DIVISION OF RESEARCH AND INNOVATION

Document Number: GOSH/ICH/SOP/R/034	Version Number: 1
Title: Informed Consent for Research	
Effective Date:	*Same as implement by date.*

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1. Scope

This SOP is applicable to

- All Great Ormond Street Hospital for Children (GOSH) or Institute of Child Health (ICH) staff working on clinical research.

Further to the requirements listed in this SOP, personnel must also comply with:

- Any additional study-specific requirements mandated by the PI, Sponsor or R&D.

2. Purpose

This SOP sets out the standards expected in relation to obtaining consent for research. It is not intended as consent training; staff not experienced with consent should seek out training (see section 5.9) and advice/support from more experienced colleagues.

3. Definitions/Abbreviations

Assent – An agreement to participant and accept the requirements of the study. Formal assent would not usually be obtained from a child under seven[i], though the study would still be discussed with them to their level of understanding and their views sought.

Clinical Research – As defined in the UK Framework for Health and Social Care Research and HRA/MRC 'Is my study research?' tool.

Impartial Witness – A person, who is independent of the study, who cannot be unfairly influenced by people involved with the study, who attends the informed consent process if the participant or the participant's legally acceptable representative cannot read, and who reads the informed consent form and any other written information supplied to the participant or the participant's legally acceptable representative.

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

Legally Acceptable Representative/ Legal Representative – An individual, or juridical or other body authorised under applicable law to consent, on behalf of a prospective participant, to the participant's participation in the clinical study.

Minor – a person under the age of 16 years

4. Responsibilities

Duties may be delegated but the responsibility always remains with those listed.

4.1 The study Principal Investigator (PI) is responsible for:

- Ensuring that the approved consenting process is followed at site.
- Ensuring compliance with this SOP, the study protocol, GCP and any applicable legislation, policies, procedures or guidelines (including the Trust Consent Policy).

4.2 All study staff are responsible for

- Ensuring their practice meets the requirements of this SOP, the study protocol, GCP and any applicable legislation, policies, procedures or guidelines (including the Trust Consent Policy).

5. Procedure

5.1 General principles of consent for research

Freely given informed consent must be obtained from/on behalf of every participant prior to clinical study participation (i.e. prior to any study specific activity) – unless otherwise agreed by the Research Ethics Committee (REC).

Neither the PI, nor the study staff, should coerce or unduly influence a participant to participate or to continue to participate in a study.

The consenting procedure and personnel must be clearly described in the study application and given a favourable opinion by the REC. This includes Participant Information Sheet(s) (PIS), Informed Consent Form(s) (ICF), Assent Forms and any other written information to be provided to the participant/person consenting, plus arrangements for if the participant/person consenting does not speak English.

The approved procedure must be followed. The consent process should be recorded (e.g. in the participant's medical notes) as evidence that the procedure has been followed (see section 5.6).

Informed consent is an ongoing process, not a single act. Ongoing willingness to continue in the study should be checked and documented in the participant's medical notes throughout the study.

Any substantial changes to the consenting procedure must be notified to the REC and a favourable opinion given before they can be implemented.

Written information should be revised whenever information becomes available that may be relevant to the participant's consent. Any revised written information must receive REC favourable opinion before it is used. The participant/person consenting must be informed and (if necessary) re-consented in a timely manner if new information becomes available that is relevant to their participation in the study. The communication of this information should be documented/tracked.

5.2 Am I the right person to seek consent?

Informed consent must be taken by a member of the study team that has been delegated this activity, and who has undertaken appropriate training both in the specific clinical study and in obtaining informed consent (see section 5.9). The consenting personnel should be clearly described in the REC application and approved by the REC and the R&D Office. For a Clinical Trial of an Investigational Medicinal Product (CTIMP), only medical doctors may take consent.

If you are seeking consent, it is critical that you appropriately support the participant/person consenting in making their decision. This includes:

- Understanding the protocol and its potential implications on participants;
- Understanding the treatment alternatives that may be available;
- Having an ability to communicate effectively with potential participants, including explaining complex scientific/medical concepts;
- Appreciating how to optimise the voluntary nature of decision making, avoiding undue influence.

Where taking informed consent is the role of someone who is not a medically qualified doctor, it is expected that a medically qualified doctor who is part of the study team is readily available during or following the consent process if the participant/person consenting requires or requests further discussion relating to the medical care to be provided as part of the study[ii].

Do not seek consent if you are not the right person or do not feel competent.

5.3 Am I asking the right person/people to give consent?

For a CTIMP, neither an adult (aged 16 or over) lacking capacity nor a minor (aged under 16) can consent to participate in a study for themselves.

A person with parental responsibility for the participant or, if no such person can be contacted, a legal representative for the potential participant must give informed consent for the individual to take part in the study. The legal representative must not be connected with the conduct of the study (e.g. member of the study team). Please see Trust Consent Policy for further information on parental responsibility/ legal representative.

For non-CTIMPs; it is commonly assumed that the principles that apply to consent for treatment apply to consent for non-CTIMP research. The Trust Consent Policy and study specific consent processes should be followed.

In addition to consent; if the potential participant cannot consent for themselves there should be an assent process where the potential participant is informed about the study to the extent compatible with their understanding and, if capable, they should sign and personally date an assent form.

The PIS and forms are often grouped by participant age. If a participant moves into a new age range during the course of the study they should receive a new age appropriate PIS and sign a new assent form. It is important the participant is informed to their level of understanding, which will develop over time.

If a participant turns 16 during a study, consent previously given on their behalf is no longer valid and the participant must be asked to provide their own consent to the research.

Where the parent/carer that is consenting on behalf of the participant is under 16, it is good practice to involve the grandparents in decision-making.

5.4 Does the consenter have capacity?

For a CTIMP, a minor (aged under 16) cannot consent to participate in a study (i.e. Gillick/Fraser competence does not apply).

For non-CTIMP studies or participants 16 or over please refer to the Trust Consent Policy with regards to assessing capacity.

5.5 Does the consenter have sufficient information? Do they understand the nature and the purpose of the study and is consent being given voluntarily?

The PI (or delegate) should fully inform the potential participant/person consenting of all pertinent aspects of the study; ensuring that they understand the study, that participation is voluntary and that they have the right to withdraw at any time. The potential participant/person consenting must be made aware that their care will not be affected in any way if they decide not to take part or withdraw from the study.

The potential participant/person consenting must be provided with an age appropriate and REC approved Participant Information Sheet (PIS), and be given adequate time and opportunity for questions, consideration and discussion (including a contact point for further information). It is important to ensure that you are using the correct version of the PIS.

There are no statutory requirements specifying the minimum time for which the potential participant/person consenting should be allowed to consider the study. The time allowed will depend on the study and should be clearly defined in the REC application, taking into consideration the length of time that is appropriate for the study to ensure that consent is informed and voluntary.

The language used in the oral and written information about the study, including the written informed consent form, should be non-technical as practical and should be understandable to the participant/person consenting. The oral and written study information must not contain any language that causes the participant/person consenting to waive or to appear to waive any legal rights, or that releases or appears to release the PI, institution, Sponsor, or their agents from liability for negligence.

Written information can be tested by consulting an appropriate group of people (patient or parent carer groups or other members of the public). This can help ensure that the language, content, and formatting are appropriate. You do not need to obtain REC approval to test your PIS with patient groups or others. The Patient and Public Involvement Research Lead (research.ppi@gosh.nhs.uk) can help organise such consultations.

Consider the process from the potential participant's point of view:

- Has it been as informative and supportive as it could have been?
- Have all their concerns been discussed and addressed?
- Have they been coerced or pressurised is some way?
- Have they understood what their commitment to participate involves?

5.6 Has the consent process (discussion and decision) been appropriately documented?

If the person taking consent is satisfied that the participant/person consenting understands the study, the participant/person consenting is then asked to sign and personally date the current version of the approved Informed Consent Form (ICF) and to indicate their approval of various statements by initialling against them (unless an alternative process is agreed by the REC). Initials demonstrate that each item was completed by the participant/person consenting and not any other person (unlike ticks). There should be a process to ensure the appropriate management of any item not consented to as this may impact the participant's participation in the study. The person receiving consent also signs and personally dates the form to confirm they are satisfied that the participant/person consenting has made an informed and voluntary decision to participate in the study. It is important to ensure that you are using the correct version of the ICF.

If the participant/person consenting is unable to read, an impartial witness should be present during the entire informed consent discussion. The witness should sign and personally date the consent form to attest that the written information was accurately explained to, and apparently understood by, the participant/person consenting, and that informed consent was freely given.

In addition to the consent process; if the participant cannot consent for themselves; they should be informed about the study to the extent compatible with their understanding and their wishes should be taken into account. If capable, the participant should sign and personally date an assent form.

In order to demonstrate that the participant/person consenting was provided with the most up-to-date information (including safety information) for the study, it should be clear which version of the PIS has been used. A copy of the PIS and completed ICF (and assent form if applicable) should be kept together in the participant's medical notes, with the originals in the Investigator Site File (ISF) and a copy given to the participant/person consenting.

It is best practice to document the consent process in the patient notes to demonstrate that the REC approved process was followed. Record the study title and R&D number, date PIS/ICF provided, PIS/ICF version number and/or date, and member(s) of staff involved.

5.7 Emergency research

In emergency situations, where the treatment needs to be given urgently and prior consent is not practicable, enrolment of the participant can occur without prior consent as long as this is in accordance with the procedure approved by the REC. The measures used to protect the rights, safety and well-being of the participant and to ensure compliance with applicable regulatory requirements should be described in the protocol, with documented favourable opinion by the REC.

The participant/person consenting should be informed about the study as soon as possible and consent/assent should be requested. If consent is withheld, the participant must be withdrawn as per protocol.

5.8 Differences of opinion

If the potential participant 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. The argument that including the child or young person in the study is in their best interests is unlikely to be valid as there is no guarantee a research treatment will be of benefit.

Where multiple people have parental responsibility, it is important that they are all supportive of the child or young person participating in clinical research, particularly if they all live with the child or young person. Disagreement between the people who care for the child or young person may lead to problems with compliance and their progress in the research in the future.

5.9 Consent training

See the Trust Consent Policy for available Trust training. The National Institute for Health Research (NIHR) offer training on consent for research:

- Introduction to GCP in Secondary Care – covers consent involving adults who have capacity to make decisions for themselves. Available as a face-to-face or e-learning course. Supplemented by the 'Valid Informed Consent' course.
- Introduction to GCP in a Paediatric Setting – covers research (including consent) in this setting; available as a face-to-face workshop. The online course is provided through a combination of an Introduction to GCP e-learning course and the Informed Consent in Paediatric Research e-learning course.
- Introduction to GCP with Adults Lacking Capacity – covers consent in this setting; available as a face-to-face workshop. The online course is provided through a combination of an Introduction to GCP e-learning course and the Informed Consent with Adults Lacking Capacity e-learning course.

5.10 Follow up when consent procedure is not followed or consent is taken by a person who is not authorised to do so

The consent process will usually be reviewed during routine monitoring or audit. Deviations should be reported as per the usual Trust and study processes.

Systematic or persistent failure to comply with the study consent procedure and/or this SOP will be seen as non-compliance to GCP and should be bought to the attention of the Head of Governance, Clinical Trials and Contracts who will decide the appropriate action.

6. Related Documents

- Trust Consent Policy

7. References

- The Medicines for Human Use (Clinical Trials) Regulations
- UK policy framework for health and social care research
- ICH Harmonised Guideline - Guideline For Good Clinical Practice E6(R2)
- MHRA Good Clinical Practice Guide (Grey Guide) – Chapters 3 and 11
- HRA proportionate approach to the process of seeking consent
- NIHR GCP e-learning, Informed Consent in Paediatric Research Oct 17
- MRC Consent and Participant Information Sheet Preparation Guidance

[i] NIHR Good Clinical Practice (GCP) e-learning, IC in Paediatric Research Oct 17
[ii] MHRA Good Clinical Practice Guide (Grey Guide) – Chapter 11 Investigator Sites