STANDARD OPERATING PROCEDURE FOR RESEACH
The Process of Obtaining Informed Consent for a Research Study

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SOP SUMMARY

This SOP describes the procedure for obtaining written informed consent from a potential research participant.

The Trust monitors the implementation of and compliance with this policy in the following ways:

Monitoring of implementation and compliance with this procedure will be undertaken by the Executive Medical Director, Research manager, Research lead, R&D department staff and R&D group.

Services	Applicable	Comments
Trustwide	✓	
Essex MH&LD		
CHS		

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STANDARD OPERATING PROCEDURE: The Process of Obtaining Informed Consent for a Research Study

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1. BACKGROUND

Informed consent in the context of clinical research is the process by which a competent subject voluntarily confirms his or her willingness to participate in a particular study having comprehended all aspects of the study. Performing any research related procedure on someone without first obtaining their informed consent, is in breach of UK Regulations, which were developed according to the European Directive on Good Clinical Practice in Clinical Trials (2001). A comprehensive definition of informed consent is to be found in The Declaration of Helsinki (1964).

Written documentation consists of three elements:

- **Documentation in the patient's casenotes** together with a copy of the signed consent form
- The **(Patient) Information Sheet** (PIS). Describes the trial in layperson's terms.
- The **Informed Consent Form** (ICF). Documents that informed consent has been taken, when and by whom.

2. PURPOSE

This SOP describes the procedure for obtaining written informed consent from a potential research participant.

3. PROCEDURE

Involvement in the Consent Process

The Research Governance Framework, (DH2005) states that all staff involved in research must be qualified by education, training and experience, or otherwise competent under the supervision of a suitably qualified person, to perform their tasks. In order for any member of the research team to play a role in the consent process, the following criteria must be met:

1. The staff member must have a comprehensive understanding of the study, potential treatment toxicities and the associated disease area. He/she should be qualified by experience and/or should have received appropriate training for this study. All training must be documented.

2. There is a written agreement between the Principal Investigator and all staff involved in the consent process describing the respective roles and responsibilities. Delegation of responsibility for aspects of the process should be documented on the Study Delegation Log/Site Responsibility Log (title can vary, but essentially a log that captures each member of the study team and their individual responsibilities in the management and conduct of the study and is signed & dated by the Principal Investigator).

3. An effective line of communication is maintained back to the Principal Investigator/person who is ultimately responsible for the patient's care.

Delegation of Responsibility to Obtain Informed Consent

The Declaration of Helsinki clearly states that the person obtaining informed consent should be a qualified physician. “After ensuring that the subject has understood the information, the **physician** should then obtain the subject’s freely given informed consent, preferably in writing” (Edinburgh 2000 amendment)

However ICH Good Clinical Practice guidelines states ‘The **investigator, or, a person designated by the Investigator** should fully inform the subject’ (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’. The delegation of Informed Consent to an appropriate, suitably qualified member of the research team should be considered on a trial-by-trial basis, taking account of local circumstances and in accordance with ICH Good Clinical Practice Guidelines.

If staff other than the investigator are to accept responsibility for the informed consent process and/or being the sole signatory on the Informed Consent Form it is important the following criteria are met:

1. The designee is prepared to take on this additional responsibility AND feels confident to take informed consent in line with their Code of Professional Conduct or other professional organisational guidelines.

2. He/she has a comprehensive understanding of the study, potential pharmacological interactions/treatment toxicities and the associated disease area. The designee should be qualified by experience and/or should have received appropriate training for this study. All training must be documented.

3. The delegation of responsibility should be documented on the Study Delegation Log/Site Responsibility Log.

4. An effective line of communication is maintained back to the Principal Investigator/person who is ultimately responsible for the patient’s care.

It is ultimately the responsibility of the Principal Investigator to ensure that subjects have fully understood what they are consenting to. All relevant consent forms must be completed and filed appropriately and the process of consent must be described in the patient notes.

The subject must sign the informed consent form prior to any study related procedures being conducted. The informed consent process should not cease once the informed consent form has been signed, the practice of giving information about the study to subjects should be an ongoing process performed by all members of the research and/or multidisciplinary team (as appropriate). This is particularly significant with the introduction of protocol amendments and the availability of important new information that may be relevant to the subject’s willingness to continue participation in the study. In these circumstances it may require the study subject to re- consent on the amended consent form in order to continue involvement in the study.

The timing of the signing of the consent form relative to study registration and the initiation of study procedures is subject to audit by governing bodies.

Informed consent can be seen as a two-step process, informing the subject and taking consent.

Informing the subject

1. Patient information should be provided to potential study subjects in both an oral and written form, this SOP describes both elements.

2. Information may be presented to potential subjects using many formats and different media, including video, posters, recorded consultations, CD Rom etc. All information presented to subjects is subject to governing body approval.

3. The language used in the oral and written information about the study including the written consent form, should be as clear and concise as practical and should be described in layman's' terms so as to be understandable to the subject. The use of diagrams may assist in this process. A comprehensive list of information that should be included in any explanation to a potential subject can be found in **Appendix A**.

4. The subject should be provided with ample time and opportunity to read the consent form. Ideally the potential subject should have a few days to review the study information in order for the individual to discuss the study with family, friends or others. HRA guidelines recommend a minimum of 24 hours between the provision of study information and obtaining a signed consent form, though under some circumstances Ethics committees may allow a shorter timeframe. Prior to the subject signing the consent form, all questions should be answered by appropriate members of the research team.

5. Any information imparted to the subject (written or verbal) should not contain any language that causes the subject to waive (or appear to waive) any legal rights, or that releases (or appears to release) the investigator, institution or sponsor from liability for negligence.

6. Neither the Investigator nor any member of the clinical research team should coerce or unduly influence a subject to participate or to continue to participate in a trial.

7. The Informed consent form should be revised when necessary i.e. when new information becomes available that maybe relevant to the subjects consent. Any revisions should be approved by the Research Ethics Committee as appropriate **before** use. The subject should be informed of new information in a timely manner. The communication of this information should be documented in the subject's medical records.

8. The informed consent form should be identifiable by date and/or version number and be printed on headed paper associated with the particular hospital/Trust where the study is being conducted.

9. Guidance for producing patient information sheets is available on the HRA website

http://www.hra.nhs.uk/resources/before-you-apply/consent-and-participation/consent-and-participant-information/

10. Guidance for inserting local information is available on the EPUT Trust Website: https://eput.nhs.uk/wp-content/uploads/2014/11/Local-Guidance-for-Researchers.docx

Taking Informed Consent

When the person taking informed consent is satisfied that the subject has been fully informed and understands what study participation entails the consent form should be signed and personally dated by the subject and by the authorised person who conducted the informed consent discussion.

The process of obtaining informed consent should be documented in the subject's medical records, detailing the study title and/or acronym and the date that consent was obtained. The entry should be dated and signed by the person authorised and responsible for conducting and obtaining the subjects informed consent.

Two copies of the signed and dated consent form should be made, the original should be filed in the relevant section of the Study File, a copy should be given to the subject and a copy should be filed in the subjects medical records. Subjects should get copies of all relevant, updated and new information, regarding the study throughout their participation.

If a study participant is not a registered patient of the Trust, and therefore does not have a Trust medical record, then a paper file must be created and maintained to record informed consent.

Informed consent of incapacitated adults

The definition of an incapacitated adult under the Medicines for Human Use (Clinical Trials) Regulations 2004 is *"an adult unable by virtue of physical or mental incapacity to give informed consent"*.

1. Points 1 & 2 below sets out the hierarchy prescribed in the Regulations for determining what type of legal representative should be approached to give informed consent on behalf of an incapable adult prior to inclusion of the subject in the trial. The hierarchy below is for England, Ireland and Wales.

1. Personal legal representative
A person not connected with the conduct of the trial who is:
(a) suitable to act as the legal representative by virtue of their relationship with the adult, *and*
(b) available and willing to do so.

2. Professional legal representative
A person not connected with the conduct of the trial who is:
the doctor primarily responsible for the adult's medical treatment, or
a person nominated by the relevant health care provider (e.g. an acute NHS Trust or Health Board).
A professional legal representative may be approached if no suitable personal legal representative is available

2. The process is the same as detailed previously with the addition of the following conditions and principles which apply to the inclusion of an incapable adult in a clinical trial

- The legal representative has had an interview with the investigator, or another member of the investigating team, in which opportunity has been given to understand the objectives, risks and inconveniences of the trial and the conditions under which it is to be conducted.

- The legal representative has been provided with a contact point where further information about the trial may be obtained.

- The legal representative has been informed of the right to withdraw the subject from the trial at any time.

- The legal representative has given informed consent to the subject taking part in the trial.

- The legal representative may, without the subject being subject to any resulting detriment, withdraw the subject from the trial at any time by revoking the informed consent.

- The subject has received information, according to his or her capacity of understanding, about the trial and its risks and benefits.

- The investigator must consider the explicit wish of a subject capable of forming an opinion and assessing the information provided. This applies both to the wish of a subject to refuse to take part, or to withdraw from the trial at any time.

- No incentives or financial inducements are given either to the subject or to the legal representative, except the provision of compensation for injury or loss.

- There are grounds for expecting that administering the medicinal product to be tested in the trial will produce a benefit to the subject outweighing the risks or produce no risk at all.

- The trial is essential to validate data obtained (a) in other clinical trials involving persons able to give informed consent, or (b) by other research methods.

- The clinical trial relates directly to a life-threatening or debilitating clinical condition from which the subject suffers.

Principles

- Informed consent given by a legal representative shall represent the presumed will of an incapacitated adult.

- The trial has been designed to minimise pain, discomfort, fear and any other foreseeable risk in relation to the disease and the cognitive abilities of the patient.

- The risk threshold and the degree of distress have to be specially defined and constantly monitored.

The interests of the patient always prevail over those of science and society.

4. OTHER RELATED PROCEDURES

CLPG19 SOP 6 - Definition of Responsibilities for Externally Sponsored Studies
CLPG19 SOP 18 - Study Files and Filing for Externally Sponsored Clinical Trials

5. APPENDICES

Appendix A: Information to be Provided to Potential Trial Subjects (Written and/or Verbal).

6. REFERENCES

UK policy framework for health and social care research (2017) http://beta.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/

European Parliament (2001) *European Directive on good Clinical Practice in Clinical Trials*

International Conference on Harmonisation (1996) *Harmonised Tripartite Guideline for Good Clinical Practice*

ICH-GCP, Guidelines for Clinical Practice, *http://ichgcp.net/*

APPENDIX A

Information to be Provided to Potential Trial Subjects (Written and/or Verbal). ICH Guidelines for Clinical Practice (4.8.10)

According to ICH GCP (4.8.10) the discussion prior to a subject consenting to participation in a trial and the patient information sheet or any other written information relating to the trial should contain the following:

1. A statement that the trial involves research
2. The purpose of the trial
3. The trial treatment(s) and the possibility of random assignment to each treatment. Diagrams may be useful.
4. The frequency of all trial procedures to be followed, including all invasive procedures
5. The subjects responsibilities
6. The experimental aspects of the trial
7. Any foreseeable risks or inconveniences for the trial subject
8. The reasonably expected benefits, if any, should be explained. If there is no clinical benefit intended, the subject must be made aware of this
9. Alternative treatments and procedure(s) that may be available and the potential benefits and risks
10. The compensation and/or treatment available to the subject in the case of any injury relating to the trial
11. Anticipated pro-rated payment, if any, to the subject for participating in the trial.
12. The anticipated out of pocket expenses, if any, to the patient for participating in the trial.
13. That the subject's participation in the trial is completely voluntary and that the subject can withdraw or refuse to participate, or withdraw from the trial at any time without penalty or loss of benefits to which they would otherwise be entitled and without affecting their future care.
14. That authorised representatives from regulatory bodies, pharmaceutical company (or other commercial company, if appropriate to the study) or the Research Ethics Committee (as appropriate) will be given access to the subjects records for the purpose of verification of the trial procedures and data collected without violating the confidentiality of the subject. That the subjects General Practitioner will also be informed in writing of their participation in the study. By signing the informed consent form, the subject is authorising such access
15. That records identifying the subject will be kept confidential and will not be made publicly available. If the results of the study are published, the subject's identity will remain confidential.
16. That the subject /legal representative will be informed in a timely manner if any information becomes available that may be relevant to the subject's willingness to continue to participate in the trial.
17. The person(s) to contact for further information regarding the trial (if possible record a 24hour phone number where the subject can receive advice out of office if required).
18. The foreseeable circumstances under which the subject's participation in the trial may be terminated.
19. The expected duration of the subject's participation in the trial

20. The approximate number of patients involved in the trial