Nominated consultee information sheet

Study title: MODET, Multiple Organ Dysfunction in Elderly Trauma

IRAS: 209230

A nominated consultee is someone unconnected with the research study who knows the potential research participant in a professional capacity and is able to advise on the person's wishes or feelings. This could be a doctor or healthcare professional primarily responsible for the patient's medical treatment.

I understand that by acting as my patient's consultee I am acting only on what I believe to be my patient's presumed wishes.

As someone who knows _____ (patients name), 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 nominated consultee, to agree to your patient 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.

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 patient being invited to participate?

Your patient is currently in hospital after an injury. The critical care staff will monitor their progress every day and they will record if your patient has developed organ dysfunction, when it started and how long it lasted. This information will be anonymised so that none of patients' personal details such as name, age or address are recorded in the research sheet.

We are asking you to provide consent to collect this anonymised information about your patients time in hospital.

Does my patient have to participate?
No, there is no obligation to take part in this study. If you decide that your patient 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 patient's standard of care in any way. Their legal rights will not be affected.

What if I change my mind?
You can withdraw your consent for them to be in the study at any time. If you decide to agree to your patient 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 they 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 patient are there through participating?
There are no risks to your patient through participating in this research. All data that we collect will be completely anonymised.

Who will know that my patient is in the study?
You and your patient's clinical team, and the person who asked your permission to give consent for the study.

Will my patients taking part in this study be kept confidential?
Yes. All information obtained during the course of this study will be kept confidential. Your patient 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 patient 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 patient 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 SouthEast Research Ethics Committee on 26th October 2016.

What if something goes wrong?
Queen Mary University of London has agreed that if your patient is 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 patient that would not have occurred if you were not in the trial. These arrangements do not affect your patient's 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 patients 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 patients information and using it properly. Queen Mary University of London will keep identifiable information about you for 20 years after the study has finished.

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

You can find out more about how we use your patients 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 your patients participation in the study.