# Participant Information Sheet for The Activation of Coagulation & Inflammation in Trauma II (ACIT II) Study

Directorate of Emergency Care & Trauma
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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

During your recent stay in hospital you were included in a research study called ACIT II (full name: **Activation of Coagulation & Inflammation in Trauma II)** This research study has been helping us for a number of years to improve the care of patients who suffer serious injuries (trauma). Before you decide whether you wish to remain in the study, 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 any part of the study with you and answer any questions you may have.

## Why is this research being carried out?

Trauma (serious injury) often causes bleeding. Blood clots are essential to stop you bleeding. We know from previous research that trauma causes changes in the body which alter blood clot formation as well as changes in the number and types of blood cells, but we do not fully understand why this happens. This research study is helping us 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 hospital as a trauma patient following your accident on _____(insert date). When you arrived in the emergency department, doctors and nurses (trauma team) took care of you. At this time, it was inappropriate to ask you if you wanted to take part ('consent') in this research study so the research team asked the doctor in charge of your care at the time to act as your Legal Advocate and give permission ('consent') to enrol you in the study.

**What are we asking for now?**

Firstly, we would like to ask your permission to keep the samples and data we have already collected during your stay in hospital so far. This includes blood and tissues samples, and some information from your hospital notes.

Secondly, we would like to invite you to continue being involved in the study. This may involve taking further blood samples and permitting us to continue to collect data from your hospital notes.

**What does taking part involve?**

When blood samples were taken (as part of your normal hospital care), a small amount of extra blood (approximately six to eight teaspoonfuls) was also taken for the purpose of this research study. If you went on to have an operation within 7 days of your admission, we may also have taken a small sample (approximately $1cm^3$ ) of muscle tissue from your operation site.

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** (if applicable) | | |
| **1 day** | | |
| **3 days** | | |
| **7 days** | | |

Each sample will be no more than 40mls (six to eight teaspoons) in volume, and they will only be taken whilst you remain in hospital. You can say no to any blood sample being taken at any time point without affecting your further involvement in the study or your normal hospital care.

**Do I have to take part?**

No. Continued participation in the study is completely voluntary. Your decision whether to remain in the study will not affect the care you receive at any point. If you are happy to remain in the study, you will be given this information sheet to keep 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.

**What will happen if I agree to continue taking part?**

1. We will process and store the samples (blood and muscle tissue (if you had an operation)) we have already collected.
2. We will collect remaining blood samples at the time points documented above).
3. We will study your hospital notes and record details such as how your organs are functioning, and if you develop any infections or have any operations during your hospital stay
4. After 28 days or on your day of discharge (whichever is sooner) we will complete a five minute health questionnaire with you. If you agree, we will contact you again in a year's time to repeat this questionnaire.

**Are there any risks to taking part in the study?**

There are no long-term risks to you from participating in this study.
The short-term 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 anaesthesia so you should be placed at no additional risk.

**Are there any benefits of taking part in the study?**

There will be no direct benefit to you from participating in this study, but the information you give us 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.

**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 and there will be no change to the type or quality of care you receive. Any information already collected will be processed as part of the study. We will ask you if we can keep and process samples that have already been collected and may ask you to sign a consent form to reflect this. If you do not agree to sample storage, any samples already collected will be destroyed.

**What if I am not happy about the study?**

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 NHS complaints mechanisms are 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 0203 594 2040, or email bartshealth.familycontact@nhs.net.. You can also visit PALS by asking at any hospital reception.

**Will my taking part in the study be kept confidential?**

Yes. We follow all relevant ethical and legal practice and in line with GDPR legislation all information about you will be handled in strictest confidence. 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. **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 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 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.

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

The Royal London Hospital 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.

The Royal London Hospital 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.

The Royal London Hospital 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 numbers, 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 only be used for the purpose of health and care research, it will not identify you and will not be combined with other information in a way that could identify you.

**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 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 to have your DNA stored, you can indicate this on your 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 (**REC number:** 07/Q0603/29) 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 the Principal Investigator: Dr Ross Davenport, Ross.davenport@qmul.ac.uk
2. If you require impartial, local advice, please contact the Patient Advice and Liaison Service, telephone: 0203 594 2040, or email bartshealth.familycontact@nhs.net.

**Thank you for taking the time to read this information.**

Date: ___/___/_____ Researcher Signature: _____