Great Western Hospitals NHS
NHS Foundation Trust

Standard Operating Procedure: Informed Consent

SOP NUMBER: 006 Version Number & Date: V1 01/04/2017 Superseded Version Number & Date(if applicable):	Effective Date: 01/04/2017 Review Date: 01/04/2019

Author:

Name: Catherine Lewis-Clarke: R&I Manager Signature: _____ Date: 1st April 2017

Approved by:

Name: [illegible] Position: R&I Director Signature: _____ Date: 01/04/2017

Name: SPEGEL Position: Lead research practitioner Signature: _____ Date: 01/04/2017

Index Page

1. BACKGROUND

Informed consent in the context of clinical research is the process by which a subject voluntarily confirms his or her willingness to participate in a particular study having been informed of the full details of the project. Informed consent is documented by means of a written, signed and dated informed consent form.

Informed consent is a three step process which involves:

1. The giving of information
2. The discussion and clarification of the information
3. Taking the subject's verbal and written consent

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):

"In any research on human beings, each potential subject must be adequately informed of the aims, methods, sources of funding, any possible conflicts of interest, institutional affiliations of the researcher, the anticipated benefits and potential risks of the study and the discomfort it may entail. The subject should be informed of the right to abstain from participation in the study or to withdraw consent to participate at any time without reprisal. After ensuring that the subject has understood the information, the physician should then obtain the subject's freely-given informed consent, preferably in writing."

2. PURPOSE

This Standard Operating Procedure (SOP) describes the process for obtaining informed consent from a study subject. It outlines the informed consent procedures for adult subjects with capacity who are able to give informed consent and informed consent procedures for more vulnerable subjects (minors and incapacitated adults) and emergency research.

3. INFORMED CONSENT OF ADULTS WITH CAPACITY

3.1 Responsible Personnel

The Declaration of Helsinki states that the person seeking informed consent should be a qualified physician: "The physician should obtain the subjects freely given informed consent, preferably in writing" (1996 version).

However ICH GCP guidelines state that "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 study by study basis. If staff other than the Chief

Investigator (CI) or Principal Investigator (PI) are to accept responsibility for the informed consent process it is important the following criteria are met:

- S/He is prepared to take on this additional responsibility AND feels confident to seek informed consent in line with their professional organisational guidelines.
- S/He has a full understanding of the study. They should be qualified by experience and/or should have received appropriate training for this study. All training must be documented.
- This delegation of responsibility should be documented on the study delegation log/site responsibility log (title can vary from centre to centre, but is essentially a log that captures each member of the study team and their individual responsibility in the management and conduct of the study and is signed and dated by the CI/PI).
- The process has been approved by the relevant Research Ethics Committee (REC).
- An effective line of communication is maintained back to the CI/PI who is the person ultimately responsible for the subject's care.

It is ultimately the responsibility of the CI/PI that subjects have understood what they are consenting to.

3.2 Procedure

- Patient information should be provided to potential study subjects in both an oral and written form, this SOP describes both elements.
- 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.
- 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. Approved documents will be given to assist in this process.
- The subject must be given the time and opportunity they requrie to read the Patient Information Sheets and Consent Form. They should have the opportunity to discuss the study with family, friends or others if they require it. (Some sponsors specify a minimum period between the giving of the study information and the receipt of informed consent). Prior to the subject signing the consent form, appropriate members of the research team should answer all questions.
- 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.
- 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.
- Patients should be informed of their right to change their minds and withdraw consent at any time without their medical care and legal rights being affected.

3.3 On-going Procedure throughout the Study

- The informed consent process should not end once the informed consent form has been signed. The practice of giving information about the study to participants should be an on-going process performed by all members of the research team and any associated health care professionals. This is particularly

important if Protocol amendments are introduced, or if important new information that may be relevant to the participant's willingness to continue taking part in the study is discovered. In these circumstances it may be necessary to re-consent the participant using an amended consent form, to continue their involvement in the study.

- The timing of the signing of the consent form, relative to study start date at site is subject to audit by regulatory/approval bodies. It is therefore essential to record dates correctly on both the informed consent form and in the subject's medical notes. The consent form must be signed by the study participant before any aspect of their involvement in the study begins.

4. INFORMED CONSENT OF MINORS

In addition to the above, there are a number of factors that must also be considered when seeking consent from Minors:

Consent for under 16s in a CTIMP:

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).
Those who are able to give consent on behalf of children / young people, to take part in a CTIMP, in the UK are:

- Parent or someone with parental responsibility (agreement of only one parent is required).
- Personal legal representative i.e. a person not connected with the conduct of the trial who is suitable to act as the legal representative by virtue of their relationship with the child / young person, and is available and willing to do so.
  A legal representative should only ever be approached if someone with parental responsibility cannot be contacted prior to the proposed inclusion of the child / young person, by reason of the urgent nature of the treatment provided as part of the trial. If a personal legal representative is not available:
- Professional legal representative i.e. a doctor responsible for the medical treatment of the child / young person if they are independent of the study, or a person nominated by the healthcare provider.

Children and young people should be involved in the decision-making process whenever possible. You should ensure that they receive information about your trial, which is understandable to them.

Consent for over 16s in a CTIMP

Young people over 16 are presumed to be capable of giving consent on their own behalf to participate in Clinical Trials of Investigational Medicinal Products (CTIMPs).
Any young person, over 16, who is not capable of giving consent, should only be included in a CTIMP in the UK in line with the adult provisions of the Medicines for Human Use (Clinical Trials) Regulations.

Consent in non CTIMPs

There is no statute in England, Wales or Northern Ireland governing a child's right to consent to take part in research other than a Clinical Trial of an Investigational Medicinal Product (CTIMP)

- In the absence of law relating specifically to research, it is commonly assumed that the principle of 'Gillick competence' can be applied not only to consent for treatment, but also to consent for research - a young person has sufficient understanding and intelligence to understand fully what is proposed, and can use and weigh this information in reaching a decision (i.e. they are 'Gillick competent'), he or she can give consent.
- A child / young person's right to give consent is dependent upon their capacity to understand the specific circumstances and details of the research being proposed, which in turn will relate to the complexity of the research itself.
- Children and young peoples' competence may well be reflected in their ability or otherwise to understand and assess risk.
- Competence to understand will be heavily influenced by how the information is presented to the child or young person, and the language used. You must ensure that you maximise a child / young person's chances of understanding what is involved in your study.
- Even when a child or young person is competent, it is still normally good practice to involve the family in the decision-making process: however, if the young person objects, you should respect their privacy.
- You should be aware that the voluntariness of a child's or young person's decision making is difficult both to determine and to secure.
- Providing information in a format that is understandable to children and young people, and doing so in a manner that fosters true voluntary decision-making, are skills that require specific experience and expertise.
- If a child or young person is not deemed to be sufficiently competent to give consent themselves to participate in non-CTIMP research; you are encouraged to inform them to the fullest of their understanding and enable them to participate in an assent process whenever this is appropriate.

Children's/Young Peoples wishes and assent

Even when a child or young person is deemed not competent to make a decision for themselves or in situations where they are not legally empowered to do so (e.g. in a Clinical Trial of an Investigational Medicinal Product (CTIMP)), it is important that:

- You give the child / young person information about your study, which is understandable to them and which explains what is involved and the potential risks and benefits.
- Staff with experience of working with children / young people should provide this information.
- If the child or young person is capable of assessing the information provided you must consider their explicit wishes. This includes their refusal to take part, or desire to withdraw from the study.
- It is usually inappropriate to ask very young children (e.g. under 5's) to sign an assent form, however their views should be considered.

Whenever practical and appropriate, a child's assent should be sought before including them in your research. Consider the child's developmental stage, knowledge of illness and experience of health care. There is a danger that children can be asked to exercise greater autonomy than normal, this must be balanced with the potential loss of trust associated with denying their assent. In circumstances where seeking assent at the outset is not appropriate, you could provide the child with information as and when required (i.e. 'drip feeding').

Consent for 16 and 17 year olds who lack capacity

CTIMPs
If a young person, aged 16 or over, is deemed not to be competent to give consent to participate in a Clinical Trial of an Investigational Medicinal Product (CTIMP); you must proceed in line with the Medicines for Human Use (Clinical Trials) Regulations.

Non CTIMPs
If a young person, aged 16 and over, is deemed not to be competent to give consent themselves to participate in a non-CTIMP; you must proceed in line with the Mental Capacity Act (in England and Wales).

5. ADULTS (AGED 16 YEARS AND OVER) WHO LACK MENTAL CAPACITY TO DECIDE TO PARTICIPATE IN RESEARCH

In any case where it is felt that an adult appears not to have capacity to consent then a formal mental capacity assessment must be undertaken by the CI/PI in accordance with the Mental Capacity Act 2005 and responsibility for the consent/capacity process should not be delegated.

This processes must be recorded in the clinical notes.

When seeking consent from an adult that is unable to provide informed consent for him/herself it is important that the Investigator adheres to the following:

CTIMPs:

- Incapacitated adults should not be included in research if the same results could be obtained using adults capable of giving consent
- Mental Capacity Act 2005 Part 1 of the Regulations outlines the factors which must be taken into consideration when obtaining consent for an incapacitated adult to participate in research and provides details on the process of involving a personal or professional legal representative to obtain consent on behalf of such individuals. http://www.legislation.gov.uk/ukpga/2005/9/contents
- A personal legal representative is 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.

- A professional legal representative is a person not connected with the conduct of the trial who is:
  (a) the doctor primarily responsible for the adult's medical treatment, or
  (b) 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.
- The legal representative must be properly informed by the researcher about the trial
- The legal representative must also have been provided with a contact point where further information about the trial can be obtained
- The legal representative must be informed of the right to withdraw the subject from the trial at any time

- The legal representative gives informed consent for the subject to be included in the trial

Non CTIMPs:

- The Mental Capacity Act 2005 applies to research that is
  (a) Intrusive (if the subject had capacity, the researcher would need to obtain their consent to involve them)
  (b) Involves people who lacks mental capacity to decide whether or not to take part in the research, and
  (c) Is not a Clinical Trial covered by the Regulations
- The researcher must consult with appropriate people about whether the person who lacks mental capacity should be included in the research.
- An appropriate person (the consultee) must be involved in the person's care, interested in their welfare and be willing to help, for example a family member. The consultee must not be a paid or professional care worker.
- If there is no-one appropriate to consult, the researcher must nominate a consultee using the following Department of Health guidance: http://www.hra.nhs.uk/documents/2013/07/guidance-on-nominating-a-consultee-for-research-involving-adults-who-lack-capacity-to-consent.pdf
- The consultee must have no connection with the research.
- The researcher must provide the consultee with information about the research and ask them:
  (a) whether the person should take part, and
  (b) what they think the person's feelings and wishes would be, if they still had capacity to decide
- If the consultee does not think that the person would have agreed to take part in the research, then they must not be included.
- Note that, in contrast to CTIMPs, consent cannot be obtained from consultees. Rather, advice should be sought from them, but the decision to include a participant rests with the Principal Investigator.
- If the person gives any indication that they do not wish to continue to be involved with the research, they must be withdrawn.

6. EMERGENCY SITUATIONS & INCAPACITATED ADULTS

CTIMPs

- There is provision within the Regulations relating to research involving incapacitated adults in emergency situations. When urgent treatment is to be given to an incapacitated adult as part of the trial, time may not allow for obtaining writte n consent from the legal representative.
- The Regulations allow incapacitated adults to be entered into a trial prior to consent being obtained from a legal representative provided that:
  - Having regard to the nature of the trial and the particular circumstances of the case, it is necessary to take action for the purpose of the trial as a matter of urgency, but
  - it is not reasonably practicable to obtain informed consent prior to entering the subject, and

  - the action to be taken is carried out in accordance with a procedure approved by the ethics committee.
- Where an incapacitated adult is recruited in an emergency situation without prior informed consent, steps must be taken to seek informed consent either from the subject (if capacity has been recovered) or from a legal representative as soon as practicable after the initial emergency has passed. Where consent is withheld, the subject must be withdrawn from the trial.

- Please refer to the Mental Capacity Act 2005 Part 1 of the Regulations for further information. http://www.legislation.gov.uk/ukpga/2005/9/contents

Non CTIMPs:

- Anyone responsible for caring for a person must give them urgent treatment if they need it.
- The research proposal should make clear how researchers will deal with urgent decisions which may be needed during the research.
- Where an adult who lacks capacity needs urgent treatment and researchers want to include them in a research study, the researchers must get agreement to include the person in the research from a registered medical practitioner, *or* follow a procedure that the REC agreed at the approval stage.

7. CONSENT TO SUPPLY HUMAN TISSUE AND RELEVANT MATERIAL TO EXTERNAL ORGANSATIONS

Most external organisations require assurances that informed consent has been appropriately and legally obtained.

If the Study requires the storage of samples for future use and/or external collaboration there are key points that should be included in the participant information sheet and consent documentation:

- Consent should be in writing from the donor, legal representative or next-of-kin as appropriate.
- Ethics approval or a statement that approval is not required should be obtained
- The participant information sheet and consent form explains the actual or potential use of tissue samples
- Statements regarding withdrawal, data protection and duration of storage (if any) are clearly stated in the participant information sheet
- A statement explaining that donated samples supplied to external non-commercial and commercial organisations do not infer the right of the donor to financial gain from any commercially viable outcomes to the use of their tissue in commercial research and development.