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 consultee is an independent doctor working with the patient or nominated by the healthcare provider.

What are the duties of a consultee?

The main responsibility of the legal representative is to give their consent for the patient 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 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, 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 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.