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Centre for Health Research and Innovation
Lancashire Teaching Hospitals NHS
NHS Foundation Trust

STANDARD OPERATING PROCEDURE

Informed Consent for Paediatrics in Research

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RESEARCH AND INNOVATION

R & I

BACKGROUND

Informed consent is '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 written, signed and dated 'informed consent form' (ICH E6 (R2) Guidelines for Good Clinical Practice, 2017).

PURPOSE
This SOP describes the procedure for obtaining written informed consent from a potential study participant/patient or his/her parent/guardian. This involves informing the subject and/or parent/guardian through verbal explanation(s) and written information.

SCOPE
This SOP relates to all research that is conducted within Paediatric Research at Lancashire Teaching Hospitals NHS Foundation Trust.

All study personnel must use the same procedure for all participants to gain informed consent. This is to ensure that we are practicing with the ICH E6 guidelines for Good Clinical Practice and with ethical principles that have their origin in the World Health Organisation's Declaration of Helsinki.

PROCEDURE

WHO?
The Principal Investigator or other designated members of the research team who can give a comprehensive verbal explanation of the study.

Except where documented on the site signature and delegation log and authorised by the lead investigator, the lead investigator or co-investigator as medically qualified persons are the only individuals who can obtain written consent from the subject.

In the case of a Clinical Trial of an Investigational Medicinal Product (CTIMP) the person seeking consent must be a medically qualified person, except in certain circumstances as listed below.

- For some studies, the investigator may choose to delegate the process of obtaining informed consent for research to another healthcare professional (most commonly a research practitioner). However, the study team need to confirm that the Study Sponsor supports that consent is taken by delegated individuals and that the Health Research Authority (HRA) / Research Ethics Committee (REC) have also approved the consent process.

- For some studies it may be acceptable for a nurse/midwife who has undertaken the appropriate training, is within the scope of their job roles and is supported by the host site and delegated by the PI to consent to CTIMPs, where appropriate approvals via the HRA / REC and the Sponsor. This would usually include evidence that the PI or a medic has confirmed eligibility in writing prior to consent and is on hand to answer any questions that may arise from the patient.

The MHRA (2012) states: "The UK regulations allow for the interview with a potential subject (or other person giving consent) to be undertaken by any member of the investigational team at the site. The application submitted to the main REC must set out the general policy for the trial in terms of what types of personnel will be involved.

WHEN?
Informed consent must be taken before any trial/study procedures take place.

Some trials/studies ask for consent several times throughout the process, as well as ongoing consent. Study personnel must understand the protocol and comply with gaining informed or ongoing consent appropriately.

HOW?

1. Study personnel obtaining consent must be fully familiar with the study protocol, information sheet(s) and consent/assent forms prior to approaching patients for informed consent.
2. Potential study patients will be identified, screened, and approached by either the investigator or other members of the research team who have appropriate knowledge. Careful consideration of the timing of approaching patients about research should be given. For hospital inpatients, the research team should liaise with the clinical team looking after the patient to understand if it is appropriate and suitable to approach the patient for research at this time.
3. Patients and their parents should first be asked if they would like to hear about an opportunity to take part in research. If they accept, a description of the study will be given to the patient and/or parent/guardian verbally using language at their level of understanding. Younger patients should have the study explained to them in a manner appropriate to their age and allowed to express their willingness, or otherwise, to take part. Opportunity should be given to ask questions and the investigator (or other research professional designated by the investigator) should make every attempt to answer questions to the patient and parent/guardian's satisfaction. If necessary, the study personnel will contact the study site when unsure of information and let the parent/guardian/participant know. Once the study personnel are confident that the participant, parent, or guardian understand their contribution and participation to the study, only then can the informed consent form be signed.
4. The participant, parent, or guardian should be given ample of time and opportunity to read all Patient Information Sheet(s) (PIS) and be able to discuss with family members or friends, if they so desire, before the informed consent form can be signed.
5. The time and date of when information has been given to a participant must be documented within their notes and on Edge.
6. The participant and family should not be coerced or unduly influenced by any study personnel, the decision must be made by the participant, parent, or guardian.
7. The consent must be signed on Sponsor approved local headed paper and must be signed with the patient information sheet version that was given to the family. The participant, parent, or guardian must write their own name, date, and signature with a black ballpoint pen, in the presence of the person receiving consent. Once signed it should be photocopied and the original stored in the site file and the copy given to the participant, parent or guardian.
8. Once consent has been obtained it must be documented in the participant's notes with study title, brief info, how they meet the criteria, the PIS version, and the date it

was signed. RD-TMP-03b_Informed consent summary-Child (on the intranet - template documents) should be used.

9. Following this at every study visit or contact it must be reconfirmed that the participant is willing to continue.

ASSENT

1. For patients under 16 years of age, signed informed consent must be obtained from a parent/guardian or person with parental responsibility. In addition, the views and wishes of the child should be considered and if the child is capable and wishes to take part, they must be asked to provide assent; however, if the young person objects, you should respect their privacy.
2. If 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 CTIMP), the child / young person must gain information about the study, in a way that they can understand and explains what is involved and the potential risks and benefits. It should be staff with experience of working with children / young people that provides this information. There should be ethically approved patient information sheets available for a range of ages in differing formats, accompanied by parent and guardian versions. If the child or young person can assess the information provided and communicate it back to you, you must consider their explicit wishes. This includes their refusal to take part, or desire to withdraw from the study.
3. Whenever practical and appropriate, a child's assent should be sought before including them in your research. An informed judgment must be made to determine when seeking assent is appropriate; the age of a child can only be taken as a guide. Also consider the child's developmental stage, knowledge of illness, and experience of health care.
4. Although there are risks when children are asked to exercise greater autonomy than normal, this must be balanced with the potential loss of trust associated with denying their assent. This judgment needs careful consideration, a record of observations and discussions, and a documented decision. In circumstances where seeking assent at the outset is not appropriate, you could provide the child with information as and when required (a little bit at a time).

4. OTHER RELATED PROCEDURES

RD-TMP-03b_Informed consent summary-Child

5. CONSULTATION WITH STAFF

S&Q Group – Review & Approval
Jessica Wolstenholme – Paediatric Ward Manager
Stephanie Horridge – Research Nurse
Cheryl Wyatt – Senior Research Nurse

Sign Off			
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