mulTiArm therapeutiC sTudy in pre-ICU patients admitted with Covid-19-Repurposed drugs (TACTIC-R)

Information for Legal Representative

(where participants are unable to consent for themselves)

Introduction

We feel your relative/friend/patient is unable to decide for himself/herself whether to participate in this research.

To help decide if he/she should join the study, we'd like to ask your opinion whether or not they would want to be involved. We'd ask you to consider what you know of their wishes and feelings, and to consider their interests. Please let us know of any advance decisions they may have made about participating in research. These should take precedence.

If you decide your relative/friend/patient would have no objection to taking part we will ask you to read and sign the consent form to give consent on behalf of your relative/friend to participate in the TACTIC-R trial. We'll then give you a copy to keep. We will keep you fully informed during the study so you can let us know if you have any concerns or you think your relative/friend should be withdrawn.

If you decide that your friend/relative/patient would not wish to take part it will not affect the standard of care they receive in any way.

If you are unsure about taking the role of legal representative you may seek independent advice.

We will understand if you do not want to take on this responsibility.

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

What is a legal representative?

In the context of clinical trials, specific legislations applies to protect the rights of people who are not able to make decisions for themselves. This includes safeguards for the conduct of research involving people who may, temporarily or permanently, not be able to consent due to a medical problem, for example because of severe illness, unconsciousness, learning disabilities, head injuries or mental health problems.
In particular, the regulations around clinical trials requires that before a person who is unable to consent is involved in a trial, another suitable person must be identified who can give consent for their enrolment in the trial. You have been given this information because you have been identified as suitable to act as a legal representative by the research team. This sheet and the following information sheet will explain what this research will involve for you and the patient.

Why have I been approached?

A legal representative may be someone who has a personal relationship with the patient but does not have a conflict of interest, such as being part of the research or gaining financial benefit. Examples of suitable people who might act in this manner are:

- A family member, carer or friend
- A court appointed deputy who has a personal relationship with the participant

When reasonable steps have been taken to identify a personal legal representative and one is unavailable, then the researcher must nominate a person to act as in their stead. This person may be involved in the patient's care in a professional capacity but they must have no connection with the research project. A suitable person who might act as a nominated legal representative is an independent doctor working with the patient or nominated by the healthcare provider.

What are the duties of a personal legal representative?

The main responsibility of the legal representative is to give their consent for the patient/friend/relative to be included in this research. The consent is optional, and if you do not provide this we would respect that decision. Please as far as possible consider what the patient/relative/friend may have wanted and set aside your personal opinion about participation.

In order to help you make the decision about acting as the legal representative, and to help you in deciding whether to give consent, you will be provided with the separate participant information sheet describes what is involved in the trial. This information is the same that given to patients who are able to make this decision for themselves.

What will happen if I agree?

If you agree for your patient/friend or relative to take part in the study then they will be a full participant. The information sheet, which will be explained to you by a researcher, describes what this will involve. If you agree now you can withdraw your agreement at any point in the future. If your friend or relative regains capacity later, they will be asked whether they would like to continue taking part.