STANDARD OPERATING PROCEDURE (SOP)

SOP Number: NCP/R&D_014

SOP Title: Obtaining Informed Consent from Competent Adults for Research Studies

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SOP Review Date			

Review History

Version	Effective Date	Review Undertaken/Significant Changes	Date Approved
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1. PURPOSE AND CONTEXT

1.1. This standard operating procedure (SOP) describes the correct procedure for obtaining written informed consent for research studies.

1.2. This SOP applies to the correct procedure to be followed when obtaining informed consent for all studies unless superseded by a study specific SOP for Obtaining Informed Consent.

1.3. This SOP applies to all Southern Health NHS Foundation staff and other collaborators involved in obtaining informed consent.

1.4. This SOP does not apply to obtaining consent from adults with incapacity or children, which should be written as study specific documents.

2. DEFINITIONS

2.1. Informed consent is defined as:

"A process by which a subject voluntarily confirms his or her willingness to participate in a particular trial, after having been informed of all aspects of the trial that are relevant to the subject's decision to participate. Informed consent is documented by means of a written, signed and dated informed consent form."

2.2. It should protect the research subject's rights and well-being, their autonomy and should be an on-going process of information exchange.

3. PROCEDURE and RESPONSIBILITIES

3.1. Providing Information to Potential Participants

3.1.1. All regulatory and local NHS approvals must be in place before any approach to potential participants is made.

3.1.2. All individuals asked to consider taking part in research should be given the fullest possible information about the research, presented in terms and in a form that they can understand. This must include (but is not limited to) the Participant information Sheet (PIS) approved by a Research Ethics Committee and appropriate university ethics committee approval if applicable.

3.1.3. A potential participant should be invited and encouraged to ask questions about the research, which should be answered to the best ability of the person obtaining consent. If additional information is needed to answer questions, then this should be obtained prior to completion of the consent process.

3.1.4. Participants should be given enough time to read the information about the research. This is often at least 24 hours except where research is conducted in an acute or emergency setting.

3.1.5. If a potential participant is unsure about participation, allow extra time for consideration and offer the option of speaking to another member of the research team or advise the potential participant to speak to an independent person (perhaps a relative or their GP).

3.1.6. Potential participants have the right to discuss their participation with their friends and family. Therefore if this is desired potential participants should be given adequate time to do this.

3.1.7. Researchers completing consent should check to ensure that a potential participant is not already consented to any other active research study that may preclude their participation in the new study.

3.1.8. Consent to participate in research activities is an on-going process therefore understanding and verbal consent to participate should be checked at every research contact. This should be recorded in line with study procedures (i.e. in patient research record)

3.2. The Informed Consent Form (ICF)

3.2.1. The ICF should be on local headed paper, have a version number and date, identify the unit and department conducting the research and should be identifiable with the study. The ICF must state the study title, and if a clinical trial of an investigational medicinal product (CTIMP), the EudraCT number, for which consent is being sought.

3.2.2. Only the currently approved, most recent version of the ICF may be used for obtaining informed consent.

3.2.3. Three copies of the ICF need to be initialed and signed: 1 copy (plus a copy of the PIS) is to be retained by the participant, 1 copy for the study site file and 1 copy for the participant's medical record. The participant's medical record ICF copy should be filed in the patient's paper medical record if available, and/ uploaded to the electronic patient record (e.g. RIO). Additionally an entry should be made on the participant's medical notes.

3.3. Obtaining Informed Consent

3.3.1. Only the investigators, co-investigators and staff named on the 'study delegation log' are allowed to obtain informed consent from participants. Investigators, co-investigators and staff named on the study delegation log cannot be consented into the study.

3.3.2. Pressure should not be put on an individual to take part in research.

3.3.3. The person obtaining informed consent must assess the potential participant's understanding of what he/she is agreeing to, that he/she is aware that he/she has the condition under study, knows that he/she may receive a control intervention and fully understands the implications of decisions that may be made within the course of the research. If there is doubt as to the potential participant's understanding, the individual should not be recruited.

3.3.4. The person obtaining informed consent must inform the participant that they are under no obligation to participate and that they can withdraw at any time, and that this will not affect their treatment now or in the future.

3.3.5. Informed consent must be obtained before the initiation of any procedures, tests or treatments that are required by the study protocol but which are not considered to be part of routine clinical care.

3.3.6. The participant's name, date of birth and study title should all be checked to ensure that they are correct and to ensure that the participant has received all appropriate documentation (PIS and any other relevant study information).

3.3.7. The person obtaining informed consent must ask the participant to read the informed consent statements and initial the boxes on the ICF, write their name, sign and date the appropriate sections, then they too must countersign and date the consent form.

3.3.8. Telephone or verbal consents are not permitted for CTIMPs. For other studies consent may be given verbally or by telephone only if approved by a Research Ethics Committee. In these instances, a study specific working practice document should be written, detailing the procedure for documenting the consent of the participant.

3.3.9. For CTIMPs, the PI or delegate must document the date in the clinical notes that the potential participant was given the PIS. For CTIMPs the PI must also document that the participant meets the inclusion/exclusion criteria and is eligible to participate in the study. For CTIMPs and when applicable to other studies the date & time that the person consented to be a participant in the trial should also be recorded in the clinical notes. This provides a clear audit trail to ensure no study specific activities occurred prior to consent being obtained.

3.4. After Consent has been Obtained

3.4.1. The original consent form must be placed in the investigator site file. Ensure a copy of the consent form is also given to the subject and a copy placed in the clinical notes and sent to the subject's GP (if required by the study protocol). The ICF's must not be stored together with data from Case Report Forms.

3.4.2. If changes are made to the study protocol, PIS and/or ICF after the trial has started, then the investigator must contact the appropriate Research Ethics Committee to obtain ethical approval for these changes and to discuss the need, or immediacy of need, to re-consent existing participants.

3.4.3. Note that Research Ethics Committees pay close attention to the informed consent process as described in the ethics application. This is an important factor in informing their decision to give a favourable opinion. Therefore any deviations from the approved informed consent process must be immediately reported in writing to the relevant Research Ethics Committee and Sponsor.

	Responsibility	Undertaken by	Activity
1	R&D Office	R&D Manager	The research staff taking consent should be adequately trained to do so and be prepared to take on this additional responsibility and should feel confident to take informed consent in line with codes of professional conduct.
2	Principal Investigator (PI)	PI	It is the responsibility of the Principal Investigator (PI) at a study site to ensure that the informed consent form, as well as other written information provided to subjects, has been approved by the research ethics committee prior to the study commencing.
3	Principal Investigator (PI)	PI	It is the responsibility of the PI to ensure that all regulatory approvals and local NHS approvals are in place before any approach to potential participants is made
4	Principal Investigator (PI)	PI	It is the responsibility of the Principal Investigator (PI) at a study site to ensure that the informed consent form, as well as other written information provided to subjects, has been approved by the research ethics committee prior to the study commencing.
5	Principal Investigator (PI)	PI	It is the responsibility of the PI to ensure that all staff working on the research study are trained and qualified to take consent and have been entered onto the delegation log before any approach is made to potential participants

6	Principal Investigator (PI)	PI	It is the responsibility of the PI to ensure that the correct versions of the informed PIS and consent forms and other patient related materials have been provided from the main research team and are provided to the R&D team
7	Principal Investigator (PI)	PI	It is the responsibility of the PI at a study site to ensure that informed consent is obtained before any research procedures, tests or data collection from the subject begins.
8	Principal Investigator (PI)	PI	It is the responsibility of the PI to ensure that in the event of an amendment the PI needs to ensure that all staff working on the research study are familiar with any new documentation or process and if necessary the delegation log updated
9	Researcher	Researcher	The person taking consent needs to check the patient details, file them appropriately and promptly

4. SUPPORTING MATERIAL and ATTACHMENTS

International Conference on Harmonisation Good Clinical Practice Guidelines (ICH GCP):
http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2009/09/WC500002874.pdf

National Research Ethics Committee Guidance on Informed Consent
http://www.nres.npsa.nhs.uk/EasysiteWeb/getresource.axd?AssetID=338&type=Full&servicetype=Attachment

Scottish Executive Health Department Research Governance Framework for Health and Community Care 2nd Edition (2006)
http://www.cso.scot.nhs.uk/Publications/ResGov/Framework/RGFEdTwo.pdf

The Medicines for Human Use (Clinical Trials) Regulations 2004,
http://www.opsi.gov.uk/si/si2004/20041031.htm

UK Policy Framework Health & Social Care Research (version 3.2 2017)

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5. TRAINING

All staff involved in taking informed consent from participants should have completed Good Clinical Practice training (GCP).

Non-clinical staff should also complete face to face Valid Informed Consent training provided locally by the NIHR.