Participant Information Sheet

DIRECTORATE OF SURGERY AND ANAESTHESIA
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Information Sheet A: Subject
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Research Ethics Committee: London – City and East
REC number: 07/Q0603/29

Title: Activation of Coagulation & Inflammation in Trauma II
Principal Investigator: Dr Ross Davenport, FRCS

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 serious injuries (trauma) in the future. Before you decide, it is important for you to understand why the research is being done and what is required from you. Please take time to read the following information carefully, and discuss it with your friends and family should you wish. If anything is unclear, we are happy to discuss the study with you and answer any questions you may have. Take your time to decide whether or not you wish to remain in the study.

Why is this research being carried out?

Trauma (serious injury) is one of the leading causes of death and disability worldwide. Over half of the deaths caused by trauma are due to the bleeding it causes. Blood clots are essential to stop you bleeding. We know trauma causes changes in the body which alter blood clot formation, but we do not fully understand why this happens. This research aims to help us better understand changes in blood clot formation after trauma. We also know that other changes in the blood occur, such as changes in the number and types of blood cells. We hope to learn more about these changes in order

to understand how the body responds after trauma and why some patients recover more quickly than others.

Why have I been chosen?

You were admitted to the Royal London Hopsital as a trauma patient following your accident on _____(insert date). When you arrived in the emergency department, doctors and nurses (trauma team) treated you according to standard hospital practices. At this time, it was inappropriate to ask you to consent for entry into our clinical trial, so the research team asked your trauma team leader (the doctor in charge of your care, who is independent to the research study) to act as your legal Advocate and give consent to enroll you in the trial.

What we are asking for now?

Firstly, we would like to ask you for consent to retain the samples and data we have already collected. This includes blood and tissues samples, and information from your hospital notes. All involvement is voluntary and any decision to withdraw or continue involvement with our study will not impact your care within hospital.

Secondly, we would like to invite you to continue being involved in the study. This may include taking further blood samples (which can be declined should you wish) and also continuing to collect data from your hospital notes.

What does taking part involve?

As part of the normal hospital care of trauma patients, a blood sample is taken and sent to the hospital laboratory for analysis. At this time, a small amount of extra blood (approximately six teaspoonfuls) was taken for research purposes. If you went on to have an operation within 7 days of your admission, we may also have taken a small sample of muscle tissue from your operation site. This muscle sample is approximately $1cm^3$ and should not affect recovery of your wound.

The table below shows the blood samples that have already been taken from you, and those that will be taken from you if you choose to remain in our study:

Sample time	Already taken	Future
Pre-Hospital (if applicable)		
Admission		
Your bleeding episode		

Date: _ _ / _ _ / _ _ Researcher Initials: ____

(if applicable)		
1 day		
3 days		
7 days		

Each sample will be no more than seven teaspoons in volume (40mls), and they will only be taken whilst you remain in hospital. You can opt out of any blood sample at any timepoint without affecting your further involvement in the trial.

Do I have to take part?

No. Participation in the trial is completely voluntary. Your decision whether or not to remain in the study will not affect the care you receive at any point. If you are happy to remain in the trial, you will be given this information sheet and asked to sign a consent form. You can withdraw from the study at any time in the future, without needing to provide a reason why you wish to withdraw.

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 collect the remaining blood samples at the timepoints documented above (if not already reached).
3. If youwent on to have an operation within 7 days of your admission, we may also have taken a small sample of muscle tissue from their operation site. This muscle sample is approximately 1cm^3 and should not affect recovery of their wound.
4. We will study your hospital notes to record details such as how your organs are functioning.
5. We will record if you develop any infections or have any operations during your hospital stay.
6. At day 28 or on your day of discharge (whichever is sooner) we will complete a short health questionnaire with you. If you agree, we will contact you again in a years time to repeat this questionnaire. Each questionnaire should take approximately five minutes to complete. The answers to the questions will provide us with valuable information about how you perceive your quality of life after the injury as well how many times you have had to visit healthcare professionals (doctors, physiotherapists, specialist nurses etc). All answers to the questions will remain confidential.

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 collected are:

- Blood samples - the risks of drawing blood include temporary discomfort from the needle stick and bruising.
- Muscle biopsy – will only be taken at time of surgery under anesthesia so you should be placed at no additional risk on top of the surgical procedure other than minor bleeding or bruising.

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 from the study 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. 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 1.

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 keep the samples we have already taken for use in future research.

Date: _ _ / _ _ / _ _ Researcher Initials: ____

What if I am not happy about the study?

We will only make very minor changes to the way you are looked after. It is extremely unlikely that this small change to normal practice will 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 is 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 3594 2040, or email RLHpals.bartshealth@nhs.net. You can also visit PALS by asking at any hospital reception.

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 in line with GDPR legislation and will be stored securely in coded form. Information about you and your samples will be identifiable only in a coded (pseudoanonymised) format, an dwill be kept separate from your personal information. Only authorised personnel such as researchers and research auditors will have access to the data.

What will happen to your study data and samples?

Study data and samples will be collected, stored, transferred and used in a secure and ethical manner that ensures protection of your fundamental rights and privacy. These will be processed at the research centre where you were enrolled, and then allocated a unique study identifier (pseudoanonymised). **Study materials will not be able to be linked back you, other than by responsible personnel at the site of your original enrolment.** Data and samples will only be accessed by authorised personnel (e.g. research fellows, study auditors). We will not share your personal details (e.g. name, address).

Research conducted may contain key personal information of necessity for research (e.g. age, gender, clinical and treatment data) but all study information will be anonymised at the end of any research project when results are published.

As part of this research study, we would also like to share some of the data and samples we collect with selected International collaborators to maximise the findings of our research. We hope that these collaborations, we will reduce the time taken to bring benefits to future trauma patients. All future

research projects will have been approved by a Research Ethics Committee. 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.

Queen Mary University of London is the sponsor for this study based in the United Kingdom. We will be using information from you and/or your medical records in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. Queen Mary University of London will keep identifiable information about you for 25 years after the study has finished.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

You can find out more about how we use your information at
http://www.arcs.qmul.ac.uk/media/arcs/policyzone/Privacy-Notice-for-Research-Participants.pdf

[INSERT HOSP NAME] will collect information from you and/or your medical records for this research study in accordance with our instructions.

[INSERT HOSP NAME] will use your name, NHS number and contact details to contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. Individuals from Queen Mary University of London and regulatory organisations may look at your medical and research records to check the accuracy of the research study.

[INSERT HOSP NAME] will pass these details to Queen Mary University of London along with the information collected from you and/or your medical records. The only people in Queen Mary University of London who will have access to information that identifies you will be people who will audit the data collection process. The people who analyse the information will not be able to identify you and will not be able to find out your name, NHS number or contact details.

[INSERT HOSP NAME] will keep identifiable information about you from this study for 25 years after the study has finished.

Queen Mary University of London will collect information about you for this research study from yourself and your medical records. This information will include your name, hospital and NHS number, contact details and health information, which is regarded as a special category of information. We will

use this information to contact you a year after your discharge to complete a follow up health questionnaire.

This information will not identify you and will not be combined with other information in a way that could identify you. The information will only be used for the purpose of health and care research, and cannot be used to contact you or to affect your care. It will not be used to make decisions about future services available to you, such as insurance.

Will any genetic tests be done?

Your study data and samples will be used for more than one study, including studies aimed at identifying genetic differences in patients that makes them more or less susceptible to the effects of traumatic injury. We will store a sample of your DNA, obtained from the blood sample for future testing. These samples are being collected to see if there are genetic differences between patients who recover quickly and those who don't. We will not be testing for genetic diseases or named inheritable conditions and therefore these tests will be of no individual significance to yourself in terms of inherited risk, insurance issues or to your children. Data will be anonymised and not traced back to individuals.

Samples containing DNA will be stored in a pseudoanonymised format 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. If you do not wish not to have your DNA stored, please sign to this effect in the appropriate part of the consent form.

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 reviewed by an independent group of people, called a Research Ethics Committee to protect your safety, rights, wellbeing and dignity. This study was reviewed by the London - City & East, Research Ethics Committee and given a favourable opinion.

Who can I contact for further information?

1. If you require further information about the study, please contact the ACIT researchers by telephone: 020 3594 0728 or by email: clinicaltrialsC4TS@qmul.ac.uk or Ross.davenport@qmul.ac.uk
2. If you require impartial, local advice, please contact the Patient Advice and Liaison Service, telephone: 020 3594 2040 or e-mail: RLHpals.bartshealth@nhs.net

Thank you for taking the time to read this information.

Date: ___/___/_____ Researcher Signature: _____

Date: _ _ / _ _ / _ _ Researcher Initials: ____