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/friend’s consultee I am acting only on what I believe to be my relative/friend’s presumed wishes.

As someone who knows __________________________ (patient’s 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.

We would like to invite you, the personal consultee, to advise on your relative/friend’s wishes on taking part in a research study whilst they are unable to consent for themselves. Before you do this, 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 encourage you to discuss this with other family members or a friend if you are unsure.

The following information is the same as would have been provided to your relative/friend.

What is the purpose of this study?

The name of the study is: FRACT, the frailty in trauma study. 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 who may be frail.

‘Frailty’ is a condition we know can affect people as they get older and means people can be weaker and more vulnerable than they used to be. The sort of thing that suggest a person may be frail include:

- Difficulty getting about – slow walking, using a stick or frame
- Recent or recurrent falls
- Being confused
- Needing help to do everyday tasks

Other research studies have shown that after an accident (which is sometimes referred to as trauma) a frailer person is less likely to recover in the same way as a younger person might. Our belief is that if we were able to identify people at risk of being frail early, for example,
as they enter the hospital, we might be able to address their needs more quickly and tailor their care more appropriately.

If we find that this is the case then we will go on to make recommendations and write guidelines about to how to best manage a person who has been identified as being frail following trauma.

If you are able to advise us on your relatives/friend wishes on taking part we will use some short questionnaires to learn whether your friend/relative is frail. We will then follow their journey through hospital until discharge. We would also like to gain feedback on their experience of recovery in the months after discharge from hospital to help us understand the longer term effects of frailty in trauma.

**Why is my relative/friend been invited to take part in this study?**

We are looking to invite patients age 65 and over being admitted to hospital following an injury or accident (trauma) and this applies to your relative/friend.

**What will happen to my relative/friend in the study?**

If your relative/friend takes part in this study they will still receive exactly the same treatment as those patients who are not taking part in the study. Their treatment will not be delayed or changed.

As part of this study the nurse will go through some short questionnaires, sometimes called ‘screening tools’, and record answers to each of the questions. This is likely to take no more than 10-minutes. If your relative / friend has already left the Emergency Department we may have already collected this information after discussion with their doctor. We are using different questionnaires that are sometimes used to find out if a person is frail. The reason for using different types of questionnaires is that we not know the best way to identify patients who are frail following trauma. Some of the information can be taken from what the doctors or nurses have already found out. Identifying frailty in a person can be easy but often it’s not that obvious and that’s why questionnaires are helpful.

Through this research we are looking to discover the questionnaire that stands out as being ‘the best’. This means the best in terms of accuracy of diagnosing frailty but also one that is practical to use in a busy emergency department and of course, a questionnaire that is manageable for the patient.

Regardless of the results of the questionnaire, your relative/friend will still receive the care that they would expect to receive at any other time. After the initial questionnaires completed in their first few hours in hospital there are two further questionnaires, one will be completed in person on the day your relative/friend is discharged from hospital and the final one can be done over the telephone 6-months after discharge from hospital. If they do...
not wish us to contact them by telephone they can tell us how you would prefer us to do this.

If you do not wish your relative/friend to participate, we will not ask them these additional questions and their information will not be gathered and used for the purposes of our study.

**What other information will we need?**

We will consult your relative/friend’s medical records (or other relevant medical records elsewhere) for some information relevant to their admission. The information gathered will include age, gender, ethnicity, past medical history, information about any injury sustained and care received whilst in hospital, as well as details regarding their current living situation. This information will be anonymised so that none of your relative/friend’s personal details such as name or address are recorded in the research sheet.

We will also contact your relative/friend at 6 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 their General Practitioner (GP) or the check the central NHS register at 5 months after injury. We will also make a note of any future admissions to hospital they might have between discharge from this hospital and our contact in approximately 6 months time.

**What are the benefits and risks of taking part in this study?**

No health risks are anticipated. Although taking part in this study will not change their treatment at this time, it is important to find out whether they have been identified your relative/friend as either ‘frail’ or ‘not frail’ from the questionnaires we will take you through on this admission. We anticipate that this information could help guide treatment for patients identified as frail in the near future.

**What will happen to the results?**

The results of this research are likely to be published in a medical journal and a report, which will enable more people to benefit from the findings. All participants in the study will remain anonymous. If you would like to hear about the results, please let us know and we will write to you when they are available.

**Who is funding this study?**

This study is being funded by the Burdett Trust for Nursing, which is an independent charitable trust.

More information on the Burdett Trust for Nursing can be found on: www.btfn.org.uk/, by email: administrator@btfn.org.uk or by telephoning: +44 (0)20 7 399 0102
What if there is a problem?

**Complaints:** if you wish to complain, or have any concerns about any aspect of the way your relative/friend have been treated during the course of this study then please contact the researchers on <local contact details>, who will do their best to answer your questions or concerns. Alternatively, you can contact the hospital’s **Patient Advice and Liaison Service (PALS)** on <local contact details>.

**Harm:** there is little risk of harm associated with taking part in this study as it will only involve asking your relative/friend a few extra questions. In the event that something goes wrong and they are harmed because of this research and this is due to someone’s negligence then you may have grounds for legal action for compensation against the sponsor (St George’s University Hospitals NHS Foundation Trust), but you may have to pay legal costs. The normal NHS complaints mechanism will still be available to you: [https://www.nhs.uk/nhsengland/complaints-and-feedback/pages/nhs-complaints.aspx](https://www.nhs.uk/nhsengland/complaints-and-feedback/pages/nhs-complaints.aspx)

Will my relative/friend’s taking part in the study be kept confidential?

If you advise us they can take part, your relative/friend’s hospital doctor and GP will be informed of their participation in the study but otherwise their participation will be entirely confidential.

St George’s University Hospitals NHS Foundation Trust is the sponsor for this study based in the United Kingdom. We will be using information from your relative/friend’s and their 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 their information and using it properly. [SITE NAME] will collect information from your relative/friend’s and/or their medical records for this research study in accordance with our instructions.

St George’s University Hospitals NHS Foundation Trust will use their name, NHS number and contact details to contact your relative/friend about the research study, and make sure that relevant information about the study is recorded for their care, and to oversee the quality of the study. Individuals from St George’s University Hospitals NHS Foundation Trust and regulatory organisations may look at your relative/friend’s medical and research records to check the accuracy of the research study. [SITE NAME] will pass these details to St George’s University Hospitals NHS Foundation Trust along with the information collected from their medical records. The only people in St George’s University Hospitals NHS Foundation Trust who will have access to information that identifies them will be people who need to contact your relative/friend for the purpose of telephone follow ups and/or audit the data collection process. The people who analyse the information will not be able to identify them and will not be able to find out their name, NHS number or contact details.
[SITE NAME] will keep identifiable information about your relative/friend from this study for 5 years after the study has finished.

Your relative/friend’s rights to access, change or move your information are limited, as we need to manage the data in specific ways to ensure the research we conduct is reliable and accurate. If your relative/friend’s withdraws their consent to participate in a research project, this will not mean we will have to remove all data as well. We will keep the information about your relative/friend’s that we have already obtained to ensure research integrity is maintained in the public’s interest. To safeguard your relative/friend’s rights, we will strive to use the minimum personally-identifiable information possible.

You can find out more about how we use your relative/friend’s information https://www.stgeorges.nhs.uk/education-and-research/research/research-privacy-notice/

For general information on how the NHS uses research data please visit https://www.hra.nhs.uk/information-about-patients/

**What will happen if my relative/friend was unable to consent initially but then recovers the capacity to consent to the study?**

If your relative/friend becomes able to consent then they will be shown the patient information sheet and one of the researchers will discuss the study with then. They will be given the opportunity to consent to participation in the study or to withdraw from the study.

**Who has reviewed this study?**

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect the interests of patients and participants. This study has been reviewed and given favourable opinion by Social Care Research Ethics Committee (19/IEC08/0006)

**If you agree to my relative/friend being part of this study, what happens next?**

You will be given a copy of the information sheet and a signed consultee declaration form to keep.

**Further Information and contact details**

If you require any additional information or have any additional questions, further information can be found on our study website [ENTER ADDRESS]. Alternatively, please feel free to contact your doctor or the study lead.

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