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<tr>
<th>Title of Standard Operating Procedure:</th>
<th>RDSOP07A  Informed Consent – Minors</th>
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<tr>
<td>Document Summary:</td>
<td>To describe the process for seeking informed consent for minors to enter a research study and to document that consent has been obtained.</td>
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| Target Audience:                    | Research Community, Internal and External Researchers involved in research projects consenting minors that require Trust R & I ‘approval’ |
| Consultation:                       | R & I Office, research community and R & I Committee members |
| Approval Committee:                 | R & I Committee |
| Cross Reference Document(s):        | Research Approval Policy  
RDSOP06, 07 Informed Consent  
All other Trust R & I SOP’s |
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<th>Minimum Monitoring Requirement</th>
<th>Frequency</th>
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<th>Evidence</th>
<th>Responsible Individual(s)</th>
<th>Response Committee(s)</th>
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<tr>
<td>Review of SOP content</td>
<td>Annually</td>
<td>Review by Author, redraft, submission to R &amp; I Operational Group</td>
<td>Minutes of R &amp; I Operational Group</td>
<td>Head of R &amp; I Office</td>
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1. Introduction

Informed consent is the process by which a subject voluntarily confirms their willingness to participate in a research study having been informed of all aspects of the study that are relevant to their decision to participate.

Informed consent is an ongoing process. It involves giving information to the subject, discussing and clarifying the information, taking the subject’s written consent and subsequently providing any new information that might affect the subject’s willingness to continue in the study.

Consent is documented by means of a written, signed and dated informed Consent Form. Further information on designing appropriate patient information and Consent Forms is available on the Health Research Authority (HRA) website.

In obtaining and documenting informed consent, the Research Team must comply with Good Clinical Practice and with the ethical principles that have their origin in the Declaration of Helsinki (see section 12).

2. Purpose

To describe the process for seeking informed consent for a minor to enter a research study, and to document that consent has been obtained.

Guidance on consenting adults and incapacitated adults is outlined in Trust Wide RDSOP06 and 07, respectively.

3. Roles and Responsibilities

3.1 Within the organisation

It is the responsibility of the Research & Innovation Office to make Trust R & I SOPs available to all research active staff working on Trust-approved research studies.

It is the responsibility of the study Chief Investigator (CI) or local Principal Investigator (PI) to ensure that up-to-date copies of Trust R & I SOPs are available to research staff.

It is the responsibility of the study Chief Investigator or local Principal Investigator to ensure up-to-date SOPs are filed in the Investigator Site File and are available to research staff, and to inform the Research Support Co-ordinator of the names of all research staff involved on a study so that copies of SOPs can be distributed appropriately.
It is the responsibility of the study Chief Investigator or Principal Investigator to designate if the SOPs of another organisation are to be followed for a study. For example those of a Clinical Research Network or commercial sponsor. If there is significant conflict between the external SOP and the Trust R&I SOP it is the responsibility of the CI or PI to resolve these with the Research Office prior to starting the study.

It is the personal responsibility of all staff to follow Trust (or the designated alternative organisations) procedural documents.

The Research & Innovation Office is responsible for managing Trust R & I SOPs including their approval, dissemination and archiving. All Trust R & I SOPs must be made available via Q-Pulse and published on the Trust website.

### 3.2 Specific to this SOP

Overall responsibility for all elements of research activity, including seeking informed consent, rests with the PI.

It is considered best practice that only those involved directly with the participant’s care, and with good knowledge of the study, should seek consent. In particular, those seeking consent must have sufficient knowledge of the study procedures and the investigational medicinal product (if applicable), and must understand the risks involved, in order to provide any information the subject may require. If the task of seeking informed consent is delegated to another member(s) of the research team, it is the responsibility of the PI to ensure that the individual(s) is suitably trained and qualified. In particular, have sufficient knowledge of the research protocol and understand the risks involved in order to provide any information the subject may require.

It is the responsibility of the PI to ensure that the delegation of the task of seeking consent is clearly documented.

It is the responsibilities of the person seeking consent to ensure they have provided a copy of their signed and dated CV for the Investigator Site File, and completed and signed the Delegation of Duties Log, with the PI countersigning.

It is the responsibility of the person seeking consent to ensure they are fully familiar with all aspects of the study as described in the latest version of the protocol and approved by the Research Ethics Committee (REC) and local NHS R&D Department (or Health Research Authority (HRA) once new process approved). They should also be able answer any questions related to the study.
4. Informed consent

Consent should be sought prior to any study related procedures being conducted. The timing of the signing of the consent form relative to study registration and the initiation of study procedures is subject to scrutiny. It is therefore essential to record dates and relevant information correctly on both the consent form and in the subject’s medical notes. 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.

The Declaration of Helsinki states that the person seeking informed consent should be a qualified physician. However, ICH Good Clinical Practice (ICH GCP) guidelines state ‘The Investigator, or a person designated by the Investigator, should fully inform the subject’ and the written informed consent form should be signed and dated by the ‘person who conducted the informed consent discussion’ (ICH GCP 4.8.5).

It is considered best practice that only those with good knowledge of the research protocol should seek consent. In the case of a Clinical Trial of an Investigational Medicinal Product (CTIMP) this should normally be a qualified physician, unless agreed by the main Research Ethics Committee and the Research Governance Sponsor.

Consent should be sought prior to any study related procedures being conducted. The timing of the signing of the consent form relative to study registration and the initiation of study procedures is subject to scrutiny. It is therefore essential to record dates and relevant information correctly on both the consent form and in the subject’s medical notes.

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.

4.1 Subject

For the purposes of this SOP the term “subject” refers to the potential research participant.

4.2 Definition of a minor

The European Union (EU) Trials Directive applies in the European Economic Area (EEA), which consists of all EU countries plus Norway and Iceland. According to the Directive a minor is defined as a person under the age of 16.

In countries outside the EEA the age of consent may differ. If the study is led by an organisation from outside the EEA it is advisable to seek clarification on the age of a minor with the study sponsor. Investigators should follow the criteria set out in the protocol, but include everyone under the age of 16 as defined in section 4.2.1.
4.3 Studies governed by the Medicines for Human Use (Clinical Trials) Regulations 2004

Written consent must be given by a parent or an individual with legal responsibility for the child. If appropriate, the child may also be asked for their assent. Unmarried fathers do not have legal responsibility for a child if the child was born before 2003 and cannot give written consent.

A legal representative is a person who, by virtue of their relationship with the minor is suitable to act as their legal representative for the purposes of the trial and is available and willing to so act. If no such person is identified, then a legal representative may be the doctor primarily responsible for the medical treatment of the minor, or a person nominated by the relevant health care provider. A legal representative should not be connected with the conduct of the trial.

4.4 Studies not governed by the Medicines for Human Use (Clinical Trials) Regulations 2004

UK law is untested with regard to the legal age of consent to take part in research (as opposed to treatment). It is possible to apply the principle of Gillick/Fraser Competence, i.e. children who are felt to be competent to understand the research proposal and thus make decisions can give consent on their own behalf. It is, however, unwise to use this for children younger than 10 years of age.

4.5 Informing the subject

Patient information should be provided to subjects in written and oral format. Where applicable, information should also be made available in a format appropriate to the need of the individual e.g. videos, diagrams, etc.

Information sheets should be designed for the appropriate age range to reflect their comprehension and development, for example:

- Children 5 years and under
- Children aged 6-10 years
- Children or young people aged 11-15 years

There should also be an information sheet for parents/guardians.

The language used in all information to be presented to the subject, 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.

All information presented to subjects, including advertisements, must have prior ethical approval.

All information presented to subjects should be version numbered and dated.
If information is to be translated into other languages it is advisable to obtain a certificate of assurance that the translation is correct.

The subject should be provided with ample time and opportunity to read the written patient information. Ideally this should be at least 24 hours, unless agreed by the Ethics Committee. This allows the subject sufficient time to review the information and discuss the study with family, friends or others.

Prior to the subject signing the Consent Form they should be given opportunity to ask questions of appropriate members of the research team.

3.1.1 If required, the subject should be given further opportunity to consider their involvement, and to ask further questions of the research staff.

If the subject does not speak English or has hearing loss and requires an interpreter, the Trust Interpretation policy must be followed. If a subject has a visual impairment, written material should be provided in a larger font or magnification, and attempts must be made to provide information in a suitable format (e.g. using a text reader) wherever possible in order to not exclude patients from participating in research studies.

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, by any means, a subject to participate or to continue to participate in a trial.

4.6 Documenting consent

The Consent Form should be printed on letter headed paper associated with the hospital/Trust where the study is being conducted.

The Consent Form should be version numbered and dated.

The Consent Form should make reference to the version number and date of the Patient Information Sheet (PIS) that the subject and parent/guardian have been given.

An Assent Form can be provided for a minor to indicate their willingness to take part in a study. The Assent Form should be version numbered, dated and approved by the REC and NHS R&D Department (or Health Research Authority, when process implemented).

When the person taking consent is satisfied that the parent/guardian has been fully informed and understands what study participation entails, the Consent Form should be completed by the parent/guardian.
It is considered best practice for the parent/guardian to initial each statement on the Consent Form to indicate their agreement.

The Consent Form should be signed and personally dated in blue or black ink by the parent/guardian and the authorised person who conducted the informed consent discussion. Each should also clearly print their name by their signature.

Where the parent is competent to decide for their child but unable to read or write, an impartial witness may act on their behalf. The witness may sign the Consent Form to acknowledge that the parent has received all the information and has verbally confirmed that they wish their child to take part in the study.

The process of seeking informed consent should be documented in the subject’s medical records or other source data documents (if applicable), detailing the study title and/or acronym, the date that consent was obtained and the version number and date of the relevant PIS and Consent Form. 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 original signed and dated Consent Form and Assent Form (if applicable) should be made, the original should be filed in the medical records or scanned and saved to the subject’s electronic patient record, together with a full copy of the patient information sheet (PIS), a copy should be given to the subject and an original filed in the Investigator Site File.

The parent/guardian should be provided with a copy of the written patient information sheet and any other information provided to subjects.

The parent/guardian should be given copies of all relevant, updated and new information, regarding the study throughout their participation.

4.7 Re-consent

If a revision to the research protocol throughout the course of the study results in changes that may affect a subject’s continued involvement in the study, then participants should be asked to re-consent.

A revised PIS and Consent Form, appropriately version numbered and dated, should be provided to the participant. All revised documentation should be approved by the REC that originally reviewed the study before use.

The participant should be informed of the new information in a timely manner and communication of this information documented in their medical notes.

The participant should be given ample time to consider their continued involvement and to ask questions before being asked to sign the revised Consent Form.
A copy of the revised documentation should be provided to the participant, and placed on the medical notes and Investigator Site file.

5. References and Bibliography

HRA/MRC: Principles of Informed Consent:
http://www.hra-decisiontools.org.uk/consent/principles.html

Health Research Authority
http://www.hra.nhs.uk/

ICH Good Clinical Practice Guidelines:

Declaration of Helsinki:
https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/