OBAFEMI AWOLOWO UNIVERSITY TEACHING HOSPITALS COMPLEX, ILE-IFE.

SUBJECT INFORMATION SHEET

Principal Investigator: Miss Ochuko M.Orherhe Telephone No:- +2348051589453
E-mail: oorherhe@oauife.edu.ng

Institution/Department: Department of Pharmaceutical Chemistry, Faculty of Pharmacy, OAU
Co – Investigators: Dr. Babatunde Adeagbo & Prof. R. Bolarinwa

Sponsor (If any): Self Sponsored

Some general things to know about the study:.

- You are being asked to join a research study.
- This consent form explains the research study and your part in the study.
- Please read it carefully and take as much time as you need.
- Participation in this study is optional. You may decide to leave at any time without being penalizes.

What is the purpose of this study:

This study will provide information on how your body handles hydroxyurea (a drug that has been globally recommended as a drug of choice for the management of sickle cell disease) and will guide the choice of the appropriate dose that will give you optimal clinical effect at minimal side effects.

Procedures:

We will ask you to do the following in this phase:

- Resume at the study location by 8 am, on the day of sample collection.
- All drugs to be taken on the day will require that you are around the study location, though not necessarily inside the laboratory.
- On arrival, blood sample (2ml) will be withdrawn before you receive the drug dose for the day (0-hour time point).
- You will be allowed to take your dose of hydroxyurea as suited to your body weight.
- Thereafter, 2ml of your blood will be collected at least 6-time points from the following time points - 0, 0.25, 0.5, 0.75, 1, 1.5, 2, 2.5, 3, 4, 6, 8, 12, and 24 hours after taking the drug.
- The last blood collection for this phase will be after 24 hours from the time of ingestion of the hydroxyurea, which will be 8 am the next day.
- The blood samples collected will be centrifuged immediately to obtain plasma and the plasma will be stored at -20ºC until the time of analysis.

Benefits:

The study will provide information on how to tailor the use of hydroxyurea to you, and the results of the study will be published for societal benefit.

Costs of Participation:

There is no direct cost to you for participating in the study.

Risks:

When taking your blood, minor pain and bleeding is anticipated from needle pricks. However, the phlebotomists that will be collecting your blood are highly skilled, so that the risks of discomfort, bleeding or bruising will be very minimal. There is also a minimal risk of infections, as all protocols to ensure that both parties are protected from cross-infection will be ensured.

Compensation:
You will not be paid for participation in this study, and it will not cost you anything to participate. You will however be compensated for the time and travel costs you will incur when coming to the study site.

Confidentiality:
All research projects carry some risk that information about you may become known to people outside of the study. However, to minimize this risk of breach of confidentiality, the following measures will be taken:

- Data collected about you during screening for your medical fitness will only be made available to you and the principal investigator, who in turn will keep them as an encrypted file.
- Blood samples collected from you will not be labelled with your real name, but a research code will be generated for each sample, and the link of each code to your personal information will be kept in a secure electronic database which only the principal investigator will have access to.
- The analysts will also not be given access to your personal information but will be told to analyse using the research code that your sample result bears on it.

Respondents' Rights:
You are under no pressure to participate in our research study, the decision is totally up to you. If you say no, it will not affect your participation in other studies you may be involved in, or your clinical treatment in any way. You can change your mind about being part of this study any time by contacting the contact above. They can then remove your sample and your data from the study.

Conflict of Interest:
The study investigators have no financial or other relationships with any persons or organisations, including the manufacturers of the drug you are taking, that may affect the conduct of the study or the interpretation of its findings.

For the Records:
A copy of this document will be given to you for your records.

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Optimisation of Hydroxyurea in the Management of Sickle Cell Disease in Nigeria: An Exploration of Pharmacogenetics and Pharmacometrics

Subject's Agreement/Consent Form:

I have read the information provided in the Subject Information Sheet, or it has been read to me.

I have had the opportunity to ask questions about the research and all questions I have asked have been answered to my satisfaction. I consent voluntarily to participate in this study and understand that blood samples will be collected from me at intervals, and I have the right to withdraw from the study at any time.

Yes ☐ **No** ☐

Signature/Thumb print of Research Respondent. Date:

If participants cannot read: Signature of Mother or Legal Guardian.

Signature/thumb print of Person Obtaining Consent. Date:

Name of witness Signature Date

Printed Name of Person Obtaining Consent: Miss Ochuko Orherhe

Phone Number: 08051589453