PATIENT INFORMATION SHEET Sub-Study	***(Insert Local Trust Letterhead and Contact Details)***

PRE-EMPTIVE PHARMACOGENTIC TESTING FOR PREVENTING ADVERSE DRUG REACTIONS (PREPARE STUDY)

PRINCIPAL INVESTIGATOR: PROFESSOR SIR MUNIR PIRMOHAMED

You are being invited to take part in a sub study. Before you decide, it is important for you to understand why the research is being done and what it will involve.

Please ensure this information leaflet is read in conjunction with the patient information leaflet relating to the general study.

If there is anything that is not clear, or if you would like more information, please ask. This is a voluntary project, and if, when you have heard about the sub- study, you would prefer not to take part, your decision will be accepted without question. This will not affect your ability to participate in the general study or affect the standard care you receive.

WHAT IS THE PURPOSE OF THE STUDY?

The purpose of the general study is to find out if personalising medication lowers the chance of experiencing serious side effects. We will do this by comparing the standard way medications are prescribed with a method that takes into account an individual's genetic information.

If you agree to take part in the general study and are prescribed a new prescription for any of the following medications, you are also eligible to participate in the sub-study:

- Simvastatin
- Atorvastatin
- Capecitabine
- Fluorouracil
- Metoprolol
- Voriconazole

The aim of the sub –study is to find out more about how your genes and any other medications you are taking may potentially affect the levels of the medication of interest in your blood.

WHAT WILL HAPPEN TO ME IF I TAKE PART?

If you decide to take part in the sub-study:

- The visit schedule will remain the same as for the general study. However we will arrange to take an additional bloods sample (approximately 1 teaspoon, 6mL) (at baseline, at the week 4 visit, at the week 12 visit, and potentially one further blood sample during your initial hospital stay. This will mean seeing you in person rather than speaking over the telephone.

For some participants follow-up visits may occur after discharge from hospital or in the community, and in this case, we will pay reasonable travel expenses to attend one of our recruitment sites in order to collect the blood sample. **In some instances it may be more convenient to the participant to conduct the follow-up visit at home. Should this happen we will contact you in advance to agree a convenient time.**

WHAT ARE THE POSSIBLE ADVANTAGES AND DISADVANTAGES OR RISKS OF TAKING PART IN THE SUB STUDY?

There are no advantages or risks of taking part in the sub-study, other than some minor short lasting discomfort from having the additional blood tests.

WHAT WILL HAPPEN TO MY ADDITIONAL BLOOD SAMPLES?

Your additional blood samples will be stored at the University of Liverpool. A small amount of your additional samples will be sent to will be sent to Dr. Margarete Fischer-Bosch-Institute of Clinical Pharmacology in Germany for analysis in order to measure the levels of drugs in these samples.

Your blood samples will be considered a gift to the University of Liverpool, which will act as custodian of all the samples obtained as part of this project. In some cases, a small amount of your sample will be provided to other researchers and may be sent to other countries inside and outside Europe. Your sample may be used in the future for unspecified research however, it is important to remember that the sample will only be identified by a code and therefore it will not be possible to trace it back to you. This testing will be restricted to investigating genes and other factors that affect how patients respond to medications.

In the short-term, it is unlikely that the sample will be of any commercial value to the University or the hospital. However, it is possible that there may be some commercial value in the future, although it is important to note that any commercial value is likely to be due to findings in a group of patients rather than from samples from a single patient. You will not be paid for taking part in the study, nor will you derive financial benefit from future discoveries.

IN RELATION TO THE FOLLOWING:

- **WILL MY TAKING PART IN THIS STUDY BE KEPT CONFIDENTIAL?**
- **WHAT WILL HAPPEN TO THE RESULTS OF THE RESEARCH STUDY?**

- **WHO IS ORGANISING AND FUNDING THE RESEARCH?**
- **WHO HAS REVIEWED THE STUDY?**
- **CONTACT FOR FURTHER INFORMATION**

The information in the above sections remains the same as detailed in the general study patient information leaflet.

THANK YOU FOR READING THIS INFORMATION LEAFLET