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**Children and Clinical Research: Ethical Issues
Response to Consultation
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1. What do you consider to be the main obstacles to recruiting children to research? How might these be overcome?

Parental and professional uncertainty about the legality of involving a child in clinical research will affect recruitment of children. There is likely to be uncertainty surrounding the circumstances, if at all, in which children can themselves consent to procedures which may not be immediately and directly to their benefit and also whether, or in what circumstances, a parent may give a valid consent to the involvement of their child in research. Professionals, who themselves will have different attitudes towards the involvement of children in decisions about their medical treatment and clinical research, will have to work with parents who will have different attitudes to the involvement of their child in decision-making and with children who will have different wishes with respect to levels of participation.¹ Given these variables, alongside the different types of research – on existing data, further tests on existing samples, requiring specific additional interventions, with some anticipated therapeutic effect etc – even a clear statement of the law, if that were possible, would not be easy to apply. As clear as possible a statement about what is legally established alongside guidance which offers a route through the legal and ethical issues which need to be addressed would, I think, be of most use in overcoming the obstacle of uncertainty about legality.

2. Who should make the final decision as to whether a child participates, or continues to participate, in clinical research when parent and child disagree? What responsibilities do health professionals or researchers have in such cases? (You may wish to distinguish between children at different stages of development and/or the different ways in which disagreement may arise or be expressed.)

The concept 'child' embraces children from the point of birth until the age of majority is reached at 18. The concept thus embraces individuals who are very different in terms of abilities to understand, to communicate, experience of life or of the medical condition for which treatment is provided or in respect of which research may be proposed. Like all people, children also differ in terms of their willingness to undergo medical interventions, their ability to withstand pain or discomfort, and their concern to help others. All of these things will also weigh differently at different points in their lives or simply at different times of the week or day. It is therefore extremely important that children are respected, and treated, as individuals.

In my opinion, that means that if the child, after being provided with age-appropriate information, advice and discussion does not want to participate, that decision must

¹ Examined in the context of treatment decisions by Priscilla Alderson, *Children's Consent to Surgery*, Open University Press: Buckingham, 1993; Priscilla Alderson, Joanna Hawthorn and Margaret Killen, 'The Participation Rights of Premature Babies' (2005) 13 *The International Journal of Children's Rights* 31-50.

be respected. But a decision can only be reached after the provision of age-appropriate, child-focused, information, discussion and advice and if the child does not wish to be involved but wants to entrust the decision to their parents, they are entitled to do so. Parents and professionals must also be responsive to the wishes of younger children who may not be able to articulate their refusal but indicate their reluctance through their behaviour. At the same time, what is required in relation to securing the involvement of children in research must accord with ordinary processes of making decisions on behalf of, and with, children. As with other parenting decisions, and as has been accepted in the medical treatment of adults, persuasion is an acceptable part of the process of arriving at decisions:

'A special problem may arise if at the time the decision is made the patient has been subjected to the influence of some third party. This is by no means to say that the patient is not entitled to receive and indeed invite advice and assistance from others in reaching a decision, particularly from members of the family. It is wholly acceptable that the patient should have been persuaded by others of the merits of such a decision and have decided accordingly. It matters not how strong the persuasion was, so long as it did not overbear the independence of the patient's decision. The real question in each case is 'Does the patient really mean what he says or is he merely saying it for a quiet life, to satisfy someone else or because the advice and persuasion to which he has been subjected is such that he can no longer think and decide for himself?'²

Good practice will be child-focused and seek to identify the extent to which the child wishes to be informed and participate in decisions or to entrust those to their parents.

In this context, I think it important to see the child as an individual situated in relationships of care. Decisions are rarely reached in isolation but through a process of communication, including reading the reassuring body language of others that indicates that they believe that you are making the right decision! I think it is important to appreciate the child in the context of those relationships, not only within a relationship of interdependency with their parents but within the professional relationships which will be important in relation to the child's health. Parents have responsibilities to their child but so too do treating physicians, nurses, researchers etc which arise from their professional relationship with the child.³ Protection of the child and his or her interests is best secured by ensuring the views of all involved in the care of the child are respected in arriving at a decision. As the RCPCH guidance states:

'As assessment of benefit and harm is complex, children are best protected if projects are reviewed at many levels, by researchers, funding and scientific bodies, research ethics committees, the research assistants and nurses working with ... the

² *Re T* [1992] 4 All ER 649, Lord Donaldson.

³ Jo Bridgeman, *Parental Responsibility, Young Children and Healthcare Law*, 2007.

children and their parents. Everyone concerned (except young children) has some responsibility.⁴

Consideration of the parental and professional responsibilities to the child in this way places the child at the centre of the decision-making process. Parents, practitioners, researchers, nurses will all have different experiences and different expertise in the needs of the individual child, different knowledge and perspectives and if all are recognised and respected then the interests of the child can more fully be understood and respected. Therefore, I would suggest that guidelines offer a route to arriving at a decision about the participation of children in clinical research which requires an assessment of the child's views, parental views and their views together as a family unit and which stresses the importance of respect for the contributions and roles of the entire professional team. If a child refuses then that refusal must be respected but at the same time the participation of the child must be a decision that all involved in his or her care are comfortable with.

3. How useful is the concept of assent? Is it helpful to distinguish between consent and assent for young people?

The concept of consent itself is not entirely unproblematic in this context. It is, however, very much the guiding principle of modern medical treatment and it would be inconsistent with an increasing perception of children as individuals, right-holders and participants if consent from parent or child or children's involvement in the decision were not to be required.

The origins of consent are in the requirement that consent be given to the touching involved in medical treatment in order to justify what would otherwise amount to a criminal and civil battery. Based upon ethical requirements of respect for individual autonomy, it has been employed as the principle for the governance of decisions such as the requirement for ongoing consent to the use of donated human material under the Human Fertilisation and Embryology Act 1990 or the use of human material under the Human Tissue Act 2004.

The Family Law Reform Act 1967, s 8(1) states that it is presumed that a child aged 16 or 17 has the capacity to give consent to 'surgical, medical or dental treatment' which is defined in s 8(2) as including 'any procedure undertaken for the purposes of diagnosis, and this section applies to any procedure (including, in particular, the administration of an anaesthetic) which is ancillary to any treatment as it applies to that treatment'. Section one is limited to therapeutic treatment but must be read with s 8(3) which states that 'Nothing in this section shall be construed as making ineffective any consent which would have been effective if this section had not been enacted.' This preserves the common law as it was when the section was enacted. So that, if the common law allowed children or their parents to consent to clinical research, that is not affected by the enactment of a provision in relation to consent to therapeutic treatment.

⁴ RCPCH, *Guidelines for the ethical conduct of medical research involving children*, 2000 Archives of Disease in Childhood, 177-182, 179.

The leading case on children's consent to treatment is *Gillick v West Norfolk and Wisbech AHA* [1986] AC 112, itself concerned with the circumstances in which a child under the age of 16 could give a valid consent to contraceptive treatment but applied to medical treatment and to children's involvement in decision-making more generally. Briefly stated, the majority of the House of Lords held that, if a child under the age of 16 could not be persuaded to inform or involve their parent, he or she could give a valid consent as long as he or she had 'sufficient understanding and intelligence to enable him or her to understand fully what is proposed'. In other words, the professional should attempt to secure the involvement of the parent. Where the child refuses to agree to parental involvement, the capacity of the child to decide depends upon the circumstances: the example given in the case was having a broken arm set, which would differ from life-saving treatment or voluntary involvement in medical research which is not of benefit to the individual. There is no direct authority in which a court has applied the principles from *Gillick* to research. However, there is authority for the application of the principles from *Gillick* beyond medical treatment, to decisions relating to children's upbringing, and confirmation of the general principles in the era of parental responsibilities and the Human Rights Act 1998.⁵ It is entirely understandable, however, that both professionals and parents would be uncertain about how a court would apply those principles to children's consent to involvement in research.

Further, *Gillick* does make it clear that health professionals should seek to secure the involvement of parents in decisions about medical treatment which would be equally applicable to decisions about involvement in research. However, any decision made by parents, or strictly speaking, those with parental responsibility, must be on the basis of the best interests of the child. See further below.

Alternatives have been suggested to the concept of consent where its application is not entirely appropriate. Assent is one alternative, although it tends to be employed as a weaker concept than consent. The RCPCH refer to assent as acquiescence, although they also use term agreement.⁶ Mason and Laurie also suggest assent/dissent in the context of use of human material after death, with assent/dissent being expressed by relatives.⁷ In a similar context, the review of organ retention in Scotland suggested that consent to the retention and use of organs from a relative was not the appropriate term as that depended upon it being in the best interests of the individual and suggested authorisation.⁸ But the use of that concept under the Human Tissue Act 1961 allowed the understanding to flourish that consent was not required and was the context in which the organ retention scandal occurred.

Although the use of the concept of consent is not without problems, I would favour its employment given the dominance of the concept within the law regulating modern medicine. The potential misreading of a decision to employ an alternative –

⁵ *R (on the application of Axon) v Secretary of State for Health & Another* [2006] EWHC 37.

⁶ RCPCH, *Guidelines for the ethical conduct of medical research involving children*, 2000 Archives of Disease in Childhood, 177-182.

⁷ JK Mason and GT Laurie, 'Consent or Property?' (2001) 64 MLR 710.

⁸ Scottish Executive, *Final Report of the Independent Review on the Retention of Organs at Post Mortem* (2001).

for example, the impression that informed permission is not an essential requirement to good practice in this area - leads me to the conclusion that this is not the context in which to employ an alternative concept. It should also be noted that in addition to questions of consent, which in law requires a broad understanding of the nature of the treatment,⁹ guidance will need to address issues surrounding the provision of information about the proposed research communicated in appropriate language and form for the participants and their parents.

4. A 'shared' or 'collaborative' decision-making model is often advocated for decisions about a child's research involvement, involving the child, relevant family members and professionals. Is this a helpful approach? How might any problems arising in this model be overcome?

I think that decisions about the involvement children in research have to be collaborative, in the way identified in 2 above, although it should be emphasised once more that the nature of the collaboration changes depending upon the circumstances. However, 'collaborative' decision-making should not be employed as a shorthand for a careful decision-making process which needs to be detailed. Furthermore, I think an emphasis upon a child-focused process not only secures a collaborative process but should be emphasised in this context.

5. Parents' views on whether (and how) children should be involved in decisions vary enormously both within and beyond the UK. How should the law and professionals take account of such different parenting approaches?

The law does place the primary responsibility for the upbringing of children with their parents and the state does not intervene into the private realm of the family unless the child is at serious risk of significant harm. However, decisions about the involvement of children in clinical research occur in the public realm where children should be respected as individuals and involve interactions with other adults. Parental views should not justify other adults treating a child with any less respect than is extended to all other children. Which, in my opinion, means that if a parent will not permit the child to be involved in a decision which affects his or her bodily, or personal, integrity such as the voluntary participation of the child in research then the child must not be involved. This would not of course affect decisions in relation to therapeutic interventions which are in the best interests of the child. If the parent wants the child to be involved in the research then the child must be able to participate in that decision. If the child wants to entrust the matter to their parents they should be entitled to do so.

6. Rewards (such as vouchers) for children participating in research may be welcomed as an appropriate way of saying 'thank you', or criticised as a form of undue incentive (to either child or parent). What forms of compensation/reward/expression of gratitude for research involvement do you think acceptable, and why?

⁹ *Chatterton v Gerson* [1981] 1 All ER 257.

Clinical research requires participants and thus the contribution of participants should be rewarded, as well as expenses incurred compensated. Which makes it important to distinguish between the reward/recognition of the child's involvement and the financial costs incurred by the parent in travel, parking fees etc. Children themselves will have ideas as to what forms of reward are appropriate, which will no doubt vary depending upon the type of clinical research. In addition to expenses and rewards for participation, as a matter of good practice children and their parents should be asked if they wish to be informed of the findings of the study: which should then be provided in an accessible form.

7. How helpful is the notion of the best interests of the child participant? How would you define 'best interests'?

The concept of the best interests of the child is of wide application in judicial determination of issues concerning children's upbringing. It has the benefit of being easily and widely understood (Jonathan Herring, 'Farewell Welfare?' (2005) 27 JSWFL 159-171). It also offers flexibility in that there can be a number of legitimate views as to what is in the best interests of a child. In the healthcare context it has been emphasised that best interests should be given a wide definition including medical, social and other factors.¹⁰ In *Simms*, the court was asked to determine whether treatment, which was new and not tested on humans, was in the best interests of two teenagers 'changed from normal, energetic teenagers into helpless invalids lying in bed and with a severely limited enjoyment of life' by probable variant Creutzfeldt-Jakob disease. Butler-Sloss LJ stated the task of the court as being to assess:

'in the widest possible way to include the medical and non-medical benefits and disadvantages, the broader welfare issues of the two patients, their abilities, their future with or without treatment, the views of their families, and the impact of refusal of the applications'.¹¹

And recently in the context of a decision about children's upbringing Munby LJ stated that best interests, synonymous with 'wellbeing' and 'welfare', 'extends to and embraces everything that relates to the child's development as a human being and to the child's present and future life as a human being'.¹² Determination of a child's best interests, his Lordship said, involves consideration of a 'wide range of ethical, social, moral, religious, cultural, emotional and welfare considerations',¹³ including cultivation of virtues and achievement of worthwhile goals,¹⁴ the 'child's familial, educational and social environment, and his or her social, cultural, ethnic, and religious community' [30] and the child's network of relationships.¹⁵ Even so, is seeking to apply the principle to research stretching it too far, as may well be argued

¹⁰ *Re Wyatt (a child) (medical treatment: continuation of order)* [2005] EWCA Civ 1181, [87].

¹¹ *Donald Simms and Jonathan Simms v An NHS Trust and Secretary of State for Health; PA and JA v An NHS Trust and Secretary of State for Health* [2002] EWHC 2734, at para. 60.

¹² *Re G (Children)* [2012] EWCA Civ 1233, [26].

¹³ *Re G (Children)* [2012] EWCA Civ 1233, [27].

¹⁴ *Re G (Children)* [2012] EWCA Civ 1233, [29].

¹⁵ *Re G (Children)* [2012] EWCA Civ 1233, [30].

occurred in the application of the concept to permit the 'donation' of bone marrow from a woman with learning difficulties in *Re Y*?¹⁶

Hazel Biggs has argued that, given the uncertainty about whether any particular child will benefit, 'the legitimacy of parental consent to the child's participation in the research [is] highly questionable'.¹⁷ There is no case law on parental consent to research. One view is that it can be justified on the same grounds as authorisation of a blood test to determine paternity in *S v S*, that is, permissible 'unless satisfied that it would be against the child's interests'.¹⁸ The Department of Health, for example, says:

'It may also be compatible with the welfare principle for a person with parental responsibility to give consent to a research intervention that is not strictly in the best interests of the child, but is not against the interests of the child either.'¹⁹

That is not good enough, even if limited to interventions which 'involve only minimal burden to the child.'²⁰

Richard Huxtable has argued that *S v S* and *Re Y* indicate an awareness of the realities of family and community in determinations of best interests which, as noted above, is a wider concept than medical best interests.²¹ In the context of decisions about children's immunisations, Richard Huxtable suggested that 'exclusive reliance on this standard may not even be appropriate in a case concerning public, and not merely individual, health'.²² This could be argued in relation to research which is not exclusively in the interests of the individual.

It may be that we have got so used to thinking in terms of the interests, welfare, benefit of the child and that the concept is developing in the more relational, altruistic sense that Jonathan Herring has argued for²³ and Munby LJ referred to, above. It may, however, be that the best interests of the child is not the most appropriate basis upon which to justify the decision to involve a child in research or to secure consent from child or parent. Whilst it is necessary to identify the circumstances in which involvement can be justified in an individual case, there is no reason to be limited by existing concepts which are not directly applicable. It might be that a model which can be applied is provided by the welfare checklist in the Children Act 1989. This is a non-exhaustive set of factors and it may be that a

¹⁶ *Re Y (Mental Patient: Bone Marrow Donation)* [1996] 2 FLR 787.

¹⁷ Hazel Biggs, 'Children and health-care research: best treatment, best interests and best practice' (2011) 6 *15-19*, 18.

¹⁸ *S v S* [1972] AC 24, 45.

¹⁹ Department of Health, *Reference Guide to Consent for Examination and Treatment*, 2009, Crown copyright, 38.

²⁰ Department of Health, *Reference Guide to Consent for Examination and Treatment*, 2009, Crown copyright, 38.

²¹ Richard Huxtable, '*Re C (A Child) (Immunisation: Parental Rights)* [2003] EWCA Civ 1148' (2004) 26 *JSWFL* 69-77.

²² Richard Huxtable, '*Re C (A Child) (Immunisation: Parental Rights)* [2003] EWCA Civ 1148' (2004) 26 *JSWFL* 69-77, 71.

²³ Jonathan Herring 'The Human Rights Act and the Welfare Principle in Family Law – Conflicting or Complementary?' (1999) 11 *Child & Family Law Quarterly* 223.

similar set of factors could be drawn up to guide decision-making about children's involvement in research and as the basis upon which consent can be provided from either child or parent.

Children Act 1989, s. 1(3)

- (a) the ascertainable wishes and feelings of the child concerned (considered in the light of his age and understanding);
- (b) his physical, emotional and educational needs;
- (c) the likely effect on him of any change in his circumstances;
- (d) his age, sex, background and any characteristics of his which the court considers relevant;
- (e) any harm which he has suffered or is at risk of suffering;
- (f) how capable each of his parents, and any other person in relation to whom the court considers the question to be relevant, is of meeting his needs;
- (g) the range of powers available to the court under this Act in the proceedings in question

Alternatively, it is possible to identify set of principles by which to determine and justify children's involvement in research. For example, EC Directive 2001 on clinical trials,²⁴ requires research to be governed by four key principles and a similar approach could be developed to govern decisions about children's involvement in clinical research.

8. How can the rights and interests of individual children (potential participants in research) be balanced against the rights and interests of all children (potential beneficiaries of the knowledge gained by the research)?

Given current challenges to our human rights as contained in the Human Rights Act 1998 and ECHR, given that the view of children as individuals entitled to respect is not universally accepted, guidance on this issue should make it very clear that children are human beings whose rights should be respected and protected. Furthermore, that obligations imposed upon the state by human rights instruments – United Nations Convention on the Rights of the Child; European Convention on Human Rights and Fundamental Freedoms; Human Rights Act 1998 – must be complied with. But asking a child to participate in research is to ask a child to be altruistic. Children may choose to participate in the interests of other, including future, children. But I think that should be recognised as an act of care for others and not be considered as something to which others, whether it is treating doctors, other children with similar conditions or future beneficiaries of the research, are entitled to.

²⁴ European Parliament and the Council of Europe Directive 2001/20/EC of 4 April 2001 relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use implemented in Human Use (Clinical Trials) Regulations 2004, subsequently amended. Schedule one of which sets out the conditions and principles of clinical good practice and for the protection of clinical trial subjects, including in Part 4, those specifically relevant to children.

9. Are there any situations in which you think it would be acceptable for a child to be invited to participate in clinical research when there will not be *any* personal benefit to them? If so, please give examples.

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10. Are there any circumstances where it would be right for a research ethics committee to approve research involving risks they would usually regard as too high, if parents and young people had clearly expressed their willingness to accept these?

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11. Do you think the current regulations strike the right balance between promoting clinical research in children, protecting child participants, and involving children in decisions about their own participation? What (if anything) would you like to change?

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12. With limited resources, how would you decide which childhood conditions should be the priorities for research? Who should be involved in making these decisions?

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13. What responsibilities do funders, researchers and stakeholder groups have to encourage the coordination of children's clinical research?

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14. What responsibilities do researchers have towards child participants and parents when the study is over?

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Please highlight any relevant areas you think we have omitted, or any other views you would like to express about the ethical issues arising in clinical research involving children.

The language used in the guidance is very important. For example, it is not uncommon for children, particularly younger children, to be spoken of as particularly vulnerable in relation to participation in research. Portrayal of children as vulnerable presents the danger of children being presented as other to adults, as 'non-adult' or 'not-yet adult, as lacking the qualities that the adult is considered to possess. Often professional guidance is written for adults with a section which considers the issues in application to children. Child-centred guidance which does not seek to draw comparisons with adults needs to be attentive to the specific vulnerabilities of children and not rely upon constructions of children's vulnerabilities.