If you are willing to participate you are kindly requested to give blood sample to the sample collectors.

WHAT ARE THE RISKS?

By participating in this research project you may fill discomfort due to wasting your time about 10-15 minute for sample collection and for provision of information. There is no other risk in participating in this study project.

ARE THERE ANY REPRODUCTIVE RISKS?

None

WILL I BENEFIT IF I TAKE PART?

If you participate in this research and if you are found to have malaria parasitic infection, you may be able to receive appropriate treatment more quickly. We will facilitate diagnosis and

medication in the health center. More over your participation helps as to assess the quality of diagnosis in malaria which will ultimately reduce the morbidity and mortality associated with pregnancy-related malaria.

DO I HAVE TO PARTICIPATE?

You have full right to refuse from participating in this research and you can refuse to give specimen

WHAT ELSE DOES MY PARTICIPATION INVOLVE?

None.

WILL I BE PAID FOR PARTICIPATING, OR DO I HAVE TO PAY FOR ANYTHING?

There is no money given for your participation.

WILL MY RECORDS BE KEPT PRIVATE?

The information collected from you will be kept confidential. It will be stored in a file using codes without your name. And it will not be used only for this particular research revealed to anyone except the principal investigator. In addition it will be used any for this particular research but not other purpose.

IF I SUFFER A RESEARCH-RELATED INJURY, WILL I BE COMPENSATED?

In the event that you suffer injury as a result of participating in this research, no compensation will be provided to you by Grand Challenges Canada, the University of Calgary, Alberta Health Services or the Researchers. You still have all your legal rights. Nothing said in this consent form alters your right to seek damages.

SIGNATURES

Your signature on this form indicates that you have understood to your satisfaction the information regarding your participation in the research project and agree to participate as a participant. In no way does this waive your legal rights nor release the investigators or involved institutions from their legal and professional responsibilities. You are free to withdraw from the study at any time without jeopardizing your health care. If you have further questions concerning matters related to this research, please contact:

Dr. _____ ( ) ___-____

Or

Dr. _____ ( ) ___-____

If you have any questions concerning your rights as a possible participant in this research, please contact the Chair, Conjoint Health Research Ethics Board, University of Calgary at 403-220-7990.

Participant's Name	Signature and Date
Investigator/Delegate's Name	Signature and Date
Witness' Name	Signature and Date

The University of Calgary Conjoint Health Research Ethics Board has approved this research study.

A signed copy of this consent form has been given to you to keep for your records and reference.