**INFORMED CONSENT DOCUMENT**

**Participants information (to be retained by participants)**

**Title of the research:** UTILIZATION OF A DIGITAL HEALTH PLATFORM TO REMOTELY MONITOR PATIENT-REPORTED OUTCOME ACUTE SIDE EFFECTS DURING RADIOTHERAPY FOR PELVIC, HEAD AND NECK CANCER

**Name(s) and affiliation(s) of researcher(s) of applicant(s):** Dr. Omolola Salako of the College of Medicine, University of Lagos, Idi-Araba, Lagos.

**Sponsor(s) of research:** Conquer Cancer Foundation

**Purpose(s) of research:** To assess the use of a web-based application for real time patient reporting and monitoring of side effects while undergoing radiotherapy for breast, pelvic, or head & neck malignancy.

**Procedure of the research, what shall be required of each participant and approximate total number of participants that would be involved in the research:** Participants undergoing radiotherapy will be required to participate in a 90-minute Focus Group Discussion to discuss their knowledge and experience on radiotherapy side-effects. Also, participants will be required to register and log in how they feel/side-effects on a daily basis via the web app.

**Expected duration of research and of participant(s)’ involvement:** Each participant is expected to spend about 5 minutes on the app daily.

Depending on your diagnosis, the duration of the study for Breast Cancer is 6 weeks, Pelvic Cancer is 8 weeks, and Head and Neck Cancers is 8 weeks.

**Risk(s):** As part of your routine care, the study will provide you with your blood level asssessment (PCV) in SYNLAB, NSIA-LUTH Cancer Centre. Your blood sample will be takne by a trained phlebotomist**.** Although there are no identifiable significant risks, patients might feel a slight pain or bleed for a brief period after the blood sample is drawn.  The research team will take measures to ensure that your medical data on the application is secured and encrypted. Access to your medical data will be strictly for the research team.

**Costs to the participants, if any, of joining the research:** None

**Benefit(s):** The goal of this study is to provide a digital platform for reporting acute side effects, improve patient experience and standardize reporting and documentation of acute radiation side-effects amongst patients with malignant tumours of the pelvis, head and neck region. Results obtained from this study will contribute to the body of knowledge and further development and iteration of the study app.

**Confidentiality:** All information collected in this study including history, physical findings and results obtained from the participants and no name will be recorded. This cannot be linked to you in any way and your name or any identifier will not be used in any publication or reports from this study. Also, all study records will be kept in locked file cabinets and encrypted, restricted access tablets or computers.

**Voluntariness:** Participation is entirely voluntary.

**Alternatives to participation:** Individuals can decline to participate and the standard of their care will not be affected by this decision.

**Due inducement(s):** Participants will not be paid for participating in this research.

**Consequences of participants’ decision to withdraw from research and procedure for orderly termination of participation:** You can decide to withdraw from the study at any point by informing the study coordinator or any other research personnel. There will be no consequences for withdrawing from the study. However, data previously collected from the participant may be included in the study report and analysis.

**Modality of providing treatments and action(s) to be taken in case of injury or adverse event(s):** None

**What happens to research participants and communities when the research is over:** Findings from the research will be communicated to the participants in writing. Details and result of the study will be communicated to the wider research community via a published peer-review article in a reputable journal.

**Statement about sharing of benefits among researchers and whether this includes or exclude research participants:** None

**Any apparent or potential conflict of interest:** None

**In case of any enquiry, please contact the following:**

1.          **The Investigator:** Dr. Omolola Salako, Department of RBRR, College of Medicine, University of Lagos, Idi-Araba, Lagos. lolasalako@unilag.edu.ng

1. **The Chairman of the CMUL HREC:** Prof. K.S. Oyedeji, College of Medicine, University of Lagos, Idi-Araba, Lagos. hrec@cmul.edu.ng

**INFORMED CONSENT CERTIFICATE**

**PROSE STUDY**

**Statement of person obtaining informed consent:**

I have fully explained this research to \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ and have given sufficient information, including about risks and benefits, to make an informed decision.

NAME:                                                                           SIGNATURE:

DATE:

**Statement of person giving consent:**

I have read the description of the research or have had it translated into language I understand. I have also talked it over with the doctor to my satisfaction. I understand that my participation is voluntary. I know enough about the purpose, methods, risks and benefits of the research study to judge that I want to take part in it. I understand that I may freely stop being part of this study at any time. I have received a copy of this consent form and additional information sheet to keep for myself.

NAME: ………………………………………………… SIGNATURE: …………………

DATE:………………………………………

WITNESS’ SIGNATURE (if applicable): ……………………………….

WITNESS’ NAME (if applicable): ………………………………….

PLEASE KEEP A COPY OF THE SIGNED INFORMED CONSENT CERTIFICATE.