COVAP Study Participant Informed Consent Document

Participant Information Sheet

Title: A mixed-methods observational study to assess the feasibility of conducting COVID-19 vaccine trials among healthcare workers in Uganda "COVAP"

Study purpose: The purpose of this study is to find out whether it is possible to conduct COVID-19 vaccine trials among healthcare workers in Uganda.

Study participants: The study will be conducted among all healthcare workers at Kisubi hospital, Kitovu hospital, and Villa Maria hospital located in Wakiso, Masaka, and Kalungu districts respectively. A list of all healthcare workers with their telephone contacts will be obtained from the respective hospital administrators of health facility**.** Each healthcare worker will be contacted by study staff via phone or in-person to arrange for a meeting at the health facility or other convenient place where the study staff will provide information about the study. At least 481 healthcare workers will participate in the study.

Study duration: The entire study is expected to take place over a duration of six months. Most participants will be interviewed only once. About 10% of participants may be invited to have a second more detailed interview within a month of the first interview. Each interview will take approximately 45 minutes

Study procedures
A study staff member will come to the hospital where you work or other agreed place, give detailed information about the study, and ask you to participate. If you agree to participate, the study staff member will ask to sign this form. The study staff member will then ask you questions about your personal life, knowledge, attitudes, and practices regarding the novel coronavirus which is the virus that causes Corona virus disease 2019 (COVID-19), your willingness to participate in COVID-19 studies, and health conditions that you may be suffering from. The study staff member will enter your responses into a tablet computer. This interview will take approximately 45 minutes.

You may be selected to be a part of a smaller group of participants who will have another more detailed interview within one month of the first interview. This interview may be conducted by another study staff member. If you are selected to take part in this more detailed interview, you will be asked questions to explore your perspectives on COVID-19 in general and COVID-19 vaccine research in particular. The interviewer will record your responses using an audio recorder and also capture your responses in his or her book.

Risks and discomforts: This study involves visits by study staff to the hospital where you work or another convenient place. This may inconvenience you by requiring that you take time off your schedule. We will try and schedule the interviews at a time that does not affect your usual work schedule. You may be embarrassed when discussing your health. We will do our best to protect your privacy and confidentiality.

We will take the following precautions to minimize the risk of coronavirus transmission. Study staff who are unwell will not be assigned work on the study. Study staff will wear a mask during

each interview. You will also be required to wear a mask and if you don't have one, the study will give you one. To minimize contact during the consenting process and interviews, a physical distance of at least two meters will be maintained between you and the study staff member. If you don't have your own pen during the informed consent process, the study staff member will provide with a new pen to sign the consent form which you will keep afterwards. The study staff member will provide this to you after sanitizing his/her hands. The signed consent forms will be placed inside separate sealable zip-lock bags and securely stored for at least 2 weeks before they can be retrieved.

Benefits: While there are no direct benefits to you for taking part in this study, you may find it satisfying that your participation will inform future COVID-19 vaccine research in Uganda and elsewhere.

Re-imbursement: You will be given UGX 40,000 to compensate for the time you spend during each interview.

Your participation is voluntary: You will sign or make a thumb print on two copies of this form to indicate that you voluntarily agree to participate in the study; one copy will be given to you and the other will be kept at the MRC/UVRI & LSHTM Uganda Research unit office in Masaka or Entebbe. You may withdraw from the study at any time if you chose to. If you decide not to participate in or withdraw from the study, you will not lose any rights or benefits.

Supervision of the study: Approvals for this study have been obtained from the UVRI Research Ethics Committee, the London School of Hygiene & Tropical Medicine Ethics committee, and the Uganda National Council for Science and Technology. The study will be monitored by someone who is not involved in its conduct.

Confidentiality: Your participation in the study, all information collected about you is confidential. You will have your own unique study number that will only be known to you and the study staff. Any documents containing your name will be locked away in a secure place at the MRC/UVRI & LSHTM Uganda Research unit office in Masaka or Entebbe.

Contact numbers: If you have any questions about the study, please call Dr. Eugene Ruzagira on Tel: …… or ……... If you have a question about your rights as a study volunteer please contact Mr. Tom Lutalo, the Chairman of the UVRI Research Ethics Committee on Tel: ……...

Informed Consent Form

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I, (name of participant) ……..……..……...

Agree to take part in the research project entitled: A mixed-methods observational study to assess the feasibility of conducting COVID-19 vaccine trials among healthcare workers in Uganda

I have read/been read the participant information sheet (Version 0.1 14Jun20). I understand the procedures in the study and know what is required of me. I understand and accept the requirements. I understand that I am taking part in the study freely and that I can stop being part of this study at any time and for any reason. If I stop taking part, the legal rights that I have will not be affected.

Participant:
Signature/Thumb Print: ……..……..……..……..

Date: ……..

Person Obtaining Consent:
I have explained the nature, demands, and foreseeable risks of the above study to the participant.

Print name:……..…… Signature:……..…….

Date: ……

Witness: (if participant was not able to read and understand the Participant Information Sheet) I affirm that the Participant Information Sheet (Version 1.0 27Jun20) has been read to the participant, and he/she understands the study and I have witnessed the participant's consent to study participation.

Print Name: …….. Signature: ……..……..……

Date: …….