Plymouth Research and Development

University Hospitals Plymouth NHS Trust

Standard Operating Procedure

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Title:	**Consent procedures for entry into a Research study**		
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Name:	Chris Rollinson	Version No:	7.0
Signature:		Effective Date:	16th June 2021
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1. Purpose

To describe the procedure for receiving written informed consent from a potential study participant.

The most comprehensive definition of informed consent is to be found in the Nuremburg Code (1947):

'The voluntary consent of the human participant is absolutely essential. This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, over-reaching or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the participant matter involved as to enable him to make an understanding and enlightened decision'.

Informed consent in the context of a research study is a process of information exchange; the giving of information, the discussion and clarification of the information and the taking of the participant's verbal and written consent. Participants must have given their informed consent prior to participating in any study procedures. The process of obtaining informed consent should be documented in the participant's medical records and a copy of the signed consent form inserted.

University Hospitals Plymouth (UHP) 'Consent to Examination or Treatment' policy does not stipulate which healthcare professionals should take consent, however, to comply with the Declaration of Helsinki and International Conference on Harmonisation Good Clinical Practice guidelines (ICH GCP), the professional must be competent to take consent; because they:

- have agreed to take on the responsibility
- carry out the procedure
- have received specialist training
- have been assessed and are aware of the limits of their knowledge
- do not take on responsibilities outside of their level of competence.

It is important that this SOP is read and understood before study personnel start receiving consent, but it should also be referred to if any doubt arises regarding the process of informed consent during the study.

2. Scope

This SOP applies to all staff involved in receiving consent including on-going consent for research hosted by, and/or sponsored by UHP.

3. Responsibilities

The Principal Investigator (PI) retains overall responsibility for ensuring a participant's consent is valid prior to entry into the study. If this responsibility for taking informed consent

is delegated, it must be to an individual with the appropriate specialist training, experience and knowledge to enable them to explain fully the implications of participating in the study to the potential participant.

The delegation of the consent process by the Investigator to an appropriate, suitably qualified member of the research team should be considered on a trial-by-trial basis, in accordance with ICH GCP and UHP guidelines.

4. Documents needed for this SOP

Study participant information sheet

Study informed consent form

Study delegation log

5. Related documents

E6 ICH GCP guidelines

Nursing & Midwifery Council (NMC) Code of Professional Conduct

Nuremberg Code 1947

UHP Consent to Examination or Treatment Policy

ICH Harmonised Tripartite Guideline for Good Clinical Practice (1996)

Declaration of Helsinki (2013)

UK Policy Framework for Health and Social Care Research (2017)

The Medicines for Human Use (Clinical Trials) Regulations 2004 (SI 2004/1031)

The Medicines for Human Use (Clinical Trials) Amendment Regulations 2006 (SI 2006/1928), and Amendment (No. 2) Regulations (SI 2006 No 2984)

The Mental Capacity Act 2005

Consent and Participant Information Sheet Preparation Guidance (HRA)

6. Definitions

ICF: Informed Consent Form is a document signed by the participant/ legal representative as well as the member of staff receiving the consent confirming the participant's willingness to taking part having been informed of all aspects of the trial.

Incapacitated Adult: A patient is deemed to lack legal capacity to consent or refuse only when they cannot be helped to reach their own decision.

Minor: A person under the age of 16 years.

PeLR: A Personal Legal Representative is a person independent from the study who is suitable to act as legal representative by virtue of their relationship with the incapacitated adult or minor, and is available and willing and willing to do so.

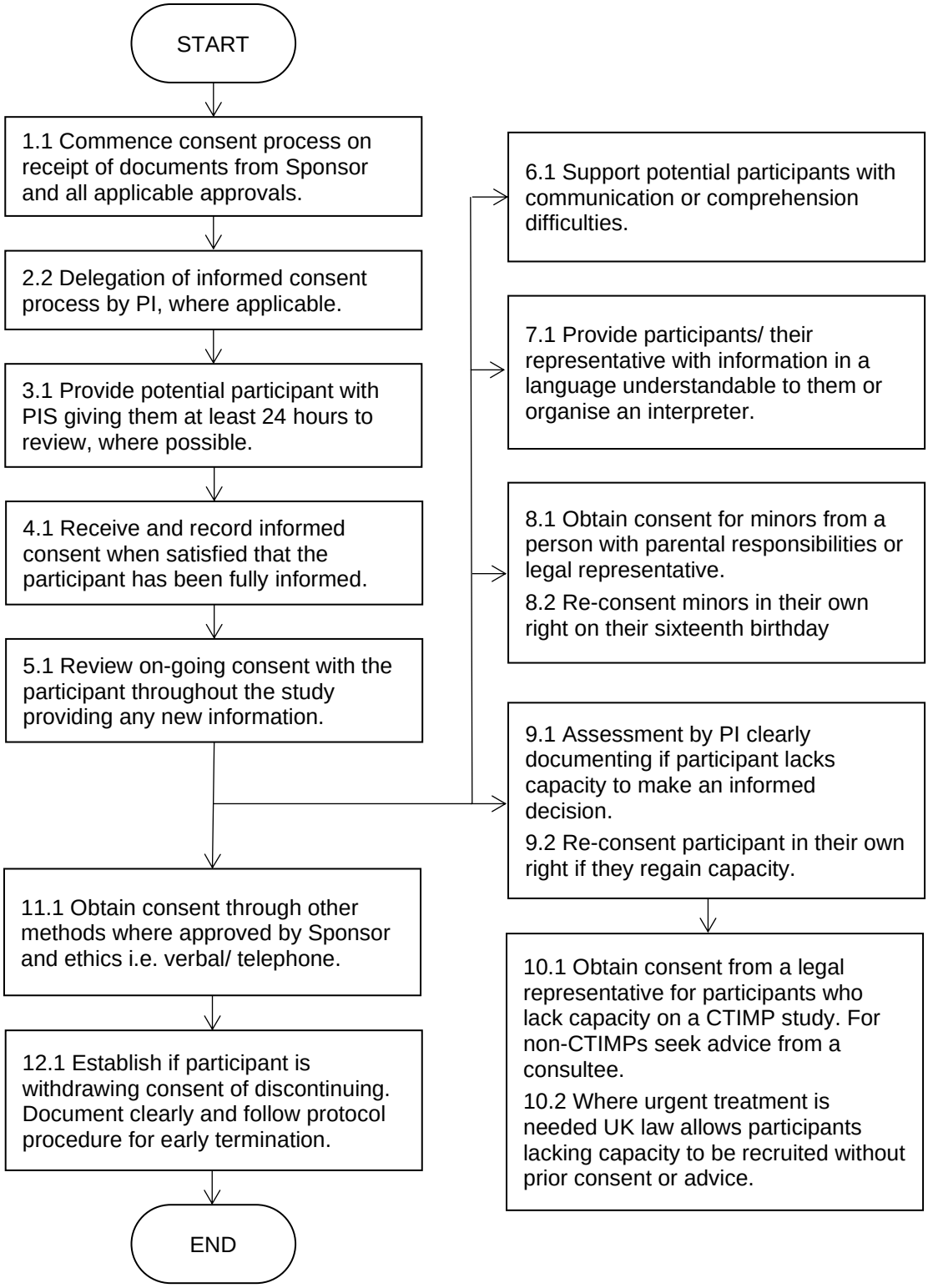
Personal Consultee: A person who cares for the adult lacking capacity or is interested in that person's welfare, but not professionally or for payment.

PIS: Participant/ Patient Information Sheet is a leaflet designed to provide the potential participant with sufficient information to allow that person to make an informed decision on whether or not they want to take part.

PrLR: A Professional Legal Representative is an independent doctor, responsible for the medical treatment of the adult, or a person nominated by the Trust *via* the R&D Dept.

Professional Consultee: A professional who is independent of the study.

7. Process map(s)/ flow chart(s)



8. Procedure

Step	Action	Responsibility
1	**When the informed consent process can begin?**	
1.1	Commence informed consent process when all approvals are in place: • Health Research Authority Approval • Clinical Trial Authorisation from the MHRA • REC Favourable Opinion • Local R&D Capacity and Capability or amendment acknowledgement Completion of training (Site Initiation Visit or amendment training) by site staff.	All research staff delegated to consenting.
2	**Who can receive informed consent and delegation?**	
2.1	Receiving informed consent shall be done by a **qualified person** as stated in the Declaration of Helsinki (2013). GCP guidelines state 'The **investigator, or, a person designated by the Investigator** should fully inform the participant' **(**ICH GCP 4.8.5) and the written informed consent form should be signed and dated by the **'person who conducted the informed consent discussion'**.	PI

2.2	Delegation of the informed consent process is the responsibility of the PI who must consider:
	• Ethics, HRA, and Sponsor approval for the delegation of informed consent.
	• Designee:
	  ○ accepts additional responsibility and feels confident to receive informed consent in line with professional organisational guidelines i.e. General Medical Council, Nursing & Midwifery Council, Code of Professional Conduct,
	  ○ has a comprehensive understanding of the proposed investigation or treatment, and risk-benefit.
	  ○ qualified by experience and/ or should have received appropriate training documented in their *Curriculum Vitae* and study training documented on the training log in Investigator Site File (ISF).
	• Task delegation recorded on the Study Delegation Log held in the ISF.
	• Effective communication line back to PI who is responsible for patient's care and for ensuring participants fully understand what they are consenting to.
		PI and staff delegated to receive consent.

Step	Action	Responsibility
3	**Information for the participant**	
3.1	Provide information in both oral and written form, ensuring the Participant Information Sheet (PIS) has been localised. Ample time (at least 24 hours) given to the participant to read the most recent approved PIS and discuss the information with family and friends. Discussion with participant (individually not in groups), giving them opportunity to understand the objectives, risks and inconveniences of the trial and the conditions under which it is to be conducted. ICH GCP (4.8.10) describes what should be explained to the participant during the discussion. Allow participant opportunity to ask questions of the investigator or delegated representative. Convey with participant their future care or treatment will not be affected if they decide not to take part and they are free to withdraw at any stage. The investigator or delegated representative must not coerce or unduly influence the participant to take part or continue to take part in the trial. Ensure, where changes are made to the PIS and/ or Informed Consent Form (ICF) during the study, participants are willing to continue under the new conditions by signing the new version.	All research staff delegated to consenting.
4	**Receiving and recording informed consent**	
4.1	Complete ICF only once person receiving consent is satisfied that the participant has been fully informed: • Participant must initial each consent item, clearly print name, sign and date. • Person receiving consent must also clearly print their name, sign and date. Record the process of obtaining informed consent in the participant's medical records or research record, if a healthy volunteer, detailing the study title, date and time of consent. Audiotaping and video of the consent process may be utilised with permission of the individual and accordance with local policies. Place original signed ICF in the relevant section of the ISF and a copy in the medical notes, along with a copy of the PIS. Provide the participant with a copy of the completed consent form. The participant may request a copy by email, ensure this is recorded in the medical notes and their email address is checked prior to sending.	All research staff delegated to consenting.

Step	Action	Responsibility
5	**Ongoing consent throughout the study**	
5.1	Giving participant's information about the study is an on-going process and should not cease once the ICF has been signed. This is especially significant with the introduction of protocol amendments or the updating of side effects associated with the treatment. Availability of important new information may be relevant to the participant's willingness to continue. In these circumstances the study participant may need to re-consent on an amended and approved ICF in order to continue involvement in the study.	All research staff delegated to consenting.
6	**Participants with communication or comprehension difficulties**	
6.1	Assume an adult is capable of taking decisions unless the opposite has been demonstrated. This applies just as much to people with learning disabilities as to any other adult. Provide appropriate help to participants with comprehension or communication difficulties enabling them to make their own decisions e.g. using visual aids, sign language etc. Involve an independent patient advocate in the consent process where there are communication difficulties. Ask mentally competent participants who understand English but do not read or write to place a "mark" on the ICF in place of their signature. Receiving verbal consent is permitted in the presence of at least one witness if the participant is unable to sign or to mark the ICF. A recording of the process may be taken, providing the participant with a copy. Document a detailed account of the consent process in the medical records.	All research staff delegated to consenting.
7	**Participants whose first language is not English or non-English speakers**	
7.1	Provide participants or their representative with information in a language understandable to them. The Sponsor is responsible for accurate translation of the PIS/ ICF, and seek ethical approval before their use. Verbal translation of an English ICF must not be substituted for a written translation. During the consent process a translator may be required to ensure the participant has a full understanding of all the issues and risk-benefit prior to consenting. Persons receiving consent from non-English speaking participant must be fluent in English and the other language, or be assisted by a translator. Family or friends of the participant or their representative may not serve as translators. How to organise an interpreter is documented in the Trust Administrative Procedure Note (APN) located in Trust Documents > APN's > Equality and Diversity.	All research staff delegated to consenting.

Step	Action	Responsibility
8	**Minors**	
8.1	Consider these factors when seeking consent from under 16s: • Study relates directly to a clinical condition the minor suffers or can only be carried out on minors. • Is there some benefit to participant and the clinical study is necessary to validate data obtained in other clinical studies able to give informed consent. • Study designed in a way to minimise pain, discomfort, fear and other foreseeable risk in relation to the disease and the minor's stage of development. • Minor receives information regarding the study according to his/ her level of understanding, from staff with experience with minors. • Person with parental responsibility or if not available, legal representative where emergency treatment is provided as part of the trial, are given opportunity to understand the study, and given informed consent. • Parent or representative provided with a contact number for the research team to obtain further information. • Parent or representative, and the minor themselves must be aware of their right to withdrawn from the study at any time. • No incentives or financial inducements must be given except for compensation in the event of injury or loss.	All research staff delegated to consenting
8.2	Re-consent minors in their own right on their sixteenth birthday. This is important on longitudinal studies.	All research staff delegated to consenting
9	**Incapacitated adults**	
9.1	Assessment by the PI or experienced independent clinician of the participant's capacity to make an informed decision. Consider these fac**t**ors: • Study relates directly to life threatening or debilitating clinical condition from which the participant suffers and the procedure/ intervention is expected to benefit the participant, outweighing the risks or producing no risks at all. • Study is essential to validate data obtained in other clinical studies involving persons able to give informed consent. • Study designed in a way to minimise pain, discomfort, fear and other foreseeable risk in relation to the disease and the cognitive abilities of the participant. Document assessment and conclusion in the medical notes.	All research staff delegated to consenting.
9.2	Re-consent participants in their own right if they regain capacity during the course of the study.	All research staff delegated to consenting.

Step	Action		Responsibility
10	**Regulations governing consenting adults lacking capacity**		
10.1	CTIMP must comply with the Medicines for Human Use Regulations Type of legal representative which should be approached for <u>consent</u>: Personal legal representative (PeLR). *If one is not available:* Professional legal representative (PrLR).	Non-CTIMP must comply with the Mental Capacity Act Type of consultee which should be approached for <u>advice</u>: Personal consultee. *If not available or unwilling:* Professional consultee.	All research staff delegated to consenting.
	Provide representative or consultee with sufficient information in an understandable form about the study. Document the consent or advice (consultee only) process, recording: • role of the patient's representative • their relationship to the patient • response of the participant • signed statement obtained • advice given by consultees recorded on a declaration form (rather than a consent form; they do not give consent)		
10.2	Obtaining consent from a legal representative or advice from a consultee in emergency research may not be reasonably practicable. UK law allows participants lacking capacity to be recruited without prior consent or advice if treatment needs to be urgently given. Approval for this procedure must be agreed by ethics and consent/ advice sought from the representative or consultee as soon as possible.		
11	**Alternative methods for obtaining consent**		
11.1	Obtaining consent in verbal or telephone form must receive ethical approval. The PI should ensure: • Verbal or telephone consent is undertaken with a colleague who can verify the process, if possible. • PIS is given or sent to participants, giving them sufficient time to review. • Follow an ethically approved script provided by the Sponsor. If not provided, be consistent when talking to participants. • Record the reading of consent statements and the participants answers indicating willingness to participate, where possible. The documented record of events verifies the telephone consent process. • Clearly document the process in the medical records.		All research staff delegated to consenting.

Step	Action	Responsibility
12	**Withdrawal of consent**	
12.1	Where a research participant, legal representative, or parent/ guardian wishes to withdraw consent from a study or the PI responsible for the participants care decides it is in the best interest of the participant, the withdrawal process and reasons for withdrawal must be fully documented in the participant's medical notes. Establish whether the participant is withdrawing consent or confirm if willing to continue follow up until the study naturally ends. Follow early termination procedures as outlined in the study protocol. Document process and the participant's decision in the medical notes.	PI and all research staff delegated to consenting.

9. Changes from last revision

SOP template change and addition of alternative consent methods.