**Introduction**

Obtaining consent varies according to the type of study design used. Clinical Trials are governed by the UK Law. The Medicines for Human Use (Clinical Trials) Regulations (2004) which unambiguously states written consent for a minor (<16 years) must be provided by a person with parental/legal responsibility (PR).

Under current UK law, PR is often difficult to determine. Mother and fathers have different criteria according to the children’s Act 2004. Mothers are automatically granted PR however the PR of fathers who are not listed on the birth certificate differs between UK countries and the year of the child’s birth. In certain circumstances, the mental capacity of a parent and the child protection status of the minor may also need to be considered when assessing an appropriate legal guardian (DoH 2005, DoH 2004).

Assent is taken to represent a child’s acquiescence. This is a crucial element of clinical research, providing minors with a voice. Despite this, there is no legal requirement to obtain assent but only to ensure that the child’s wishes be considered.

Current clinical trials regulations do not apply to any other types of clinical research such as observational studies. Therefore, principles embedded in common law, the Declaration of Helsinki (1964), ICH GCP guidelines (1996) and The Children’s Act (2004) must be applied to ensure that health professionals are equipped obtain valid informed consent. In such instances the determination of the child’s competence to consent on their own behalf is paramount.

Common law arising from the case of Gillick v West Norfolk and Wisbech AHA and Department of Health & security (1986) is generally applied when considering competence to consent to the provision of medical care. However, no such legal precedent exists for the purposes of research. This may mean health professionals are reluctant to use this case law in research with the vulnerable paediatric population.

In exceptional circumstances the requirement to obtain valid informed consent prior to research participation is waived. This is only permitted for essential research in emergency medical, neonatal and surgical care settings where obtaining consent is impractical whilst ensuring that medical care is provided expeditiously. Such research is essential for the improvement of treatments in these settings. The deferred consent process must however be approved by a specialist paediatric Research Ethics Committee beforehand.

**Case Study**

A minor is taking part in a clinical trial of an investigational medicinal product (CTIMP) reaches 16 years of age. Under UK law they would then be considered to be an adult and are required to consent for themselves at this stage unless they are deemed to lack mental capacity. There are concerns regarding the patients mental capacity to give valid informed consent due to their condition and education status. The Principle Investigator and nursing staff make a full assessment of the patients understanding of what the study involves, use of the information given to make a decision and their ability to communicate their wishes. For example the patient asked “can I have this infusion as a tablet instead?” and “will it be dangerous for me to try a new drug that nobody has had before?”. It was decided that the patient demonstrated sufficient mental capacity and that it would be appropriate for them to give valid informed consent themselves. This decision is fully documented in the patients medical records referring to the Mental Capacity Act (2005) and the Medicines for Human Use Clinical Trials Regulations (2004).

**Informed consent guidelines for research in children**

**Basic Informed Consent Principles**

- Consent for examination and/or treatment (2009)  
- Mental Capacity Act (2005)  
- Gillick Competence (1986)  
- Family Law Reform Act (1969)  
- Declaration of Helsinki (1964)  
- ICH GCP (1996)

**Consent with a minor**

**NON-CTIMP**  
- Declaration of Helsinki (1964)  
- ICH GCP (1996)

**Paediatric Research**  
- CTIMP  
- Medicines for Human Use (Clinical Trials) Regulations (2004)

**Conclusion**

Obtaining valid informed consent in paediatric research requires health professionals to have a clear understanding of the complex legal, ethical and professional barriers imposed on them before they embark on gaining truly valid informed consent within this population.

**References**

- Reference guide to consent for examination or treatment, second edition (2009). HMSO; London  
- Mental Capacity Act (2005), HMSO; London  