# Personal consultee information sheet

**Study title: MODET, Multiple Organ Dysfunction in Elderly Trauma**

**IRAS: 209230**

A personal consultee is someone unconnected with the research study who knows the potential research participant in a personal capacity and is able to advise on the person's wishes or feelings. This could be a family member or close friend. I understand that by acting as my relative/friends consultee I am acting only on what I believe to be my relative/friends presumed wishes.

**As someone who knows _____ (patients name) well, you are being invited to consider whether he/she would be willing to take part in this research study based on your knowledge of him/her.**

The name of the research study is: **MODET, Multiple Organ Dysfunction in Elderly Trauma.** The title of the study means it is research that will be carried out with patients who are admitted to hospital following an injury (trauma) and may have developed a complication known as organ dysfunction. Older people (over 65 years of age) appear to suffer more of these problems and we wish to investigate the differences between older and younger trauma patients to try to understand why the elderly are more affected.

We would like to invite you, the personal consultee, to agree to your relative/friend taking part in a research study whilst they are unable to consent for themselves. Before you make a decision on their behalf, you need to understand why the research is being done and what it would involve, so please take time to read the following information carefully. We will visit you again in a day or two to see if you have any questions about the study. We encourage you to discuss this with other family members or a friend if you are unsure.

**What is the purpose of this study?**

Trauma or injury can cause both physical and psychological problems for patients. After admission to hospital the injured patient may be physically unwell for a time and need to be cared for in a critical care unit. Some patients may develop organ dysfunction after their injury. The definition of organ dysfunction is where one or more organs (such as the liver or lungs) are temporarily not working as they did before the injury. The affected organs will require medical intervention, such as oxygen or medications until they recover over a period of days or weeks.

The aim of this study is to understand how many trauma patients develop organ dysfunction, how severe it is and at what stage it occurs after their injury. We would also like to gain feedback from trauma patients on their experience of their recovery in the months after discharge from hospital to help us understand the longer term effects of organ dysfunction.

**Why is my relative/friend being invited to participate?**

Your relative/friend is currently in hospital after an injury. The critical care staff will monitor their progress every day and by analysing things such as their oxygen levels and blood test results the staff can see how their organs are functioning. They will record if your relative/friend has developed organ dysfunction, when it started and how long it lasted. This information will be anonymised so that none of your relative/friends personal details such as name, age or address are recorded in the research sheet.

**We are asking you to provide consent to continue to collect this anonymised information about your relative/friends time in hospital. We also ask you consent to allow us to contact your relative/friend at 12 months after discharge from hospital to see how their recovery is progressing. To find out where they are at this time point, we will need to contact the central NHS register and your relative/friends General Practitioner (GP) at 10 months after injury, and therefore ask for your consent to do this.**

**There are no extra medications used or extra blood tests taken as a result of being in this study.**

**Does my relative/friend have to participate?**
No, there is no obligation to take part in this study. If you decide that your relative/friend can participate you will be given this information sheet to keep and you will be asked to sign a consent form on their behalf. A decision not to take part or to withdraw will not affect your relative/friends standard of care in any way. Their legal rights will not be affected.

**What does participation involve?**
Approximately one year after your relative/friend is discharged home we would like to contact them via telephone, post or email, to complete a short questionnaire (whichever your relative/friend would prefer). This will take approximately 15 minutes to complete and will help us to evaluate their longer term recovery.

**What if I change my mind?**
You can withdraw your consent for them to be in the study at anytime. If you decide to agree to your relative/friend taking part in the study, you are still free to change your mind on their behalf at any time without giving a reason. A decision not to continue or to withdraw will not affect their care in any way and your relative/friend will not be contacted for follow up.

**What are the benefits of participating?**
Whilst there are no immediate benefits for those people participating in the project, it is hoped that the results will help us to understand the experience of organ dysfunction and improve the recovery of future trauma patients.

**What risks to my relative/friend are there through participating?**
There are no risks to your relative/friend through participating in this research. All data that we collect will be completely anonymised.

**Who will know that my relative/friend is in the study?**
Your relative/friends clinical team, the person who asked your permission to give consent for the study and the person who contacts your relative/friend a year after injury will know.

**Will my relative/friends taking part in this study be kept confidential?**
Yes. All information obtained during the course of this study will be kept confidential. Your relative/friend will be identified using a unique study number rather than using any personal information. The anonymised data will be kept for 20 years after the end of the study and stored in secure storage.

**What will happen to the results of the research study?**
Once the study is completed the results may be published in Scientific and Medical Journals and presented at health professional meetings. Your relative/friend will not be identifiable in any publications or presentations resulting from this study.

**Will I ever be contacted again in the future about this?**
No you will not be contacted in the future with regards to this study. However, you and your relative/friend can track progress of the study and other trauma studies on our website: http://www.c4ts.qmul.ac.uk/

**Who has reviewed this study?**
This study has been given a favourable ethical opinion by the London South East Research Ethics Committee on 26th October 2016

**What if something goes wrong?**
Queen Mary University of London has agreed that if your relative/friend are harmed as a result of your participation in the study, they will be compensated, provided that, on the balance of probabilities, an injury was caused as a direct result of the intervention or procedures they received during the course of the study. These special compensation arrangements apply where an injury is caused to your relative/friend that would

not have occurred if you were not in the trial. These arrangements do not affect your relative/friends right to pursue a claim through legal action.

Queen Mary University of London is the sponsor for this study based in the United Kingdom. We will be using information from your relative/friend's 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 relative/friend's information and using it properly. Queen Mary University of London will keep identifiable information about your relative/friend for 20 years after the study has finished.

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

You can find out more about how we use your information at http://www.jrmo.org.uk/

**If you have any questions about the study please contact the Chief investigator Dr Elaine Cole at Queen Mary University London on 020 359 40731 or via email: e.cole@qmul.ac.uk**

**Thank you for taking the time to consider participation in the study.**