

ASSENT TO PARTICIPATE IN HEALTHCARE RESEARCH

Helen Fisher, PhD, RN (Child)

King's College London, UK

Correspondence

Helen Fisher, e-mail helen.r.fisher@kcl.ac.uk

EDITORIAL COMMENTARY – SHARON KLING, SECTION EDITOR: ETHICS

Dr Helen Fisher, from King's College London, has contributed an excellent article reviewing child assent in research. Most of what she writes is universally applicable, but the legislative framework in the UK differs slightly from that in South Africa. According to both the Children's Act (No. 38 of 2005) and the South African Bill of Rights, a child is defined as a person younger than 18 years. Section 129 of the Children's Act states that children older than 12 years may consent to medical treatment on themselves and their children provided they are of sufficient maturity to do so. Children older than 12 years may give consent to surgical treatment provided they are of sufficient maturity to do so and assisted by the parent or guardian. In children younger than 12 years, the parents, legal guardian or caregiver may give consent for medical procedures, while parental or guardian consent is required for surgical procedures.

The National Health Act (No. 61 of 2003) deals with refusal of consent to health services. The Act requires healthcare providers (HCPs) to inform patients that they have a right to refuse medical treatment, and it also places an obligation on HCPs to explain what the refusal will mean. If a child over the age of 12 years refuses medical treatment, even after counselling, and is considered mature enough to understand the implications of such refusal, the refusal should be respected. Even if that treatment would be life-saving and the parents consent to the treatment, the courts in South Africa may well be reluctant to overrule the child's wishes, unlike the UK courts. If the child is under the age of 12 years, however, the child may be treated against his/her will with the consent of the parents or guardian if that treatment is regarded as being in the child's best interests.

Research involving children is covered by the National Health Act (No. 61 of 2003) and not the Children's Act. Participation in research by a minor (i.e. a person less than 18 years of age) must be accompanied by parental or guardian consent and child assent. The legislation is currently under review, but therapeutic research is distinguished from non-therapeutic research in minors, and the latter requires Ministerial consent.

REFERENCES

- McQuoid-Mason D. The National Health Act and refusal of consent to health services by children. *S Afr Med J* 2006;96(6):530-532.
McQuoid-Mason D. Provisions for consent by children to medical treatment and surgical operations, and duties to report child and aged persons abuse: 1 April 2010. *S Afr Med J* 2010;100(10):646-648.

ABSTRACT

This article explores the issue of research in children and whether it is possible for a healthcare professional (HCP) who is directly involved in a research project to accurately gauge the child's willingness to be involved in the study. Consent for research participation requires participants to understand complex information and, when children participate in research, formal consent is obtained from their parents or legal guardian. The assent or agreement of the children should also be sought, and the only difference between consent and assent should be that assent is not legally binding. The ethical principles underpinning the requirement of assent are justice (i.e. recognising children's rights) and respect for autonomy. At the same time, the HCP should uphold the principle of beneficence (doing good) by ensuring the best interests of the children who participate in research and simultaneously furthering the interests of those children who will ultimately benefit from the research findings. As children taking part in research will not always derive direct benefit from participation, the principle of non-maleficence requires that harm must not be inflicted on the research participants. The harm principle features strongly in research ethics guidelines and in research ethics committees' assessment of research involving children. The multifaceted nature of acquiring assent makes it difficult to accurately assess the quality of a child's assent to research. This is particularly true in situations where the need to conduct research to benefit the wider community conflicts with the needs of individual participants and, in the case of children, the wishes of the parent. While HCPs can and do accurately determine the assent of children participating in healthcare research with which they are directly involved, they should be alert to potential biases or conflicting interests that may prohibit an impartial appraisal, and, if in doubt as to the validity of the assent of a child on their study, should seek impartial advice.

INTRODUCTION

The use of empirically derived evidence aids the provision of high-quality health care, but with this comes the need to conduct research (Greenhalgh 2006). In the recent past research participants, particularly vulnerable groups such as children, have been subjected to unnecessary and unpleasant procedures in the name of research (Fox 2007). Indeed, the atrocities that occurred in the name of research during the Second

Ethics articles are accredited for ethics CPD points. Please see the questionnaire in this issue (p.112) and log in to the ALLSA website www.allergysa.org and click on My CPD to submit your answers. Kindly send submissions or suggestions for topics to the section editor, Sharon Kling at sk@sun.ac.za

World War were the trigger for international recognition that healthcare research should be underpinned by a set of ethical principles (Diekema 2006). The resultant guidelines, including the Nuremberg Code (the first internationally agreed set of guidelines to be developed), require, among other principles, that voluntary consent for participation be obtained from research participants (World Medical Association [WMA] 2004). Consent for research participation often requires participants to understand complex information and, furthermore, is legally binding. Therefore when children under 16 years of age participate in research, formal consent is obtained from their legal guardian. However the assent or agreement of the children themselves should also be sought (McHale and Tingle 2007), and the only difference between consent and assent should be that assent is not legally binding (Dimond 2005).

The acquisition of assent for participation in healthcare research has legal, ethical and professional connotations (Medical Research Council 2004; Dimond 2005; Johnson and Long 2006). While acquiring assent may initially appear straightforward, in practice the reverse is often true. This article examines the professional, legal and ethical aspects of assent, and synthesises these using a scenario to consider a question that has troubled the author: can a healthcare professional (HCP) who is directly involved in a research study accurately gauge the assent of children on that study?

AN OVERVIEW OF THE PROFESSIONAL, LEGAL AND ETHICAL ISSUES REGARDING THE ASSENT OF CHILDREN TO PARTICIPATE IN HEALTHCARE RESEARCH

HCPs are required by the professional bodies that regulate their practice to treat individuals in their care with respect and dignity (Chartered Society of Physiotherapists 2005; College of Occupational Therapists 2005; General Medical Council 2006; Nursing and Midwifery Council 2008). As children are an especially vulnerable group when they participate in healthcare research, upholding these principles requires particular care (Johnson and Long 2006). One of the means by which the respect and dignity of children involved in research may be upheld is by acquiring their assent to participate in the relevant study (WMA 2004), and failure to obtain this assent constitutes professional misconduct (General Medical Council 2006; Nursing and Midwifery Council 2008). Regardless of their professional codes of conduct HCPs have a personal responsibility to consider the ethical implications of the care they provide (Cameron *et al.* 2001). Although ethics committees must approve healthcare research, such approval does not replace the need for HCPs to be alert to their own practice.

Beauchamp and Childress (2009) suggest using the common morality theory, which incorporates the principles of justice, beneficence, non-maleficence and autonomy to consider the ethical implications of practice. In the following section these principles will be used to discuss the ethical implications of the assent of children to participate in healthcare research.

The notion of **justice** relates to that which is fair and right (Beauchamp and Childress 2009), and the aforementioned abuses of research participants have resulted in the violation of justice during research conduct (Ashcroft 2007). A variety of safeguards have been introduced to minimise the risk of such abuses, including the recommendation that studies are only conducted with the vulnerable, including children, if the same results cannot be obtained with competent adult patients (WMA 2004). However, some question whether such guidance is actually fair or right, as it restricts the paediatric evidence base which is, in itself, unjust (Harris 2005). The healthcare community now generally agrees that, to treat children fairly, paediatric research is necessary. At an individual level justice is promoted by acquiring assent to participation, thus bestowing children with similar rights to those afforded to competent adults when they provide consent for research participation.

Closely linked to justice is the concept of **beneficence**, or doing good (Beauchamp and Childress 2009). This is relevant to children's assent for research in predominantly two ways. HCPs have a duty to do their best by children who participate in research (Fried 2001). Furthermore HCPs conducting the research, and children who assent to research participation uphold the principle of beneficence to those who will ultimately benefit from the research findings (Harris 2005). While it is hoped that research participation would allow both aspects of beneficence to be upheld and that children taking part in research would always derive benefit from participation, this is not necessarily the case. Research, by nature, is characterised by uncertainty. Hence if it were to be held that participation in research must result in good for the participating child, then limitations would be imposed on the type of research that could be conducted. For example placebo-controlled trials could not be undertaken as children in the placebo arm, notwithstanding the possibility of placebo effect and inclusion benefit, are unlikely to derive direct benefit from participation. Yet such designs are important to ensure robust research findings and advance practice (Bowling 2002), so to overcome this problem, the principle of **non-maleficence** may be applied (Beauchamp and Childress 2009). In this context, non-maleficence requires that, even if direct benefit is not derived from research participation, harm must not be inflicted (Ashcroft 2007). This notion is used by ethics committees considering new research

who recognise that, while studies in which participants derive direct benefit are preferable, if this is not possible then research which benefits the wider community is permissible, as long as children are subjected to no more than minimal harm (Medical Research Council 2004).

Children's assent to research relates most closely, perhaps, to the principle of **autonomy**. Autonomy is defined as the right to make choices (Beauchamp and Childress 2009), and respect for autonomy requires both that individuals are assisted in making choices and that the decisions they make are respected (Beauchamp and Childress 2009). Exercising autonomy requires decision-making abilities which, in turn, require the capacity to attain and process relevant information; abilities that are acquired with age and at different rates by different individuals (Griffith 2008), and thus upholding this principle when caring for children may be complicated (Boddington and Gregory 2008). While good ethical practice requires that children under 16 provide assent for research participation (WMA 2004), legal consent must be still obtained from the child's legal guardian, usually the parents. Yet parents and children do not always agree, resulting in situations in which HCPs must balance their professional and ethical need to uphold a child's autonomy with their duty to adhere to the law (Boylan-Kemp 2009).

While there is limited legislation and case law pertaining to children's assent to healthcare research, there is some legal precedent within health care *per se*. Failing to obtain consent for research participation constitutes battery and/or trespass, and may result in the HCP facing criminal and/or civil proceedings in the law courts (Fox 2007). Although consent for non-medicinal research is currently governed only by common law (Medical Research Council 2004), since the Medicines for Human Use (Clinical Trials) Regulations 2004 were introduced, informed consent to research involving medications is a legal requirement. While these regulations require that consent to research participation is obtained from the legal guardian of children aged less than 16 years, the views of the child also have a place in law.

The historically held views that the opinions of children are not important are changing (John 2007), and this change was reflected within health care by The Family Law Reform Act 1969, which states:

'The consent of a minor who has attained the age of sixteen years to any surgical, medical or dental treatment ... shall be as effective as it would be if he were of full age; and where a minor has by virtue of this section given an effective consent to any treatment it shall not be necessary to obtain any

consent for it from his parent or guardian.'

Family Law Reform Act 1969 s8(1)

Differing interpretations of this section of the Act resulted in the lawsuit of Gillick v West Norfolk and Wisbech Area Health Authority.¹ In this landmark case, which is used internationally as a benchmark for children's health care, a mother challenged the right of a health authority to provide advice or treatment to her teenage children without her consent. She took her case to the House of Lords but was finally ruled against. In another similar case² a mother challenged the right of HCPs to provide contraceptive treatment to her children who were under 16 years of age, arguing that such treatment contravened the Human Rights Act (HRA) 1998 which states:

1. *Everyone has the right to respect for his private and family life...*
2. *There shall be no interference by a public authority with the exercise of this right except such as is in accordance with the law and is necessary...for the protection of health or morals, or for the protection of the rights and freedoms of others.*

HRA 1998 (c42) Art 8

However the judge in this case also found against the mother, corroborating the judgement in the Gillick case by Fraser¹ that: *'parental rights...exist for the benefit of the child and they are justified only in so far as they enable the parent to perform his duties towards the child...'* (p. 70).

Arguably these cases have changed how HCPs view consent and assent in paediatric health care, and it is now accepted that children's wishes should be given due consideration (Dimond 2005). Indeed the Medicines for Human Use (Clinical Trials) Regulations 2004 stipulate:

'The explicit wish of a minor who is capable of forming an opinion and assessing the information...to be withdrawn from the clinical trial...is considered by the investigator.'

Clinical Trial Regulations 2004 s1 Pt2 (4)

The Gillick case helped to clarify that children aged less than 16 years can consent to treatment, although no lower age limit was applied and the primary condition requires only that children must be able to understand that for which they are providing consent (Al-Samsam 2008), a notion often referred to as 'Gillick competence' (Delaney 2007). However, assessing the level of a child's understanding is complex (Boddington and Gregory 2008) and determining Gillick competence can prove difficult. This may leave HCPs unsure as to a child's understanding of complicated issues and trying to balance the legal rights of the child and parent.

It is unsurprising that HCPs in such quandaries have turned to the courts for assistance and case law relating to two scenarios exists. The first considers the course of action when a child attains an age at which she may be considered Gillick competent and refuses medical treatment to which her parents consent. While the Gillick ruling permits that children may provide consent despite the wishes of their parents, as yet there have been no successful cases of children dissenting from treatment. In the case of *Re M*,³ for example, a girl of 15 refused a heart transplant which her mother consented to. The judge ruled against the child citing a similar case, *Re W*⁴ in which a 16-year-old was prevented from refusing life-saving treatment for anorexia. In both cases, the ruling judge referred to the Children Act 1989 s 1 (1) that: *'...the child's welfare shall be the court's paramount consideration'*. He acknowledged that, while the child's wishes were important, there were situations in which they may not understand the ramifications of their situation and so may not be considered Gillick competent. In response some have argued that the law only acknowledges competence when the child agrees with those in authority (Fortin 2006).

The second area of case law considers situations where HCPs and parents disagree as to how the best interests of a child are met. The Children Act 1989 exhorts the courts to consider the welfare of the child, and it seems reasonable that this should also apply to HCPs caring for children. When determining the welfare of children, particularly the very young, it is usual to refer to their parents. However, parents may not always be able to determine the child's best interests and the courts may again be asked to rule. In one such case,⁵ the parents of a 7-month-old baby refused to allow her to undergo a bone-marrow transplant but were ruled against. In another,⁶ parents refused a liver transplant for their 18-month-old and had their wishes upheld. These differences illustrate the complexity of the assessment of a child's welfare and while, to date, the courts have not heard a case in which the child has been old enough to offer his/her own opinion, this situation does arise in clinical practice.

It is clear that there are a variety of professional, legal and ethical principles that should be considered in relation to a child's assent to research participation. These principles will now be synthesised using a scenario, described in Box 1, which is similar to situations that HCPs may experience in practice. The synthesis explores how children's assent to research may be approached and considers a question that the author has pondered: Is it possible for an HCP who is directly involved in a research study to accurately gauge the assent of a child on that study?

Box 1

A drug that has been shown to cure hay fever in adults is being trialled in children. This double-blinded placebo-controlled trial involves 6-weekly subcutaneous injections, and children participate for 3 years. In accordance with the requirements of the Ethics Committee that approved the study, the HCP obtained consent for participation from the mother of a 6-year-old girl, Anna, and assent from the child at the start of the trial. Initially Anna was happy and relaxed but after 6 months she appears withdrawn during the appointments, and cries during the injections. The HCP becomes concerned that Anna's behaviour suggests that she does not want to participate in the study and asks whether she wishes to continue in the trial. Anna shrugs her shoulders, but the mother replies that they want to carry on. The HCP again asks Anna whether she wants to keep taking part in the trial, and Anna shakes her head, but her mother states: 'She's just being silly - I'm sure she really wants to carry on.' What should the HCP do?

ACQUIRING A CHILD'S ASSENT TO PARTICIPATE IN RESEARCH; APPLICATION OF THE LEGAL, ETHICAL AND PROFESSIONAL PRINCIPLES TO PRACTICE

In the given scenario the HCP fulfilled her professional, legal and ethical duties at the start of the study by acquiring Anna's assent and her mother's consent for research participation (Dimond 2005; Fox 2007). However, consent/assent is a dynamic process and may be withdrawn (Medical Research Council 2004); hence the HCP should reassess this. While Anna's mother reconfirms her consent, Anna intimates she does not want to continue in the trial and therefore the HCP must consider a variety of legal and ethical principles when deciding upon a course of action.

Anna has stated she does not wish to continue in the trial, and the Clinical Trials Regulations 2004 require that an active request to withdraw from research by a child who is capable of assessing the information and forming an opinion should be upheld. Although this wording is somewhat subjective, it relates closely to the notion of Gillick competence described earlier, and the HCP should therefore consider whether Anna understands the information required to make such a decision.

The knowledge and skills required to be considered Gillick competent develop throughout childhood (Griffith 2008) and may not be held by a child of 6, particularly when considering the complicated knowledge that is required to understand a research study. Ondrusek *et al.* (1998) found children under the age of 10 have limited ability to understand most aspects of research and usually defer to their parents. Conversely a study by Wendler

(2006) showed that, while children may not comprehend the intricacies of research, they do understand specific procedures, and make autonomous decisions regarding particular aspects of the research. Hence while Anna is unlikely to understand all facets of the research study, she does understand certain aspects: that the injections hurt and will continue for a long time, for example, and this understanding may be underpinning her desire to cease trial participation.

Anna's mother has stated that she wishes her to continue to participate and while there is no legal precedent covering a situation in which a child wishes to dissent from research that her parent consents to, within case law relating to health care, children have not been able to dissent from treatment if their parents consent.^{3,4} Thus as Anna's legal guardian her mother may consider that she has the right to overrule her decision. While it may be easier for an HCP to accept this decision rather than challenge the mother, the case law described earlier^{1,2,6} highlights that this right must reflect the will of the child and uphold her best interests. Yet parents, however well-meaning, have not always been found to fulfil these criteria. Rossi et al. (2003) found that, in certain instances, parents will actively ignore the clearly articulated wishes of their children regarding their research participation. Furthermore the courts have, on occasion, considered that a parent's decision does not uphold the best interests of the child.⁶

To treat Anna with the respect that is required by law and their professional and ethical codes of conduct, the HCP must independently consider whether Anna's participation in the trial is in her best interests, a concept that relates closely to the notion of beneficence. Yet this principle has two applications within this context. The HCP must act beneficently towards Anna who is in her care, and furthermore by conducting and participating in this trial, the HCP and Anna are doing good for the wider community. Some have argued that, to be moral agents, individuals have a duty to participate in research (Harris 2005), and that considering children devoid of such morals, because of age and a lack of understanding of the wider issues involved in research, does not uphold their best interests (Harris and Holm 2003). It could be suggested that Anna is too young to fully understand the wider implications of her participation and so her wishes should not be upheld. Taking such a viewpoint is contentious, although if the first aspect of beneficence, that Anna will derive benefit from participation, could also be said to apply, the HCP might defend such a decision. However, the study is a double-blind placebo-controlled trial and it is not known whether Anna is receiving the active treatment. Furthermore, even if Anna is receiving the active drug, research, by nature, is experimental

and so there is no guarantee that the medication will be beneficial.

The HCP therefore faces a dilemma: to provide evidence-based care it is necessary to conduct research and the HCP's involvement helps to uphold the principle of justice, in that she is contributing to the development of a potential new cure for children using a drug that has been shown to be effective in adults. However, the HCP also has a duty of care to Anna and is accountable for this care to the relevant professional body (Dimond 2005) and through the courts of law (Hodgson 2007). The notion of non-maleficence may be useful in overcoming this dilemma. This key ethical principle, to avoid doing harm (Beauchamp and Childress 2009), is reflected in professional codes of conduct, the case law detailed previously,¹⁻⁶ and legislation such as the Children Act 1989 which asserts that the welfare of the child should be at the heart of all decisions. While it could be argued that the duty of an ethics committee is to ensure that research does not violate this principle (John 2007), these committees may only judge whether a clinical trial is likely to cause harm in the majority of the population. The HCP conducting the research must consider Anna's individual circumstances and, despite the wishes of Anna's mother and the potential benefits to society of her continued participation, if the HCP considers that Anna's participation in the trial is likely to cause her harm, this principle should take priority and she should withdraw her from the study regardless of her parents' wishes.

CONCLUSION

This article aims to explore the assent of children to participate in research and to question whether it is possible for a HCP who is directly involved in a research project to accurately gauge the assent of a child on that study. In considering the direct and lateral application of a variety of legal, ethical and professional principles of a child's assent to research it is apparent that there are times when these principles oppose each other. Although it was not possible to explore the opposite scenario, when a child wishes to participate in a research study that her parents do not consent to, it is clear that the multifaceted nature of acquiring assent makes it difficult to accurately assess the quality of a child's assent to research. This is particularly true in situations where the need to conduct research to benefit the wider community conflicts with the needs of individual participants (Fox 2007) and, in the case of children, the wishes of the parent. The article highlights that, while attempting to uphold the best interests of the children participating in the research, it is easy to believe that, providing a study has ethical clearance and the child's parent has provided consent, then one's ethical, legal and professional obligations have been met. The ease with which a child's wishes may be overlooked, particularly when the child has not

reached an age at which she is likely to understand the intricacies of research and so may not be considered Gillick competent, is also evident. While HCPs can and do accurately determine the assent of children participating in healthcare research with which they are directly involved, they should be alert to potential biases or conflicting interests that may prohibit an impartial appraisal, and, if in doubt as to the validity of the assent of a child on their trial, should seek impartial advice.

1. *Gillick v West Norfolk and Wisbech Area Health Authority* [1986] AC 112
2. *Regina (Axon) v Secretary of State for Health (Family Planning Association intervening)* [2006] EWHC 37 (Admin)
3. *Re M (Child: Refusal of Medical Treatment)* [1999] 52 BMLR 124
4. *Re W (A Minor) (Medical Treatment: Court's Jurisdiction)* [1992] 3 WLR 758
5. *NHS Trust v A* [2007] EWHC 1696
6. *Re T (A Minor) (Wardship: Medical Treatment)* [1997] 1 WLR 242

ACKNOWLEDGEMENTS

HF was supported by the National Institute for Health Research (NIHR) Biomedical Research Centre at Guy's and St Thomas's NHS Foundation Trust and King's College London. The views expressed are those of the author and not necessarily those of the NHS, the NIHR or the Department of Health.

REFERENCES

Al-Samsam, R. (2008). "Legal aspects of consent to treatment in children." *Paediatrics and Child Health* 18(10): 469-473.

Ashcroft, R. (2007). *An Ethical Perspective: Nursing Research*. Nursing Law and Ethics. J. Tingle and Cribb, A. Oxford, Blackwell Publishing.

Beauchamp, T. L. and Childress, J. F. (2009). *Principles of Biomedical Ethics*. Oxford, Oxford University Press.

Boddington, P. and Gregory, M. (2008). "Adolescent carrier testing in practice: the impact of legal rulings and problems with "Gillick competence". *Journal of Genetic Counselling* 17(6): 509-21.

Bowling, A. (2002). *Research methods in health*. Maidenhead, Open University Press.

Boylan-Kemp, J. (2009). "The legal system. Part 2: it's not just for lawyers." *British Journal of Nursing* 18(3): 178-80.

Cameron, M. E., Schaffer, M., et al. (2001). "Nursing students' experience of ethical problems and use of ethical decision-making models." *Nursing Ethics* 8(5): 432-47.

Chartered Society of Physiotherapists. (2005). "Rules of Professional Conduct." 02/06/09, from http://www.csp.org.uk/director/members_practice/rulesandstandards.cfm#code.

Children Act (1989). Ch 41. London, Her Majesty's Stationery Office.

College of Occupational Therapists. (2005). "Code of Ethics and Professional Conduct." 02/06/09, from www.cot.org.uk.

Cribb, A. (2007). *The Ethical Dimension: Nursing Practice, Nursing Philosophy and Nursing Ethics*. Nursing Law and Ethics. J. Tingle and Cribb, A. Oxford, Blackwell Publishing.

Delaney, L. (2007). *The Critically Ill Patient*. Nursing Law and Ethics. J. Tingle and Cribb, A. Oxford, Blackwell Publishing.

Diekema, D. S. (2006). "Conducting ethical research in pediatrics: a brief historical overview and review of pediatric regulations." *Journal of Pediatrics* 149(1 Suppl): S3-11.

Dimond, B. (2005). *Legal Aspects of Nursing*. London, Pearson Longman.

Family Law Reform Act. <http://www.legislation.gov.uk/ukpga/1969/46>

Fortin, J. (2006). "Children's Rights - Substance or Spin " *Family Law* 757 36: 759-766.

Fox, M. (2007). *Clinical Research and Patients*. Nursing Law and Ethics. J. Tingle and Cribb, A. Oxford, Blackwell Publishing.

Fried, E. (2001). "The therapeutic misconception, beneficence, and respect." *Accountability in Research* 8(4): 331-48.

General Medical Council. (2006). "Good Medical Practice (online)." 21/05/09, from www.gmc-uk.org/guidance/good_medical_practice/GMC_GMP.pdf.

Greenhalgh, T. (2006). *How to read a paper: the basics of evidence based medicine*. London, Blackwell Publishing.

Griffith, R. (2008). "Assessing decision making capacity: children under 16." *Nurse Prescribing* 6(6): 266-269.

Harris, J. (2005). "Scientific research is a moral duty." *Journal of Medical Ethics* 31(4): 242-8.

Harris, J. and Holm, S. (2003). "Should we presume moral turpitude in our children?--small children and consent to medical research." *Theoretical Medicine and Bioethics* 24(2): 121-9.

Hodgson, J. (2007). *The Legal Dimension: Legal System and Method*. Nursing Law and Ethics. J. Tingle and Cribb, A. Oxford, Blackwell Publishing.

Howard, D. E., Lothen-Kline, C., et al. (2004). "Using the case-study methodology to teach ethics to public health students." *Health Promotion Practice* 5(2): 151-9.

Human Rights Act:
http://www.opsi.gov.uk/ACTS/acts1998/ukpga_19980042_en_3#sch1-pt2

John, J. E. (2007). "The child's right to participate in research: myth or misconception?" *British Journal of Nursing* 16(3): 157-60.

Johnson, M. and Long, T. (2006). *Research Ethics. The Research Process in Nursing*. K. Gerrish and Lacey, A. Oxford, Blackwell Publishing.

McHale, J. and Tingle, J. (2007). *The Law and Nursing*. Philadelphia, Butterworth Heinmann Elsevier.

Medical Research Council (2004). *MRC Ethics Guide; Medical Research Involving Children*. London, MRC.

Medicines Act:
<http://www.uk-legislation.hmso.gov.uk/si/si2004/20041031.htm>

NMC (2008). *The Code: Standards of conduct performance and ethics for nurses and midwives*. London, Nursing and Midwifery Council.

Nursing and Midwifery Council (2008). *Duty of Care*. London, NMC.

Ondrusek, N., Abramovitch, R., et al. (1998). "Empirical examination of the ability of children to consent to clinical research." *Journal of Medical Ethics* 24(3): 158-65.

Rauprich, O. (2008). "Common morality: comment on Beauchamp and Childress." *Theoretical Medicine & Bioethics* 29(1): 43-71.

Rossi, W. C., Reynolds, W., et al. (2003). "Child assent and parental permission in pediatric research." *Theoretical Medicine and Bioethics* 24(2): 131-48.

Timmons, J. (2006). "Using case reports to aid reflective practice in wound care." *British Journal of Community Nursing* 11(3): S14, S16, S18, S20.

Wendler, D. S. (2006). "Assent in paediatric research: theoretical and practical considerations." *Journal of Medical Ethics* 32(4): 229-34.

World Medical Association (2004). *Declaration of Helsinki*, World Medical Association.