York and Scarborough Teaching Hospitals NHS Foundation Trust R&D Unit
Standard Operating Procedure
R&D/S10

Receiving Informed Consent in Research Studies

IT IS THE RESPONSIBILITY OF ALL USERS OF THIS SOP TO ENSURE THAT THE CORRECT VERSION IS BEING USED

All staff should regularly check the R&D Unit's website and/or Q-Pulse for information relating to the implementation of new or revised versions. Staff must ensure that they are adequately trained in the new procedure and must make sure that all copies of superseded versions are promptly withdrawn from use unless notified otherwise by the SOP Controller.

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This SOP will normally be reviewed every 3 years unless changes to the legislation require otherwise

Version History Log

This area should detail the version history for this document. It should detail the key elements of the changes to the versions.

Version	Date Implemented	Reviewers	Details of significant changes
1.0	8th April 2008		
2.0	22nd March 2010		General update and document put into revised template.
3.0	1st September 2014		Change of SOP Controller. Removal of references to the North and East Yorkshire R&D Alliance. Revised to include CTIMP and non CTIMP studies. Change of title.
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5.0	4th November 2020		Change of author. Change of link to R&D website. General minor updates made
6.0	4th October 2023	Paul Brittain	Minor grammatical changes

Contents

1. Introduction, Background and Purpose

Informed consent is the process by which a person 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 take part.

Informed consent is an ongoing process. It involves giving information to the potential participant, discussing and clarifying the information, seeking their written consent and subsequently providing any new information that might affect their willingness to continue to participate in the study.

In obtaining and documenting informed consent, the research team must comply with Good Clinical Practice (GCP) and with the ethical principles that have their origin in the Declaration of Helsinki.

The purpose of this SOP is to describe who should receive consent, the procedure for receiving informed consent and how consent should be documented. It distinguishes between consent procedures for a Clinical Trial of an Investigational Medicinal Product (CTMP) and non-CTIMP studies, where applicable, especially regarding the process for adults lacking capacity and children.

2. Who Should Use This SOP

This SOP applies to all investigators and research team members involved in conducting research studies.

3. When this SOP Should be Used

This SOP applies to i) research studies sponsored or co-sponsored by the Trust and ii) studies hosted by the Trust that are not covered by the sponsor's standard operating procedure on informed consent.

4. Procedures

4.1 Who Should Receive Informed Consent

Consent, including consent to take part in a CTIMP can, in principle, be received by any member of the research team who is appropriately qualified by education, training and experience to undertake this task. This may include members of the team who are not medically qualified, providing this has the approval of the study Sponsor, an appropriate Research Ethics Committee, the Lead Research Nurses and the R&D Unit of the NHS organisation where the study will take place. However please see the section, below, on determining eligibility in a CTIMP study.

In order to provide the appropriate amount and level of detail the potential participant will need to make a decision, the member of the research team receiving consent must have a good knowledge and understanding of the study procedures, the intervention / investigational medicinal product (if applicable), alternative treatments, and the potential benefits and risks involved.

All members of the research team receiving consent must also ensure they work within their scope of professional practice and adhere to their relevant professional codes of conduct if applicable.

Delegating the process of receiving informed consent to appropriate, suitably qualified members of the research team should be considered on a study by study basis. This may be delegated to named individuals and may include Research staff working under an honorary arrangement where this has been agreed by the REC and the R&D Unit. It is the responsibility of the Principal Investigator (PI) to ensure that all individuals are suitably trained and qualified. The process for delegating the receipt of informed consent is described in section 4.2.

Determining eligibility in CTIMP studies
The task of determining whether an individual meets the inclusion criteria to enter a CTIMP study **must be carried out by a medically qualified person** who is named on the study delegation log. Confirmation of eligibility for a CTIMP study is regarded as a medical decision which means it **must not** be delegated to non-medically qualified individuals within the research team.

If eligibility will be assessed and documented in the CRF and / or medical records (including electronic records such as CPD when applicable) by medically qualified personnel, then the process of taking informed consent may be delegated as described in section 4.2.

4.2 How to Delegate the Task of Receiving Informed Consent

If you are the Chief Investigator (CI) or Principal Investigator (PI) for a research study you *may* delegate the task of undertaking the informed consent process and/or being the signatory on the Informed Consent Form. The delegated individual must be appropriately qualified and trained member of the research team, such as Research Nurse/ Midwife/ AHP/ Research Practitioners and other research staff who may be working in the Trust under an honorary research contract or letter of access.
NOTE: Research staff working under an honorary research contract or letter of access must agree appropriate training requirements with the R&D department before receiving consent from York Trust patients.

(Refer also to R&D/S03, Delegation of Tasks for Trust Sponsored Research Studies, and R&D/F16, Study Delegation and Signature Log.

In doing so, it is the responsibility of the CI/PI to ensure that the following listed criteria are met. [Note: There may be exceptional occasions or studies where the following criteria are not required and these will be discussed and agreed on a study by study basis with the R&D department]. In all other cases the following criteria should apply:

- The designee is prepared to take on this task AND feels confident to receive informed consent in line with the Nursing and Midwifery Council (NMC) Code of Professional Conduct or other professional organisational codes of conduct, as relevant.
- Research Practitioners should work within the scope of their JD and role protocol and be supervised by experienced Research Nurses/ Senior Research Nurses and/or Lead Research Nurses
- The designee has reference to receiving consent from patients as part of their job description (where applicable)
- The designee has a comprehensive understanding of the study, potential pharmacological interactions / treatment toxicities and the associated disease area (as applicable). The designee should be fully aware of the risks and potential benefits of taking part in the research study. They should be qualified by experience and/or should have received appropriate training for this study. The designee must have completed the following training:

  An NIHR Consent in Clinical Trials course or one of a similar standard

  Read the Trust Policy and SOP for receiving informed consent.

  - Following this training the designee must complete a period of supervised practice by experienced research nurses or medical staff with a final sign off by a band 7 or 8a Senior Research Nurse (or equivalent)
  - All training and confirmation of supervised practice must be documented in the relevant training logs and competency document
  - Staff competence may change and it is the responsibility of the designee to access further or refresher training if required.

- The delegation of informed consent should be documented on the Study Delegation and Signature Log (R&D/F16).
- The delegation of informed consent, especially to members of the team who are not medically qualified, has been approved by an NHS Research Ethics Committee, the study sponsor and the NHS organisation hosting the study. An effective line of communication is maintained back to the CI/PI who is ultimately the person responsible for the patient's care and for ensuring that participants have fully understood what they are consenting to.

- Each person who receives written informed consent must have a copy of their signed and dated CV in the study site file and must be named on the Study Delegation and Signature Log (R&D/F16).

4.3 Information Provided to Potential Participants to Read and /or Watch

All information given to potential participants, for example the participant information sheet, participant information leaflet, consent form, study advertisement, in whatever format (written documents, CD, DVD) must have a favourable opinion from an appropriate NHS Research Ethics Committee (REC) and NHS permission from the Trust.

All information should be version numbered and dated.

The York and Scarborough Teaching Hospitals NHS Foundation Trust logo should appear on all written documents that are given to potential participants within this Trust.

4.4 Process for Receiving Informed Consent (face to face)

Informed consent to take part in a study must be obtained before any study related procedures take place. Occasionally there may be a separate consent process for carrying out screening procedures before eligibility is confirmed and consent to participate in the study is sought. However, if a two stage process is in place, it must have received a favourable opinion from an NHS REC and been approved by the Trust.

The timing of when people are first approached about a study, what information they receive and when, how they receive that information, at what point in time they are given an opportunity to ask questions and the length of time they have to consider whether or not to take part will vary from study to study and patient to patient. Potential participants must only be identified and approached in accordance with the process that has been authorised by an appropriate NHS REC and the Trust. Even when that is the case, consideration should also be given as to whether it is appropriate to approach a particular individual at a given time.

The privacy and dignity of the potential participant should be taken into consideration and a private area sought for the discussion/s that take place about the study.

Whatever specific process is in place, verbal explanations of the study must be given to the potential participant (and friends and family if appropriate). Diagrams may also be used to explain the study. The person must be given an opportunity to ask questions and receive satisfactory answers to those questions. It is regarded as good practice to ask potential participants to describe what they understand the study to involve. This allows investigators to gauge the person's level of understanding more appropriately than just receiving answers to closed questions about the study.

The potential participant must be informed of their right to withdraw from the study at any time. A general list of topics that investigators should cover when talking to potential participants about a study can be found in the International Conference on Harmonisation E6 Good Clinical Practice Guideline.

4.5 Seeking Informed Consent by Post

For particular studies, and under certain circumstances, it may be appropriate to seek consent from potential participants via letter. If this process is used, it must have received a favourable opinion from an NHS REC and been approved by the Trust.

The recommended process is to send the ethically approved information sheet and consent form in the post. Participants who then agree to take part in the research will sign and date the consent form and return it to the appropriate address. A member of the research team, to whom this task has been formally delegated, will sign the returned consent form to acknowledge receipt of the form and thus the person's participation.

A note should be made in the patient's notes that information has been sent out and the date this was done. A copy of the signed consent form should also be filed in the medical notes to indicate the patient's agreement to participate and a written entry made. The original signed version of the consent form should be placed in the study site file. See section 4.6.

The names of participants who do not return the consent form or who do not agree to take part should be noted to make sure they are not contacted again with regards to that particular study.

More research studies are now gaining ethical approval for consent via the sponsors internet website or smart phone apps. These will have their own electronic audit trail however the consenting process described in the IRAS application must be adhered to.

4.6 Documenting the Informed Consent Process

Completion of the consent form
The current version of the REC approved Consent Form should be used and the Trust logo should appear on the form. The Consent Form must make reference to the version number and date of the Participant Information Sheet (PIS) Participation Information Leaflet (PIL) that the participant was given.

The Consent Form must only be completed once eligibility has been confirmed by an appropriate member of the research team and the person seeking consent is satisfied that the potential participant has been fully informed and understands what involvement in the study entails.

The potential participant should initial (rather than tick) against each statement on the Consent Form to indicate their agreement (unless indicated otherwise on the REC approved version).

The Consent Form must be signed and personally dated by the participant and the authorised person who conducted the informed consent discussion. Each should also clearly print their name by their signature.

The person receiving consent must not complete any of the boxes or the information on behalf of the participant.

Medical notes
The process of seeking informed consent must also be documented in the participant's medical records or other source document (if applicable). This entry should give details of the study title and/or acronym, the version number and date of the relevant PIS/PIL the potential participant has been given, the date that the PIS/PIL was given to them and the date that refusal or consent was received. The entry should be dated and signed by a person who was involved in conducting the informed consent process.

A copy of the appropriate version of the PIS/PIL and a copy of the signed and dated Consent Form should also be filed in the medical records.

Site file
The original completed, signed and dated version of the consent form should be placed in the study site file.

Participant
A copy of the signed and dated consent form should be given or posted to the participant.

4.7 Ongoing Consent and Re-Consenting

The informed consent process does not cease once the consent form has been signed; the practice of giving information about the study to participants should be an ongoing process performed by all authorised 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 participant's willingness to continue in the study.

If an amendment to the research protocol is made during the course of the study and this results in changes that may affect a participant's continued involvement in the study, then participants must be asked to re-consent, as directed by the sponsor.

A revised PIS/PIL and Consent Form, appropriately version numbered and dated, must be provided to the participant. All revised documentation must have received a favourable opinion from the NHS REC that originally reviewed the study *before* use. NHS permission must also be obtained from the Trust prior to implementing an amendment.

The participant must be informed of the new information in a timely manner and communication of this new information should be documented in their medical notes or other source documents (as applicable).

If the amendment requires that the participant's eligibility has to be re-confirmed, this should be documented in the medical notes or other source documents (as applicable). For CTIMP studies, re-confirmation of eligibility should be completed by a medically qualified person who has been delegated that role. As before, the date of entry of re-consideration of eligibility should correspond with the date of informed re-consent.

The protocol amendment must also be checked to ensure that it does not affect who is able to re consent the participant.

The participant must 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 must be provided to the participant and placed in the medical notes and study site file.

4.8 Special Considerations

Providing certain criteria are met, approval may be granted for research studies that involve adults lacking capacity or minors (children under the age of 16 years). If the study is a CTIMP, the informed consent process as described in the Medicines for Human Use (Clinical Trials) Regulations (as amended) must be followed. For all other types of studies in England and Wales the Mental Capacity Act (2005) will apply. Scotland and Northern Ireland have separate provision.

4.8.1 Adults lacking capacity

There is a legal presumption that persons aged 16 years or older have capacity to give consent unless it is established otherwise.

The relevant definitions of incapacity are as follows:

'Unable to make a decision for themselves in relation to the matter because of an impairment of, or disturbance in the functioning of, the mind or brain. It does not matter whether the impairment or disturbance is permanent or temporary' (Mental Capacity Act, 2005)

'Unable by virtue of physical or mental incapacity to give informed consent' (Medicines for Human Use [Clinical Trials Regulations], 2004)

Assessment of capacity
Where it is suspected that a person may lack capacity, an assessment must be made to establish whether the individual can:

- Understand information relevant to the decision
- Retain information relevant to the decision
- Use or weigh up the information in order to arrive at a decision

- Communicate their decision

There is no such thing as 'blanket' incapacity under the Mental Capacity Act i.e. incapacity is specific to a particular situation and a specific point in time. The Mental Capacity Act informs assessment of incapacity for both CTIMP and non CTIMP studies.

When the assessment is carried out within the context of a research study, it must be conducted by the CI/PI, or another appropriately experienced clinician. The assessment and its results must be recorded in the patient's medical notes.

If, as a result of the assessment, a person is deemed to meet the above criteria then they should be regarded as capable of giving informed consent to take part in the study. However, when a person is deemed to lack capacity, special provision must be made with regard to consent.

If the study is a CTIMP, the Medicines for Human Use (Clinical Trials) Regulations (as amended) must be followed and consent must be received from a Legal Representative. For all other types of intrusive research studies in England and Wales the Mental Capacity Act (2005) applies and advice must be sought from a Consultee (Scotland and Northern Ireland have separate provision).

CTIMPs
In a CTIMP study that involves incapacitated adults, written informed consent must be provided by either a Personal or Professional Legal Representative. A Personal Legal Representative is a person who is suitable to act as the Legal Representative by virtue of their relationship with the patient, for example a family member or friend, and is available and willing to do so. A Professional Legal Representative can be either i) a doctor who is responsible for the medical care of the patient, providing they have no connection with the study or ii) a person nominated by the relevant healthcare provider. A Personal Legal Representative (PeLR) should be used in preference to a Professional Legal Representative (PrLR) wherever possible.

The involvement of the Legal Representative must follow the process that has received a favourable opinion from an appropriate NHS REC. The Legal Representative must be given sufficient verbal and written information about the trial to enable them to make an informed decision and they should be told that they are:

- Being asked to give consent on behalf of the incapacitated adult
- Free to decide whether they wish to make this decision or not
- Being asked to consider what the incapacitated adult would want

Members of Trust staff who are willing and able to act as a PrLR for a specific study should be identified while setting up the study and their names included

on the application to the Trust for NHS permission. The PrLRs should understand the legal framework surrounding consent in vulnerable people and may require training before undertaking such a role. They must have a full understanding of the study concerned and be given information about how to contact the PI or another key member of the research team.

Incapacitated adults who are conscious should receive information about the study even if a Legal Representative is providing consent. The investigator should judge the format and level of information that is appropriate for the incapacitated individual, for example simple written information that can be read to the person.

Any advance directive or wishes must be respected as should any explicit wish from the patient to refuse participation.

During the study, the Legal Representative (LR) who provided consent should be informed of all material changes to the study and the participant's condition. The LR has the right to withdraw the participant at any point in the study without it affecting the participant's care. Researchers must always respect the opinion of the LR.

If a participant subsequently regains capacity, the consent provided by the Legal Representative remains legally valid but even so, the participant should be informed about the study. The participant should be given appropriate verbal and written information. The participant's wishes about whether or not to continue their involvement in the study should be respected. The Legal Representative should be kept informed of this process and its outcome.

Consent from the Legal Representative and, if relevant, from the participant once they regain capacity, must be obtained in writing; the Clinical Trials Regulations make no provision for telephone consent. All other aspects of the informed consent process should be documented as outlined in 4.6

If the participant refuses their consent when they regain capacity, or subsequently withdraws, they must be withdrawn from the study without delay unless this would pose a significant risk to their health. It should be made clear whether data that has already been collected up to the point of withdrawal can be included in the study or not.

CTIMPs in emergency situations

Where the treatment in a CTIMP needs to be given urgently to an incapacitated adult, there may not be time for informed consent to be received from a Legal Representative before enrolment. The Medicines for Human Use (Clinical Trials) Regulations (as amended) allow incapacitated adults to be entered into a trial prior to consent being received from a Legal Representative provided that:

• It is not reasonably practicable to obtain informed consent prior to entering the participant into the study

and

• The action to be taken is carried out in accordance with a procedure that has received a favourable opinion from an NHS REC.

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 participant (if capacity has been recovered) or from a Legal Representative **as soon as practicable** after the initial emergency has passed. Within 48 hours is the suggested time and justification should be given where this has not been possible. Reasonable steps should be taken to seek a Personal Legal Representative before approaching a Professional Legal Representative.

If the Legal Representative refuses consent at this stage, or the participant is subsequently withdrawn, they must be withdrawn from the study without delay unless this would pose a significant risk to their health. It should be made clear whether data that has already been collected can be included in the study or not.

Consent from the Legal Representative and, if relevant, from the participant once they regain capacity, must be obtained in writing; the Clinical Trials Regulations make no provision for telephone consent. All other aspects of the informed consent process should be documented as outlined in 4.6.

Non-CTIMP studies

For non-CTIMP studies in England and Wales the Mental Capacity Act (2005) should be followed and **advice** (rather than consent) must be sought from a Consultee on whether or not the incapacitated person should take part in the study.

The Consultee may be a 'Personal' Consultee or a 'Nominated' Consultee. The researcher must take reasonable steps to identify a Personal Consultee before approaching a Nominated Consultee.

A Personal Consultee should be a person who is i) involved in caring for the potential participant (other than in a professional or paid capacity) or is interested in their welfare and ii) is willing to be consulted.

A Nominated Consultee is a person who is nominated by the relevant healthcare provider in accordance with Department of Health guidance and who is independent of the project.

Members of Trust staff who are willing to act as a Nominated Consultee should be identified while setting up the study and their names included on the application to the Trust for NHS permission. The Nominated Consultee should

understand the legal framework surrounding consent in vulnerable people and may require training before undertaking such a role. They must have a full understanding of the relevant study and be given information about how to contact the PI or another key member of the research team.

The Consultee must be told that they are:

- Being asked to give advice on whether the incapacitated adult might wish to participate in the study or not
- Free to decide whether they wish to provide this advice or not

There may be occasions when the researcher wishes to seek advice from more than one Consultee (e.g. several family members) in accordance with the best interest's principle. When this is the case and there is disagreement between the Personal Consultees, the incapacitated person should be excluded from taking part in the study.

The involvement of the Consultee must follow the process that has received a favourable opinion from an appropriate NHS REC.

The additional safeguards described under Section 33 of the Mental Capacity Act must also be followed. These are that the interests of the participant outweigh those of science and society and nothing must be done

- 'to which the participant appears to object unless it is to protect them from harm, or reduce or prevent pain or discomfort'
- 'contrary to an advance decision to refuse treatment or any other advance statement'

The advice given by the Consultee should be recorded on a Consultee Declaration Form that has received a favourable opinion from an appropriate NHS REC.

During the study, the Consultee should be informed of all material changes to the study and the participant's condition. The Consultee has the right to withdraw the participant at any point in the study without it affecting the participant's care. Researchers must always respect the opinion of the Consultee.

If a participant subsequently regains capacity, informed consent must be sought from the participant as consent is not legally in place under the terms of the Mental Capacity Act; the Consultee has only provided advice. The Consultee should be informed that the participant has regained capacity and the participant should be provided with an appropriate Participant Information Sheet, Participation Information Leaflet, that has received a favourable opinion from an NHS REC. Consent from the participant must be obtained in writing and the process should be documented as outlined in 4.6.

If the participant refuses their consent at this stage, or subsequently withdraws, they must be withdrawn from the study without delay unless this would pose a significant risk to their health. It should be made clear whether data that has already been collected can be included in the study or not.

Non-CTIMP studies in emergency situations

Where the treatment in a non CTIMP study needs to be given urgently to an incapacitated adult, there may not be time to identify and seek advice from a Consultee before enrolment. The Mental Capacity Act allows incapacitated adults to be entered into a study prior to advice being received from a Consultee provided that:

- Treatment needs to be given urgently to the person lacking capacity
- It is not reasonably practicable to identify and seek advice from a Consultee prior to enrolling the person into the study, and
- The action to be taken is carried out in accordance with a procedure that has received a favourable opinion from an appropriate REC.

Where an incapacitated adult is recruited in an emergency situation without prior consent or advice, steps must be taken to seek informed consent from the participant (if capacity has been recovered) or advice from a Consultee **as soon as practicable** after treatment for the initial emergency has been given. The consent or advice should be recorded using the REC approved Consent Form or Consultee Declaration Form, as applicable.

Where consent is withheld, or advice from the Consultee does not support ongoing participation, the participant must be withdrawn from the study without delay unless doing so would pose a significant risk to their health.

People with Communication Problems/Comprehension Difficulties

When prospective participants have capacity to consent but have some comprehension or communication difficulties they must be given all appropriate help to enable them to understand information about a study and make their own decisions e.g. using visual aids, sign language etc.

If a decision is taken to enrol subjects with communication problems or comprehension difficulties then investigators must have a clear plan about how these matters will be managed and documented during the consent process. Any such plan should be approved by an NHS REC. For example, if the difficulties are due to visual impairment then the information sheet can be read to the prospective participant and audio recorded at the same time to provide a copy for the participant to keep.

Where there are communication difficulties, a relative or an independent patient's advocate should be involved in the consent process. The latter's role

is to help the prospective participant express their views. Therefore two types of information sheet may be required: one for the relative / advocate and one for the patient. The latter should be designed to overcome or minimise some of the communication problems, for example, the use of pictorial information. Sufficient time must be allowed for the person seeking consent to explain and discuss the proposal with the potential participant and the relative or advocate, and for the relative or advocate to have a discussion with the prospective participant.

For the consent to be valid the research participant must be able to communicate their decision. If the person is unable to sign or to mark the consent form so as to indicate their consent, then consent may be given orally in the presence of at least one witness, usually a relative or patient advocate. The role of the relative or advocate in the consent process, for example acting as a witness or explaining the study to the prospective participant, must be documented in the medical records. Consent could also be recorded to provide a complete record with a copy of the tape for the participant.

All hospital staff who provide information and request consent from patients with communication problems or comprehension difficulties must be appropriately trained and have experience of working with such patients.

An NHS REC and the Sponsor must agree to the process for informed consent.

4.8.3 Children under 16 years of age

The process for receiving consent from children is dependent on the type of study. If the study is a CTIMP, the Medicines for Human Use (Clinical Trials) Regulations must be followed. For other types of studies the process is less well defined.

CTIMPS

Under the Clinical Trial Regulations a person under the age of 16 years is deemed to be a ‘minor’ and an appropriate adult must give consent for that child/ young person to take part in a CTIMP.

An appropriate adult may be i) a person or local authority with parental responsibility for that child or ii) a Nominated Legal Representative.

The appropriate adult must sign the REC approved Consent Form.

Children should receive information about the study that is appropriate to their age even if someone else is providing consent. The information must be given by a member of staff who has experience of working with children.

The person receiving consent must consider the explicit wish of a child who is capable of assessing the information and forming an opinion, even if the child is a minor i.e. the child’s ‘assent’ should be sought. The child’s assent should be recorded on an assent form that has been approved by an NHS REC. A child’s refusal to participate, or continue, in a study should always be respected.

CTIMPs in emergency situations
Where the treatment to be given to child as part of a trial needs to be given urgently, time may not allow for the written consent of a person / local authority with parental responsibility / Legal Representative to be received first. The CTIMP Regulations allow children to be entered into a trial prior to consent being received from an appropriate adult provided that:

• It is not reasonably practicable to obtain informed consent prior to entering the child into the study

• The action to be taken is carried out in accordance with a procedure that has received a favourable opinion from an NHS REC.

Steps must be taken to seek informed consent from a person with parental responsibility or a Legal Representative as soon as practicable after the initial emergency has passed. Within 48 hours is the suggested time and justification should be given where this has not been possible. Where consent is then withheld, the child must be withdrawn from the trial.

Non-CTIMP studies
For non-CTIMP studies there is no clear definition in law as to the age at which a child can give consent for him or herself, or when this has to be provided by someone with parental responsibility. The process for non-CTIMP studies may therefore vary from study to study. The informed consent process that is followed must have received a favourable opinion from an NHS REC.

In planning a non-CTIMP study consideration should be given as to whether the child or a person with parental responsibility is going to be asked to give consent.

With regard to consent to medical treatment, the courts have determined that children under 16 years of age can be legally competent to provide consent if they have 'sufficient understanding and maturity to enable them to understand fully what is proposed'. This concept is referred to as 'Gillick competence' and/ or 'Fraser competence' (some authorities refer to ‘Fraser competence’ when talking about contraception and ‘Gillick competence’ when talking about wider areas of consent. In many cases the two terms are used interchangeably).

It is generally accepted that the principles of ‘Gillick competence’ can be applied to research.

If a child is going to be asked to give consent in a non-CTIMP study, an assessment of ‘Gillick competence’ should be made and where the child is deemed competent to provide informed consent, then the child should be asked to sign a consent form. If the child is not deemed to be Gillick competent then a person with parental responsibility must provide consent on the child’s behalf.

If the informed consent process dictates that someone with parental responsibility must give consent, or the child is not deemed to be Gillick competent, the person receiving consent must consider the explicit wish of a child who is capable of assessing the information and forming an opinion, at least to some extent, i.e. the child's 'assent' should be sought. The child's assent should be recorded on an assent form that has been approved by an NHS REC. A child's refusal to participate, or continue, in a study should always be respected.

The process that has been followed should be documented in the child's medical notes.

The issue of who has parental responsibility for a child is not straightforward and more information about this can be found in Appendix A.

5. Related SOPs and Documents

Declaration of Helsinki (1996 Version)

Research Governance Framework for Health and Social Care (2nd Edition, April 2005)

The Medicines for Human Use (Clinical Trials) Regulations 2004 Statutory Instrument 2006/1031, implemented on the 1st May 2004 as amended[1]

The Mental Capacity Act, 2005

R&D/S03 Delegation of Tasks for Trust Sponsored Research Studies

R&D/F16 Study Delegation and Signature Log

[1] The Medicines for Human Use (Clinical Trial) Regulations 2004 and the Medicines for Human Use (Clinical Trial) Amendment Regulations 2006 (SI 2006 No. 1928), the Medicines for Human Use (Clinical Trials) Amendment (No.2) Regulations 2006 (SI 2006 No. 2984), the Medicines for Human Use (Clinical Trials) and Blood Safety and Quality (Amendment) Regulations 2008 (SI 2008 No. 941), and the Medicines for Human Use (Miscellaneous Amendments) Regulations 2009 (SI 2009 No. 1164).

Appendix A

Parental Responsibility

- The law does not define parental responsibility in detail, but key roles include:
  - Protecting and maintaining the child
  - Agreeing to the child's medical treatment
  - Allowing confidential information about the child to be disclosed
- Mothers have automatic parental responsibility for their child from birth
- If parents are married at the time of birth or have jointly adopted a child they have joint parental responsibility
- Parental responsibility remains in place even after divorce
- A father *does not* have automatic parental responsibility for a child if he was not married to the mother at the time of the child's birth unless the child was born after 1/12/2003 and the father is named on the birth certificate
- If a father does not have automatic parental responsibility he can acquire parental responsibility for his child via:
  - Formal agreement with the mother
  - Subsequent marriage to the mother
  - An order of the court
  - A residence order in relation to the child