Written Consent to Participate in the Study

Principal Investigators: Dr. Peter Olupot- Olupot

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Study Title: Assessing the quality of wellbeing of patients with sickle cell disease Taking Vs those not taking Hydroxurea.

Background and Purpose:

Sickle cell anemia (SCA) is among the world's most common forms of inherited hemolytic anemia, and results in significant morbidity and early mortality. SCA is most prevalent in Africa, with as many as 300,000 babies born annually, representing up to 2% of newborns in some sub-Saharan countries. Assuming most of these babies die early in childhood, the World Health Organization (WHO) estimates that SCA causes 6-16% of under-five mortality for many African countries, and this burden is projected to further increase substantially in the next 40 years. This alarmingly high contribution of SCA to under-five mortality makes the recognition and management of SCA an important cornerstone of efforts by many African countries toward achieving Millennium Development Goal #4, the reduction of child mortality. Since deaths due to SCA mostly occur in children under 5 years old, efforts to save lives must include early diagnosis and treatment. In addition to early death, SCA also causes profound adverse effects among surviving children on their education and future employment with resultant loss of productivity.

One of the medications used for the management of sickle cell disease is Hydroxurea which is the only disease modifying drug for sickle cell disease. Hydroxyurea is a cytotoxic, antimetabolic, and antineoplastic agent used for several decades to treat a variety of medical disorders, most notably myeloproliferative neoplasms, chronic myelogenous leukemia, and HIV.

The first clinical application of hydroxyurea for patients with SCA was reported in 1984, when Platt and colleagues demonstrated a rapid and dramatic increase in HbF-containing reticulocytes without significant bone marrow toxicity. This and other 'proof-of-principle' experiments led to a critical phase I/II study of adults with SCA treated with

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hydroxyurea at maximum tolerated dose (MTD), which demonstrated significant dose-dependent increases in hemoglobin and HbF along with concurrent reduction in total white blood cell count, neutrophils, and reticulocytes. Similar results were observed in phase I/II studies involving school-age children, toddlers, and infants, all documenting the safety, laboratory benefits, and clinical efficacy of hydroxyurea for young patients with SCA.

Study Procedure: On agreeing to participate in the study you will be asked to complete a questionnaire that will be administered by a researcher. All your answers will be recorded in a confidential manner. The questions will be about sickle cell disease and the you knowledge about hydroxyurea medicine.

Benefits: There is no direct benefit to you from participating in this study. However, we will provide you with information about sickle cell and the drug called hydroxyurea.

Risk: There will be no risk to you from participating in the study; you may experience some anxiety or discomfort while being interviewed.

Incentives: There is no incentive that will be given to you for participating in this study.

Right to refusal or withdrawal: Your participation in this study is strictly voluntary and you are free to take part or withdraw at any time in the course of interview. You may choose not to answer any individual question or all of the questions. However, I hope that you will participate in this survey since your views are important.

Confidentiality: All the information given in this study is considered confidential and will be used for research purpose only. Your identity will not be disclosed in any report or publication resulting from this study.

Questions: If you have any further question(s), you can contact the PI Dr. Peter Olupot-Olupot. **Tel: 0772-457217**

Consent: I understand the statement that has been read to me and I consent to take part in the study. By signing this form, I accept to participate in this study.

Did you read this consent form on your own? Yes ☐ No ☐

If No to the above, who translated

Name of the Translator:.....

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Sign:..... Date:.....

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Participant.....Date.....

Researcher.....Date.....