ARTIC PC WPD Informed Consent Minors

Working Practice Document Title:	**Informed Consent – Minors**

Working Practice Document Number:	**01**

Version Number:	**V.1**

Effective Date:	

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	Date: 2/9/16

Review date	**Date:** 01SEP2017

Review History

Version No.	Date	Amendments
1	30/08/2016	New document

1. Introduction, Background and Purpose

While we have a responsibility to protect children, we also have an ethical obligation to ensure that they receive the best treatment and medical research involving children is essential for advancing child health and wellbeing. It is not sufficient, scientific or ethical to apply adult research finding to children, because children are not simply small adults: physiology and disease processes may differ, as may the pharmacokinetics of many drugs and many disorders can only be understood in the context of a child's growth and development.

This Working Practice Document (WPD) describes the correct procedure for receiving informed consent on research studies which involve minors,in line with ICH GCP guidelines and The Medicines for Human Use (Clinical Trials) Regulations 2004 (Statutory Instrument 2004/1031) as amended.

ICH GCP defines **Informed Consent** 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' Informed consent protects the research participants' rights and well-being, is an on-going process of information exchange, and ensures practice is carried out in line with governing professional bodies and UK law.

With regard to research involving children, in the UK there are two legal systems running in parallel:

1.1 The **common law** applies to research not covered by the Medicines for Human Use (Clinical Trials) regulations. (see 1.2)

This states that the age of majority is 18. Whilst not considered to have fullyreached adulthood, young people between the age of 16 and 18 are presumed to be competent to give consent.

No statute governs the rights of those under the ageof 16 to give consent for medical treatment or research. However, case law providesthe example of the Gillick case with respect to treatment.This case determinedthat where a young person has sufficient

understanding and intelligence tounderstand fully what is proposed, and use and weigh this information in reaching adecision, he or she can give consent to treatment and consent from parents is notlegally necessary – although parental involvement should always be encouraged. Theterm "Gillick competent" is used to describe a young person's ability to make adecision regarding consent. In the absence of case law relating directly to research , it is best practice to obtain parental consent when the research involves a child under the age of 16, however the child's agreement or assentshouldbe obtained in addition to the consent of the minor's legal guardian.

The Research Ethics Committee approving the study will have evaluated this process considering the nature of the study and whether it involves observation or intervention, and appropriate information sheets/consent/assent forms for differing ages of children will be approved.

For all research conducted in the NHS, the **Department of Health Research Governance Frameworkfor Health and Social Care**, Second Edition 2005 applies and can be accessed at

https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/139565/dh_4122427.pdf A scenario on pages 10-12 asks: What does it really feel like to be asked to participate? This provides researcher responses to questions from parent and child.

Further advice is provided by the GMC: Consent to research: Research involving children or young people http://www.gmc-uk.org/guidance/ethical_guidance/6469.asp

"Before involving a child or young person in research you must get consent from a parent, but you should get consent from both parents, if possible, particularly if the research involves more than low or minimal risk of harm. If a parent is under 16 years of age, you must get consent from them if they have the capacity to make a decision about whether their child should take part in the research project. If a child or young person is able to consent for themselves, you should still consider involving their parents, depending on the nature of the research (para16).... If disagreements cannot be resolved informally, you should not involve the child or young person in research, unless the treatment can be accessed only as part of a research project and you assess that it is in their best interests. In these circumstances, if the decision about entering the child or young person in research has significant consequences for the child or young person, you should seek legal advice about whether you should apply to the appropriate court for an independent ruling." (para17)

When parents are themselves under 16 years of age, they will only be able to give valid informed consent on behalf of their child if they are compentent to take the decision in question. An individual must be able to:

- Comprehend and retain information material to the decision, especiallyconsequences of having or not having any intervention;
- Use and weigh this information in a decision making process;
- Reach and communicate a decision.

1.2 The requirements for the involvement of minors in a Clinical Trial of an Investigational Medicinal Product (CTIMP) are specified in **the Medicines for Human Use (Clinical Trials) Regulations (SI 2004/1031Schedule1 Part 4)**

These regulations require that:

- A Research Ethics Committee (REC) considering the trial must receive advice on the relevant field of paediatric care
- A person with parental responsibility or a legal representative must give informed consent and may withdraw the young person at any time.

With relation to the minor :

- Staff with experience of young persons must inform him/her of the risks and benefits of the trial according to her/her capacity to understand;
- The investigator must consider his/her explicit wish to refuse to participate or be withdrawn from the trial at any time;
- The clinical trial must relate directly to an illness from which he or she suffers or that can only be carried out on minors; and
- The trial must aim to provide some direct benefit for the group of patients involve;
- The clinical trial must be designed to minimise pain, discomfort, fear and any other foreseeable risk in relation to the disease and the minor's stage of development;
- The risk threshold and the degree of distress must be specially defined and constantly monitored;
- The interests of the patient always prevail over those of science and society;
- No incentives or financial inducements are given to the minoror to a person with parental responsibility or the minor's legal representative, except provision for compensation in the event of injury or loss, and reimbursement for travel and

other expenses RECs may also consider allowing small non-monetary gifts to minors as a thank you for participation (provided these are not seen as an inducement);

- Where there is parent/child conflict relating to consent, the will of the child should take precedence after full age-appropriate explanation has been provided. A child's refusal to participate or continue in research should always be respected.

1.2.1 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.

If the parents of a child are married to each other at the time of birth, or if they have jointly adopted a child, then they both have legal parental responsibility.

Parents do not lose responsibility if they divorce, and this applies to both the resident and the non-resident parent.

A mother automatically has parental responsibility for her child from birth.

A father does not always have parental responsibility for the child ifhe was not married to the mother at the time of birth. Living with the mother does not give a father legal parental responsibility. In the case of children born after 01 December 2003, where the father's details are registered on the birth certificate, the father will also have parental responsibility.

Parental responsibility does not always pass to the natural father if the mother dies.

Fathers can acquire parental responsibility but this must be done formally. If the parents are unmarried and the father is not named on the birth certificate, a father can acquire parental responsibility by entering into a formal agreement with the mother, by

- subsequent marriage to the mother;
- order of the court;
- obtaining an order of residence, under the Children Act 1989 (which governs where a child is to live) in relation to the child.`;
- adoption.

A parent's **Civil Partner** can obtain parental responsibility in relation to their partner's child, either by

- entering into a parental responsibility agreement, or
- on application to the court.

Parental responsibility gained in this way will not be lost if the partnership is subsequently dissolved. There are distinct rules relating to the status of parents of children born as a result of assisted reproduction.The Government has announced its intentions that civil partners and other same sex couples will have the same rights to be recognised as parents in those circumstances as heterosexual couples.

When the **child is the subject of a care order in favour of a Local Authority**, the local authority shares parental responsibility with the mother or both parents. Where a child is in care voluntarily, parental responsibility remains with the parents.

Persons who may have day to day responsibility for children, such as teachers and child-minders do not have parental responsibility but are under a duty of care to act as a responsible parent would do to ensure the child's safety andin emergency circumstances may take reasonable steps to promote a child's welfare. These persons cannot provide consent for the child for research purposes.

For further information and guidance on other situations, refer to Gov.UK

https://www.gov.uk/parental-rights-responsibilities/who-has-parental-responsibility

1.2.2 Legal Representative: In the absence of the individual(s) with Parental Responsibility, Informed Consent may be given by a LegalRepresentative.

A **Personal Legal Representative** is someone, other than a person involved in the conduct of the trial, who

- by virtue of their relationship with the minor, is suitable to act as their legal representative for the purposes of that trial, and

is available and willing to so act for those purposes

Or if there is no such person:

A **Professional Legal Representative** is someone, other than a person involved in the conduct of the trial, whois

- the doctor primarily responsible for the medical treatment provided to that child, or

- a person nominated by the relevant health care provider

The Investigator must be satisfied a Legal Representative has sufficient knowledge of the minor and an interest in their welfare.

2. Abbreviations

See Reference Document: CRN Primary Care Abbreviation List and Glossary of Terms.

3. Scope

This Work Instruction (WI) should be followed by all staff involved in the process of receiving consent for involvement in research studies (both CTIMP and Non-CTIMP) which involve children under the age of 16. The principles for receiving informed consent, as set out in SOP XX, must also be observed.

4. Responsibilities

If staff other than the investigator are to accept responsibility for the informed consent process in studies involving minors, it is important that the individual delegated the role has appropriate experience, is prepared to take on this additional responsibility and feels confident to receive informed consent in line with the Medicines for Human Use (Clinical Trials) Regulations orthe Research Governance Framework and/or other professional organisational guidelines, as applicable. This should be recorded on the Authorised Delegation Log.

An effective line of communication must be maintained back to the Principal Investigator (PI)/person who is ultimately responsible for the patient's care.

It is ultimately the responsibility of the person receiving consentto confirm that the person giving consent **has parental responsibility or is an appropriate legal representative** and has fully understood what they are consenting to on behalf of the minor. It is usual practice for the PI to sign/countersign the consent form for clinical trials.

It is recommended all staff undertaking informed consent procedures complete ICH GCP training,including the process of Informed Consent in a Paediatric setting when a study includes minors.

5. Procedures

5.1 At the Informed Consent visit, **confirm the relationship** of the accompanying adult to the minor adult to check whether this person has parental responsibility (hereafter referred

to as parent) This may include the confirmation that the mother of the child is.over 16. If the mother is herself a minor she may consent for the child's participation in a study, if she is competent to take the decision in question.

5.2 Confirm that the parent/legal representative has been given the latest **study documentation (PIS and ICF)** and any other relevant study information, providing up to date versions if necessary.

Check that this person has had time to read all the information and whether theyhave any questions relating to the study documentation. Potential participants(including those with parental responsibility or legal representatives) should be given ample time (often 24 hours), after receiving the study information, to consider participation unless the EthicCommittee has approved a shorter time, due to the nature of the research. Check the terms of ethical approval for the study if in doubt.

5.3 Give a **full explanation** of the study and what is involved in language appropriate to the responsible adult's level of maturity and competence. Include:

- The purpose of the research;
- The practicalities and procedures involved in the minor's participating;
- The benefits and risks of participation, and if appropriate the alternative therapies;
- Randomisation: trial treatments and probability;
- How data about the minor will be managed and used, including access by monitors, audit and inspection;
- The consent form;
- The minor's role if they agree to participate in the research;
- How information will be provided to them throughout the study;
- That the participation of the minor is voluntary;
- That they can withdraw from the study at any time, without giving any reason and without compromising the minor's future treatment;
- The insurance indemnity arrangements for the conduct of the research where appropriate;
- That the research has been approved by a Research Ethics Committee.

5.4 Give an **explanation of the study to the child** covering the points above, as appropriate to the child's age and understanding,making use of the appropriate approved children's information sheet and assent form.

Encourage the parent/legal representative and child to ask questions and gauge their understanding of what is being asked of them.

5.5 Check if the parent/young person/child would like more time to consider the study, speak to a member of the research team or their GP, family or an independent advisor

Once you are satisfied that the parentand child understand the study and that all their questions have been answered, ask if they are willing for the minor to participate in the study.

If they do not want to proceed, inform them that their decision has no effect on the current treatment the child receives.

If they are happy to go ahead, check the inclusion/exclusion criteria as per study protocol.

5.6 **Completing the consent form:**

- Ensure the correct version of consent is being used
- The consent form must be completed in black ink only.
- Ask the parent/legal representative to read eachstatement and initial the box on the consent form if they are agreeing to that statement. Allow time to read and ask questions.
- Ensure the parent/legal representative has printed full name, signed and dated at the end of the consent form. This must be completed by the individual.
- Whoever has conducted the consent procedure will countersign and date the consent form as required by the study.

5.7 **Complete the Assent Form** with a child who is able to do this. Remember the assent process is more about fully ensuring the child has sufficient understanding rather than the completion of a form. . it is important to involve the child whenever possible ensuring the child is fundamental to the decision and feels valued.

5.8 **Filing:**1 copy of the consent form is given to the parent/legal representative for their records; 1 copy is filed in the Investigator Site File (ISF) and 1 copy is placed in the participants medical notes (if appropriate) with a copy of the PIS.

In General Practice, the consent form is normally scanned into the participant's notes along with the PIS.

The study consent visit is documented on the patient electronic record as a consultation. Provide the parent/legal representative with the contact name and telephone number for the study. This will be detailed on the PIS or on the contact card provided by the sponsor.

5.9 Remember that informed consent is an **on-going process** and participants, including those with parental responsibility or legal representatives, should receive copies of all relevant, updated and new information, regarding the study throughout the child's participation. Any clinician is responsible for checking that participants are happy to continue at each visit on a study. This must be recorded at each study visit.

5.10 If a **participant turns 16** part way through a study, they will need to consent to continue to take part.

2. 6. Related SOPs, Working Practice Documents and Reference Documents

6.1 SOPs

None

6.2 Working Practice Documents

None

6.3 Reference Documents

Declaration of Helsinki

ICH Good Clinical Practice – GCP

EU Clinical Trials Directive

DH Research Governance Framework

CRN Primary Care Glossary of Terms and Abbreviations

RCN Informed Consent

Nursing and Midwifery Council http://www.nmc-uk.org/code

GMC: Consent to research: Research involving children or young peoplehttp://www.gmc-uk.org/guidance/ethical_guidance/6469.asp

MRC EthicsGuide Medical research involving children 2004 Revised Aug 2007 http://www.mrc.ac.uk/Utilities/Documentrecord/index.htm?d=MRC002430

NPSA NRES :Information Sheets and ConsentForms ...

www.nres.nhs.uk/EasySiteWeb/GatewayLink.aspx?alId=338

Children Act 2004

3. 7. Appendices

There are no appendices associated with this WPD.