

CONSENT IN THE SWiFT STUDY

Frequently asked questions

Purpose

The purpose of this document is to describe the different types of consent and the flow of consent activities for this study.

Who is it for?

This is for research teams at receiving hospitals who are initiating or completing the consent process.

Why is it required?

It is important that all levels of consent are accurately recorded to be able to objectively demonstrate to the Confidentiality Advisory Group (part of the HRA) that this study is compliant with HRA approval.

Types of consent

Participants are entered into the study by Air Ambulance teams under an emergency waiver of consent, as they lack capacity to consent at the time of injury. This means that participants can stay in the study whilst informed consent is sought in hospital.

1. Professional legal representative

A doctor or nurse who has had the requisite Trust training to be a Professional legal representative and be aware of the study aims and what is involved. They must NOT be a member of the core research team (e.g. Principal Investigator, Research Nurses) and NOT be listed on the delegation of duties log.

2. Personal legal representative

This is usually a member of the participant's family. However, it can also be a friend, a member of the clergy or a lawyer. It is important to remember that this could also be someone with a Health and Welfare Lasting Power of Attorney.

3. Parent or Guardian consent

The Medicines for Human Use (Clinical Trials) Regulations prohibit children under the age of 16 from giving consent to take part in a Clinical Trial of an Investigational Medicinal Product (CTIMP). This study is a CTIMP, so parent or guardian consent is required for minors. If the child is under the care of the local authority, the legal guardian must sign the consent form. It is important that where possible, young adults under 16 years of age understand the study and sign an assent form where/if appropriate.

4. Participant consent

Participant informed consent should be sought when the participant has capacity to begin the consent process.

What is the difference between a type of consent and a level of consent?

The type of consent relates to who provides it.

The level of consent is the last type of consent obtained for the participant.

What level of consent should I aim for?

You should always aim to obtain informed consent from the participant. However, this may or may not be possible, depending on the participant's medical status and personal circumstances.

Which order should I obtain consent in?

Typically, we would expect:

1. As soon as possible/practicable - Professional legal representative
2. When possible - Personal legal representative / parent or guardian consent
3. When possible - Participant informed consent / participant assent for minors

At the very least, your final level of consent should be a Professional legal representative.

Examples

The following examples may be useful to illustrate types and levels of consent in real world scenarios.

Scenario	Types of consent obtained	Final level of consent
Participant A is 86 years old and had a serious fall from a ladder. They had a rapid sequence induction pre-hospital. Since arrival at hospital 5 days ago, they were admitted to critical care where they remain intubated. Participant A has no friends or family. Participant A dies from their injuries without regaining consciousness.	Professional legal representative <i>No other consent is possible</i>	Professional legal representative
Participant B is 22 years old and was out on their motorcycle when they were injured in a road traffic collision. Participant B was given ketamine and morphine pre-hospital. Their brother is travelling to the hospital but won't arrive for another 2 days. Participant B was admitted to a ward and regained capacity 4 days after the accident.	1. Professional legal representative <i>As the participant lacks capacity and no personal legal representative is available for 2 days</i> 2. Personal legal representative <i>Their brother provides personal legal representative consent when they arrive</i> 3. Participant informed consent <i>When the participant regained capacity, they provided consent</i>	Participant informed consent

Scenario	Types of consent obtained	Final level of consent
Participant C is a 4 year old child who fell from the garden swing whilst at home with their parents.	1. Professional legal representative <i>The parents lack capacity on the grounds of distress at the time of admission</i> 2. Parent or guardian consent <i>The parents are approached the day after the accident on the ward or when appropriate</i>	Parent or guardian consent
Participant D is 17 years old. They were shot in the leg and admitted late last night. The participant was visited by the research team the following morning and they had regained capacity.	Participant informed consent <i>Participant consent was obtained before a professional legal representative could be approached so a professional legal representative was not required</i>	Participant informed consent
Participant E and their family were injured when a coach they were travelling in was involved in an accident on the motorway. The spouse of Participant E travelled with them to the hospital. Participant E was transferred to critical care where they died the next day.	1. Professional legal representative <i>The spouse lacks capacity on the grounds of distress. This study has approval from the REC and HRA not to approach the family of those who have been bereaved to obtain consent on their behalf</i>	Professional legal representative
Participant F is a 14 year old who was hit by a car whilst walking down the street. On arrival at hospital, they underwent emergency orthopaedic surgery. They carried no ID, and it was the following day before their identity was confirmed. They are under the care of the local authority.	1. Professional legal representative <i>As the participant identity is unknown</i> 2. Parent or Guardian consent <i>If the participant is a ward of the state, the form should be signed by the appropriate legal guardian</i>	Parent or Guardian consent <i>The assent form is not a consent form</i>

Participant G is a 35 year old who had an early morning accident at work using heavy machinery. They regained capacity that evening and were visited by the research team. They informed the team that they did not wish to continue in the trial.	(A) Professional legal representative if this was obtained before speaking to the patient. OR (B) None, if no professional legal representative was obtained	(A) Professional legal representative, participant is withdrawn. OR (B) None, participant is withdrawn
Participant H is 25 years old and was involved in an altercation in a pub. They were severely agitated in the Emergency Department and continued to be so on the ward. Their family arrived and they were also disruptive, and had threatened staff.	Professional legal representative <i>If in your opinion (or those of their clinical care team), approaching a participant or their family/friends would put you at risk of abuse or harm, please approach a professional legal representative instead and document this</i>	Professional legal representative
Participant J was stabbed on a Friday night. Participant J is homeless and has no General Practitioner. Your Trust research team has no weekend cover. Participant J self-discharged before they could be approached by the research team and left no contact details.	Professional legal representative	Professional legal representative
Participant K is 22 years old and has attempted suicide. They were assessed under the Mental Health Act in the Emergency Department. They do not have capacity to consent. Participant D was transferred to a mental health trust.	1. Professional legal representative <i>As the participant has continuing lack of capacity and has moved to a non-participating Trust</i>	Professional legal representative