To be place on local headed paper

Participant Information Sheet

Title of study: **Mechanistic sub-study to the Adjuvant Steroids in Adults with Pandemic Influenza (ASAP) Trial**

The study has been reviewed and approved by the South Central –Oxford C Research Ethics Committee (ref.13/SC/0436)

We would like to invite you to take part in a research study. Before you decide whether to take part please take time to read the following information carefully. One of our team will go through the information sheet with you and answer any questions that you have.

What is the purpose of this study?
The purpose of this research study is to improve our understanding of the role of the immune system in pandemic influenza and the effect of steroid treatment on influenza infection. Previous studies have shown that steroids may benefit some patients but not others and that they may be useful at certain stages of disease but not at others. The aim of this study is to determine who benefits the most and when steroids are most effective.

Why have I been invited to take part?
You have been invited because you have been admitted to hospital with an influenza-like illness and agreed to participate in the ASAP pandemic flu trial. This study is aiming to recruit 200 patients who are also participating in the ASAP trial.

What will happen to me if I take part?
If you agree to take part we will ask you to sign a consent form. We will then require two blood samples from you and a swab from your nose.

The first blood sample will be taken either before you start taking your ASAP study medication or within four hours of taking the first dose. We will collect 16ml of blood which is the equivalent of about 3 teaspoons. We will also take a swab from your nose at the same time. The second blood sample will be taken approximately 48 hours after your first dose of study medication, or when you are discharged home from hospital if this is sooner. For this blood sample we will take 20ml of blood which is equivalent to 4 teaspoons.

What are the possible benefits to me of taking part?
There will not be any direct benefits of this research to you. We hope this research will help improve our understanding of pandemic influenza and help people in the future.

What are the possible disadvantages and risks of taking part?
You may have some discomfort from the collection of the samples.

Do I have to take part?
No, it is up to you to decide whether or not to take part. If you agree to take part you may still change your mind at any time and are free to withdraw without giving a reason. You do not need to take part in this study to participate in the ASAP trial.

Will my information be kept confidential?
The blood sample that you give will be labelled with an anonymous code and sent to the Liverpool School of Tropical Medicine where it will be analysed. With your permission, any left-over blood sample will be stored anonymously for possible use in future ethically approved studies.

The nasal swab will also be labelled with an anonymous code and sent to The Royal Liverpool University Hospital where it will be analysed.

The data collected about you as part of your participation in the ASAP trial will be shared with the research team who are based at the Liverpool School of Tropical Medicine and the University of Liverpool for the purpose of this study, however no identifiable information will be shared. It is also possible that your study and clinical details may be seen by auditors who conduct regular checks of research sites to ensure research is conducted to a high standard.

Who is organising and funding the study?
This study is being funded by the National Institute for Health Research. Nottingham University Hospitals NHS Trust is sponsoring the study and the Nottingham Clinical Trials Unit is coordinating the study.

Results of the study
The results of the study will be available after it has finished and will usually be published in a scientific journal and be presented at a scientific conference. However, you will not be identified in any report to publication.

What if there is a problem?
If you have a concern or questions about any aspect of the study you should speak to your local study team who will do their best to answer your questions; contact details can be found at the end of this information sheet.

If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints Procedure. Details can be obtained from your hospital.

In the event that something does go wrong and you are harmed during the study there are no special compensation arrangements. If you are harmed and this is due to someone's negligence then you may have grounds for legal action for compensation but you may to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you.

To be place on local headed paper

Further information and contact details

If there is anything that is not clear or if you would like more information please ask when you meet the study team or by using the contacts at the end of this document during normal working hours.

[local contact details to be added]