CONSENT DOCUMENT

Participant's Information

Study Title: **Impact of mobile technologies on cervical cancer screening practices in Lagos, Nigeria: A randomised controlled trial "mHealth-Cervix"**

Principal Investigator: **Dr. Kehinde Okunade**

1. **Research introduction:**
   We are conducting a study to ascertain the efficacy of an intervention using mobile technologies on Pap smear screening adherence compared to a control condition and also determine the factors affecting the uptake of Pap smear screening services among women in Lagos, Nigeria. You are being requested to participate in this research as a female patient and NHIS-enrollee attending the Lagos University Teaching Hospital (LUTH) and the Lagos State University Teaching Hospital (LASUTH). This consent form gives you information about the study. You are requested to read it and you are free to ask any questions and they will be answered. After you have understood and if you decide to participate, you will be requested to sign at the bottom.

   If you chose to take part of the study, you have the right to withdraw from the study at any time, without having to state a reason.

2. **Background and purpose of study:**
   Cervical cancer is a major public health problem and is the fourth most common cancer in women worldwide accounting for an estimated 570,000 new cases annually. More than 80% of the global burden of cervical cancer occurs in the less developed regions, where it accounts for almost 12% of all female malignancies. In 2018, an estimated 311,000 deaths were attributed to cervical cancer, which accounts for 7.5% of all female cancer deaths with 70% of these occurring in developing countries. Early detection of precursor lesions of cervical cancer through the use of screening tests has drastically reduced the incidence of the disease especially in the Western countries where Pap smear (cytology) screening has been introduced and now covers almost all eligible women. However, in the resource-constraint countries of the world such as Nigeria, cervical cancer incidence and mortality have remained high due to many obstacles facing the implementation of organized screening programs. There is limited evidence supporting mHealth technologies in cancer prevention and there is currently no reported randomized controlled trial in Sub-Saharan Africa (SSA) that examines the use of mobile health technologies in cancer prevention. This study will, therefore, aim to ascertain the efficacy of an intervention using mobile technologies on Pap smear screening adherence compared to a control condition and also determine the factors affecting the uptake of Pap smear screening services among women in Lagos, Nigeria.

3. **Procedures:**
   The study involves you participating in a 20 to 30-minute interview with a research assistant. During this interview the research assistant will ask you questions about yourself and you'll be asked to consent to providing other information during your subsequent visits to the hospital.

4. **Who will participate in the study?**
   Eligible women are NHIS enrollees aged between 25 and 65 with no prior history of cervical cancer or cervical dysplasia; those not adherent with current recommendations for Pap smear screening (have not had a Pap smear within the last three years); those owning and using a personal cellphone; those free from any mental or physical disabilities that inhibit them from understanding the

implications of the study and those not considering relocating from their current residence within the next year.

5. **Risks/Discomforts:**
   There are no expected physical risks or discomfort from participating in this study.

6. **Benefits:**
   You will likely not derive any direct benefit from participating in this study. Once the data is gathered and analyzed, we will use the findings to develop new approaches to improving cervical cancer screening adherence. If you would like to discuss any findings from the study, please mention this to the research assistant who will contact you when the study has concluded to share the main findings with you.

7. **Cost:**
   Participating in this study will not have any direct cost to you except for your time.

8. **Reimbursement/compensation:**
   You will be compensated with N1,000 credit card for your time and participation in the study.

9. **What are your rights in this study?**
   Participation in this study is entirely voluntary. Your subsequent care will not be affected in any way if you participate.

10. **Confidentiality:**
    The results of this study will be kept strictly confidential and used only for research purposes. Your name will not appear anywhere on research findings. Paper records will be kept locked in a secure research office and any electronic documents will be stored securely and only accessed by the research team.

11. **Contacts for concerns/Questions:**
    If you have questions or concerns regarding this study, you can contact the lead academic researcher (**Dr. Kehinde Okunade**, Department of Obstetrics and Gynaecology, College of Medicine, University of Lagos; email - kehindeokunade@gmail.com; phone - +2348034728139).

    If you have concerns about your rights as a research participant contact: Prof. S. A. Omilabu, Chairman, Health Research Ethics Committee, CMUL, College of Medicine, University of Lagos Research Management Office, email - hrec@cmul.edu.ng; +2348028642463, +2348023119431, +2348025187261

12. **What does your signature mean?**
    By signing or putting a thumbprint on the consent form you declare that you have been informed about the research study and are voluntarily agreeing to participate in the survey. Signing or putting a thumbprint means that you understand the information in this consent form. You retain the right to withdraw from the study at any time. You do not waive any of your legal rights by signing this form.

Consent Form

Consent to take part in the study of: **Impact of mobile technologies on cervical cancer screening practices in Lagos, Nigeria: A randomised controlled trial "mHealth-Cervix"**	Add your initials or thumb print next to the statements below if you agree
I confirm that I have read and understand the information sheet dated [……] explaining the above research project and I have had the opportunity to ask questions about the project.	
I understand that my participation is voluntary and that I am free to withdraw at any time before or during the interviews without giving any reason and without there being any negative consequences. In addition, should I not wish to answer any particular question or questions, I am free to decline. Contact number of lead researcher is: **+2348034728139** I also understand that participants can withdraw their data at any point.	
I give permission for members of the research team to have access to my anonymised responses. I understand that my name will not be linked with the research materials, and I will not be identified or identifiable in the report or reports that result from the research. I understand that my responses will be kept strictly confidential.	
I agree for the data collected from me to be stored and used in relevant future research in an anonymised form. I understand that the results of the study will be published in academic journals.	
I agree to take part in the above research project and will inform the lead researcher should my contact details change.	

_____ _____ _____

Name of Participant Signature /thumbprint Date