Study Title: Assessing SARS-CoV-2 seroprevalence from routine antenatal care visits in Zambia

Version Date: 16 February 2021

Appendix I: Participant Information Sheet - English

Centre for Infectious Disease Research in Zambia (CIDRZ)
Consent to Participate in a Research Study
Participant Enrolment
Biomedical Form

Title of study: Assessing SARS-CoV-2 seroprevalence from routine antenatal care visits in Zambia
IRB Study #:
Consent Form Version Date: Version 1.0, 16 February 2021
Protocol: Version 4.1, 13 June 2021

Principal Investigator: Izukanji Sikazwe, M.D. Centre for Infectious Disease Research in Zambia (CIDRZ)
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Co-Investigators: Professor Lloyd Mulenga; Sombo Fwoloshi, Muzala Kapina, Nyambe Sinyange, Carolyn Bolton, Theodora Svaory, Jonas Hiness, Elizabeth Heilmann
Funding Source and/or Sponsor: US Centres for Disease Control and Prevention
Study Contact telephone number: +260 0211 293 772

What are some general things you should know about research studies?
You are being asked to take part in a research study. Joining the study is voluntary. You may refuse to join or withdraw your consent to be in the study at any time and for any reason. Research studies are designed to obtain new information. This information may help other people in the future. You may not receive any direct benefit from being in research studies. There also may be risks to being in research studies. Deciding not to be in the study or leaving the study before it is done will not affect your relationship with the researcher or your health care provider. If you are a patient with an illness or the caretaker of a child with an illness or possible illness, you do not have to be in the research study in order to receive, or have your child receive, health care.

Details about this study are discussed below. You want to make an informed choice about being in this research study. You will be offered a copy of this consent form. You should ask any questions you have about this study at any time.

This is an information sheet. It gives you information about this study. The study staff will talk with you about this information. You are free to ask questions about this study at any time. If you decide that you would like to take part in this study, we will ask you to sign or thumbprint the consent form on the last page of this information sheet.

What is the purpose of this study?
COVID-19, caused by the virus SARS-CoV-2, is spreading rapidly across the globe. The Ministry of Health would like to better understand the spread in Zambia. It is important to try and understand how many people have the virus and recover without having symptoms. By looking at the rate of infection among pregnant women, we hope to gain an understanding of what has happened in this area.

How many people will take part in this study?
Women attending first antenatal care visits at selected facilities in Chadiza, Chipata, Chongwe, and Lusaka districts will be approached to take part in this study. Up to 200 women per district per month will take part over a period of 12 months.

How long will your participation in this study last?
Your participation in this study will last about 10 minutes to answer the questionnaire and take a blood sample.

What will happen if you take part in the study?
If you agree to participate in the research, we would like to ask you some questions about your health and test you for antibodies to SARS-CoV-2. This will tell us if you had the virus in the past. A healthcare worker will collect a few drops of blood from your finger onto a filter paper for antibody testing. Your name will not be on the filter paper. We will not be able to provide you with the results for the SARS-CoV-2 antibody test. The filter paper will be safely stored at the clinic until the study team takes it to the hub laboratory for testing.

What are the possible benefits from being in this study?
There are no direct benefits to participating in this study. You will not be paid for taking part in the study. What we learn in the study may help us in our efforts to control the spread of SARS-CoV-2 in Zambia.

What are the possible risks or discomforts involved with being in this study?
There is little risk to you from taking part. You will feel a pinch that lasts a few seconds when we take the blood for testing. There is a very small risk of infection, but we will clean your finger thoroughly to prevent infection. You may feel embarrassed, anxious, worried, and/or uncomfortable talking about your opinions and experiences around SARS-CoV-2. You do not have to answer any question you do not want to and you can stop the discussion at any time. Research team members will state their commitment to confidentiality. Whatever you share during the interview will not affect your health care or your child's health care.

What happens if you choose not to be in the study?
You are free to choose whether to answer the questions and give a blood sample. You do not have to be in this research study to access antenatal care. Nor do you have to be in this study to access COVID-19 treatment.

How will your privacy be protected?
We will protect your privacy. We will not record your name or any other information which could be used to identify you on the questionnaire or filter paper. These will be identified with a study ID that is not linked to you. We may share survey responses and filter papers with other investigators, including ones outside of Zambia, but we will not share your name or personal information. We will not use any personal information in presenting results of the study. The data we collect in this study will be shared with the funder. Your research records will be confidential to the extent permitted by law.

Your records may be reviewed by the Centre for Infectious Disease Research in Zambia (CIDRZ), the University of Zambia Biomedical Research Ethics Committee (UNZA-BREC), Centres for Disease Control and Prevention (CDC), and the Zambian Ministry of Health, research team members, and study monitors.

What if you want to stop before your participation in the study is complete?
There is no penalty if you do not want to take part in the interview. If you start the interview but do not want to continue, you may leave the research study at any time.

Will you receive anything for being in this study?
You will not be paid for taking part in the study.

Will it cost you anything to be in this study?
There will be no cost to you associated with participating in this study.

Who is sponsoring this study?
This research is funded by the U.S. Centres for Disease Control and Prevention (CDC). This means that the research team is being paid by the sponsor for doing the study. The researchers do not, however, have a direct financial interest with the sponsor or in the final results of the study.

What if you have questions about this study?
You have the right to ask, and have answered, any questions you may have about this research. If you have questions, complaints, concerns, or if a research-related injury occurs, you should contact:

Dr. Izukanji Sikazwe
Centre for Infectious Disease Research in Zambia
PO Box 34681, Lusaka, Zambia
Tel: 0211 293 772
Email: Izukanji.Sikazwe@cidrz.org

What if you have questions about your rights as a research participant?
All research on human volunteers is reviewed by a committee that works to protect your rights and welfare. If you have questions or concerns about your rights or if you would like to obtain information or offer input, you may contact:

The Chairperson
University of Zambia Biomedical Research Ethics Committee
Ridgeway Campus, Nationalist Road, Lusaka
Tel: 0211 256 067
Email: unzarec@unza.zm

Participant Consent Forms - English

Centre for Infectious Disease Research in Zambia (CIDRZ)
Consent Form – Signature Page
Participant Enrolment
Biomedical Form

UNZA BREC Protocol #:
Consent Form Version Date: Version 1.0, 16 February 2021
Title of Study: Assessing SARS-CoV-2 seroprevalence from routine antenatal care visits in Zambia
Protocol: Version 1.0, 16 February 2021

Principal Investigator: Izukanji Sikazwe, M.D; Centre for Infectious Disease Research in Zambia (CIDRZ)
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Funding Source and/or Sponsor: US Centers for Disease Control and Prevention
Study Contact telephone number: +260 0211 293 772

Participant's Agreement:
I have been read the information provided above. I have asked all the questions I have at this time. I voluntarily agree to participate in this research study.

_____

Signature/Thumbprint of the Research Participant Date

_____
Printed Name of Research Participant

_____

Signature of Research Team Member Obtaining Consent
Date

_____
Printed Name of Research Team Member Obtaining Consent

_____

Signature of Witness Date

_____
Printed Name of Witness

*Note: Witness name, signature and date are required on this consent form only when the consenting volunteer is not able to read (illiterate).