[redacted]

Patient information sheet

DIRECTORATE OF SURGERY AND ANAESTHESIA

ROYAL LONDON HOSPITAL, WHITECHAPEL, LONDON E1 1BB

Information Sheet A – Subject

Version 1.3, 20.09.2007

East London and the City Research Ethics Committee 1

REC number: 07/Q0603/29

Title: Activation of Coagulation & Inflammation in Trauma II

Principal Investigator: Mr. Karim Brohi, FRCS FRCA

Date: ___/___/_____

Subject Name: _____. NHS Ref: _____ Study Ref: _____

Introduction

You are being invited to take part in a research study. This research will help us to improve the care of patients who suffer severe injuries in the future. Before you decide, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully. Talk to others about the study if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

Why is this research being carried out?

Trauma (serious injury) is the leading cause of death and disability in children and young adults worldwide. Over half of all trauma deaths are due to bleeding or the complications resulting from it. Injury, shock and blood loss all contribute to a failure of the body's normal blood clotting mechanisms (coagulation), which then leads to more bleeding. The mechanisms of these disorders in blood clotting and how they affect the body are not well understood, and we hope that this research will help us to determine why, when and how the blood clotting mechanisms fail, and what the consequences of this are.

Why have I been chosen?

On ___ - ___ - _____ (date), you were injured and admitted to the Royal London Hospital. At the time, you were unable to give informed consent. When you arrived in the emergency department, a full trauma team of doctors and nurses attended to you. The trauma team leader, who is not part of this research study, gave consent as your representative for you to be enrolled in this study. As part of the immediate management blood is taken and sent to the laboratory for analysis. A small amount of extra blood (approximately four teaspoonfuls) was drawn and saved for research purposes. We are now asking for your consent to allow us to use the samples we have collected and to continue to participate in the study, since all the procedures have not yet been completed. Should you not wish to continue your involvement in the trial we may ask for your consent to place the samples already collected in a registered research tissue bank for use in future research.

Do I have to take part?

No, participation is completely voluntary. It is up to you to decide whether or not to take part. If you do, you will be given this information sheet to keep and be asked to sign a consent form. You are still free to withdraw at any time and without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care you receive.

What will happen to me if I take part?

If you agree to continue with the study the following will happen:

1. We will store and process the samples we have already collected.

2. We will continue to collect blood samples until the third day in hospital. We will draw ___ blood samples in total. ___ (number) of these have already been obtained. Each blood sample is equivalent to four teaspoonfuls, and the total amount of blood drawn over three days is less than four fluid ounces. Wherever possible we will draw the blood out of a line already in a blood vessel, or coincide the blood draw with tests required for your care, in order to minimise any discomfort from the procedure.

3. While you were unconscious, we used a small catheter to collect bronchial washing samples from your lungs. Bronchial washing and aspiration is a safe procedure that is performed on the intensive care unit by trained personnel. During the procedure a small, flexible tube is passed down the breathing tube into the windpipe and air passages. A small volume of fluid is then passed down the tube into the lung, and then sucked back and collected in a specimen jar. Now that you are awake, no further bronchoscopies will be performed.

What do I have to do?

If you agree to continue with the study the following will happen:

We will collect ___ (number) of further blood samples from you, on _____

(date/times)

What are the possible disadvantages and risks of taking part in the study?

There are no long-term risks to you from participating in this study. The specific risks associated with each sample are as follows:

1. Blood samples
   The risks of drawing blood include temporary discomfort from the needle stick and bruising.

2. Bronchial lavage & aspiration
   The risks of obtaining bronchial washings in patients with a breathing tube in place are rare, and are limited to episodes of low oxygen in the blood (hypoxemia). To minimise this risk we will administer extra oxygen during the procedure and continuously monitor the level of oxygen in the blood. Again, now that you are awake, no further aspirates will be performed.

What are the possible benefits of taking part in the study?

There will be no direct benefit to you from participating in this study, but we hope that the information we get will help to improve the care of trauma patients in the future.

What if there is a problem?

Any complaint about the way you have been dealt with during the study or any possible harm you might suffer will be addressed. The detailed information on this is given in Part 2.

Will my taking part in the study be kept confidential?

Yes. We will follow ethical and legal practice and all information about you will be handled in confidence. The details are included in Part 2.

This Completes Part I.

If the information in Part 1 has satisfied you and you are considering continuing in the study, please read the additional information in Part 2 before making any decision.

PART 2

What will happen if I don't want to carry on with the study?

If you decide, at any time, to withdraw from the study all study procedures will be stopped immediately. Any information and samples that have already been collected will be processed as part of the study unless you wish to have your samples withdrawn from the study, in which case we will destroy them. Your decision will in no way result in a change in the type or quality of care you subsequently receive. Should you not wish to remain in the trial we may ask for your consent to place the samples already collected in a registered research tissue bank for use in future research.

What if I am not happy about the study?

We will only make very minor changes to the way we look after you. It is extremely unlikely that this small change to normal practice would cause any problems. However, if you are harmed by taking part in this study, there is no special compensation arrangement. If you are harmed due to someone's negligence, then you may have grounds for legal action but you may have to pay your legal costs. Regardless of this, if you wish to complain or have any concerns about any aspect of the way you have been approached or treated during the course of this study, the normal National Health Service complaints mechanisms should be available to you. Please contact Patient Advisory Liaison Service (PALS) if you have any concerns regarding the care you have received, or as an initial point of contact if you have a complaint. Please telephone 020 7377 6335, minicom 020 7943 1350, or email pals@bartsandthelondon.nhs.uk, you can also visit PALS at any hospital.

Will my taking part in the study be kept confidential?

All information which is collected about you during the course of the research will be kept strictly confidential and will be stored securely in coded form. Data collected may be sent outside of the Trust for statistical analysis but uncoded identifiable personal patient information will not leave the local research group. If you consent to take part in the research the people conducting the study will abide by the Data Protection Act 1998, and the rights you have under this Act. Only authorised personnel such as researchers and research auditors will have access to the data. We will store your information for 15 years and your samples until the end

of this research project. Any subsequent use of the samples will have to be performed with approval from a research ethics committee, otherwise the samples will be destroyed.

What will happen to the samples that I give?

These samples will be used for more than one study, but one of these is a study aimed at identifying genetic differences in patients that makes them more or less susceptible to the effects of traumatic injury. We hope that this will allow us to identify new areas of investigation and potentially allow future trauma care to be specifically tailored to the characteristics of each individual patient. Your samples will be stored in a secure facility that can only be accessed by authorised researchers. Some samples may be sent outside of the Trust (and the UK) for processing by other research laboratories. Your samples will be identifiable only in a coded format separate from your personal information. Any further use of your samples outside of this research study will have to be approved by a research ethics committee.

Will any genetic tests be done?

We will store a sample of your DNA, obtained from the blood sample for future testing. This is performed to see if there are genetic differences between patients that make them more or less susceptible to the effects of injury. We will not be testing for genetic diseases or named inheritable conditions and therefore this test will be of no individual significance to yourself in terms of inherited risk, insurance issues or to your children. The DNA will be stored in a coded form in a special DNA bank, with the same data protection safeguards that apply to your other blood samples. Any future studies outside the scope of this study that would use your DNA will have to be independently authorised by a research ethics committee.

What will happen to the results of the research study?

We hope to publish the results in a scientific journal. It will not be possible to identify any individual who has taken part from this scientific report. Copies of the report will be available on request.

Who has reviewed the study?

All research in the NHS is looked at by independent group of people, called a Research Ethics Committee to protect your safety, rights, wellbeing and dignity. This study has been reviewed and given favourable opinion by East London Research Ethics Committee 3.

Who can I contact for further information?

1. If you require further information about the study, please contact the ACIT Study offices via the Trauma Surgery secretary at [redacted] or email: [redacted]
2. If you require impartial, local advice, please contact the Patient Advice and Liaison Service, telephone: [redacted] or e-mail: [redacted]

Thank you for taking the time to read this sheet.

Date: ___/___/_____ Researcher Signature: _____ _____