Application for Ethics Committee Approval (Human Subjects)

Consent Form 1

Note: Title and names of investigators will be used from the other forms

1. **Identification of project**

a. What is the purpose of this research?

The purpose of this research is to see the effect of a medication on the function of your platelets. Platelets are cells circulating in your blood that helps in clotting

b. How long it will take to complete this project?

The research will be conducted for a total duration of three months

c. Why are you selected for this research?

Because you are attending the hospital for a heart disease and you are required to take antiplatelet medication, you have been selected in this research to study if the medication is effective

d. Why is this document for obtaining informed consent important?

This document is not only an invitation for you to either consenting or declining to participate in the research after understanding thoroughly about the research, but also a legal document which governs your participation in this research. If you are under age of legal consent, there is a need for parental or guardian's consent, since they are the ones legally entitled to provide this approval

2. **Description of Procedures**

a. What do we expect you to do in this study?

We need you to understand the implications of participating in this research and once you are satisfied, we will enroll you. We will give you the guidelines and protocols as described below until the duration for the study

b. What are the procedures done are investigational? What is the expected duration, how frequently you have to participate and where will the activities take place?

We will provide you with the medication. Although this medication is new, this has been approved by the FDA and this research involves seeing the efficacy in the local population. You need to take the tablets once a day for the next three months. You need to come into the cardiology clinic at EWMSC once in a month to do some blood tests

c. How many numbers of participants are involved in the study approximately?

The estimated total number of participants in this research is 360 patients

3. **Risks and Discomforts**

a. What are the risks or discomforts that may result from your participation in the study?

The medication is an approved antiplatelet drug. However, some subjects may experience nausea/vomiting (10%), stomach upset (5%), rashes and itching (1.5%) and very rarely (<0.5%) bleeding disorders

b. What help and treatments are available if any adverse reactions occur? How can you access them? Is there any compensation available if serious adverse effects occur?

You can contact the researcher at 1 300 300 3000 at any time should you encounter any side effects. If you experience any serious adverse effect please approach the closest hospital Emergency Room (ER) immediately and still call the above number. One the members from the research team will immediately approach you and deal with the situation. You can get further information on the ER at www.moh.gov.tt

c. Are there any potentially beneficial treatments or procedures that are withheld for the purpose of the study?

The research is not withholding any treatments due to you; it is only testing the efficacy of a newly approved medication in our local population

d. Is this research regulated by FDA? If so, is there a possibility that FDA may inspect the records?

This drug is already approved by FDA; hence FDA will not inspect the records

4. **Termination of Research**

a. Are there any anticipated circumstances under which the study/participation may be terminated by the researchers without regard your consent?

If the researchers find that too many subjects have side effects, this will be reported to the Ethics Committee and the research will be stopped. For any other reason if the Ethics Committee cancels the approval, the study may be aborted.

But you will be informed of all the events.

5. **Benefits**

a. What are the benefits to you (and the wider society) by this study? (State clearly if there is no direct benefit to the participant, but only societal benefit)

The medication that has been approved has a novel mechanism of action, which targets platelets specifically without affecting other systems. This is beneficial for your condition.

6. **Alternatives**

a. Does this study involve more than minimal risk? Are there any appropriate alternative procedures or courses of treatment that might be advantageous to you?

This study does not involve more than minimal risk. There are alternative antiplatelet drugs; however, there is no added advantage

b. Do you have the right to pursue the alternatives?

Most certainly; if you do not want to try the new drug, you will be prescribed the alternative

7. **Confidentiality**

a. How will confidentiality be maintained regarding your data? Who will have access to the data, how the data will be reported and /or published?

We do not record any data along with your personal identification material. You will be assigned a code and the data will be kept confidential in a researcher's computer which is password protected for a duration of 5 years. A research article will be published in a scientific journal, but no confidential information will be reported and/or published.

8. **Cost and Payments**

a. Are there any costs involved and are there any compensations provided?

You will be paid 200 TT$ to cover the costs of you coming to the hospital for the purpose of the study. This is not provided as an inducement for you to participate in the study, this is exclusively a compensation for the inconvenience caused to you by way of travel etc.

9. **Freedom to Withdraw**

a. Do I have the freedom to withdraw from the study anytime?

Participation in this study is voluntary and you are free to withdraw at any time if any problems occur, or if you simply change your mind. You also have the option to exclude from the study data, should you decide to withdraw

b. Will withdrawing from the study have any impact on my treatment?

Refusal to participate or withdrawal thereafter will not adversely affect your relationship with the investigator(s) or your right to any other treatment or services available to them at the University of the West Indies or its affiliated institutions

10. **<u>Opportunity to ask questions</u>**

a. Do you have to right to ask questions anytime during the study? Whom should you contact? (including a member of the UWI Ethics Committee)

You have the right to ask questions and we will answer before the start of or anytime during the study

Following is the list the names and telephone numbers of persons who can be contacted for answers to questions about the study:

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