Chapter 6

Taking part in research: professionals' responsibilities

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Chapter 6 overview

Responsibilities of researchers

Researchers who invite children and young people to take part in research should:

- treat children and young people as individuals of value in themselves;
- support parents in their attempts to help their children develop in their ability to make autonomous choices;
- act in accordance with children's and young people's immediate and longer term welfare; and
- act in accordance with the professional virtues outlined in Chapter 5: trustworthiness, openness and courage.

Communication

- Professionals responsible for recruiting children and young people to take part in a study must ensure that the invitation (which the REC has deemed a 'fair offer') is extended in a fair manner. Good communication is essential, both in terms of the clarity and accessibility of the information materials provided (whatever the format), and, critically, in terms of the quality of face-to-face communication.

Making decisions: consent and assent

- Where children and young people have sufficient maturity and understanding to make their own decision about research participation, but are not yet treated as fully 'adult' by the law of their country (Case Three), consent should, wherever possible, be sought from both the children or young people concerned, and from their parents.
- Where children and young people are not yet able to make their own decision (Case Two), there is an ethical imperative to involve them in the decision as much as possible. Requirements to seek assent from children invited to take part in research should be understood as requirements to involve children, as much as they wish and are able, in decisions about participation. In devising assent processes, researchers should be concerned primarily with how best to develop trusting relationships with children and communicate information appropriately throughout the research.

Responding to disagreement

- In most cases, if there are disagreements within families about participation, then it is best if this particular child or young person does not take part. Professionals should respect parents' views with respect to their child's participation in decisions about research, but parental preferences cannot cancel out professionals' own responsibilities. While parental consent renders their child's participation in research legally permissible, it does *not* make it mandatory. This leaves an important area for professional discretion and judgment.

Responsibilities in the absence of parents

- Children and young people who lack parental support should not automatically be excluded from the opportunity to participate in research. In such cases, the role of the REC in scrutinising the risks, burdens and benefits of research will take on added importance, as will local stakeholder involvement. Where it can be foreseen at the planning stage that children without parental support are likely to be eligible to participate, additional protections, such as an independent advocate able to witness the recruitment process, could be considered.

Introduction

6.1 In Chapter 5, we considered how our characterisation of children and young people, and the responsibilities of their parents towards them, might help us to understand the role of professionals responsible for those aspects of clinical research that are often invisible to research participants and the general public: the prioritisation, design and review of research studies. We now turn to consider those professional responsibilities in connection with professionals' *direct* interactions with children, young people and their families: those that arise when children and young people are invited to take part in research, and indeed those that arise throughout and after the study itself. We use the terms 'researchers' or 'professionals' very broadly, to include all those staff members who interact directly with children and young people at any point during the research, while recognising that the specific responsibilities may differ depending on a professional's role. Looking at the issue from the perspective of children, young people and their families, the question is therefore what they should feel able to expect both of an ethical recruitment process and of ongoing participation in an ethically-conducted study. In other words, what might a 'fair offer' to participate in worthwhile research look like to the children, young people and families to whom the 'offer' is made?

6.2 We begin with the premise that the ethical considerations identified in Chapter 4 which underpin how parents make decisions with or on behalf of their children may also apply to researchers who have direct interactions with children and young people in the context of clinical research. Clearly researchers do not take on a parental role, but at particular points in time they occupy a professional role with respect to particular children or young people which, as an adult-child relationship, brings with it associated responsibilities.[573] Together with these direct responsibilities to children and young people, we suggest that researchers also owe responsibilities to parents, reflecting the fact that parental responsibilities to their minor children continue to run in tandem with temporary responsibilities borne by other adults. The manner in which these two sets of responsibilities interact will shift as children mature, just as the nature of parental responsibilities evolves through the paradigm cases (see paragraph 4.35). Finally, as professionals, researchers also have obligations to maintain particular standards of professional conduct.

6.3 Researchers' responsibilities might therefore be characterised as obligations to:

- treat children and young people as individuals of value in themselves (a direct obligation to children and young people, that arises independently of family dynamics).
- support parents in their attempts to help their children develop in their ability to make autonomous choices (hence an indirect obligation to children and young people, exercised through obligations to their parents);
- act in accordance with children's and young people's immediate and longer term welfare (for example minimising any distress arising in connection with research involvement, only proceeding if confident that participation in research is compatible

[573] See, for example, the argument that, in the context of a child's healthcare, paediatricians and parents are 'co-fiduciaries' of children who are patients: McCullough LB (2009) Contributions of ethical theory to pediatric ethics pediatricians and parents as co-fiduciaries of pediatric patients, in *Pediatric Bioethics*, Miller G (Editor) (New York: Cambridge University Press). Similar responsibilities arise for other adults who have a time-limited, but nevertheless responsible, relationship with children, such as doctors, teachers, and those providing childcare.

with their interests, and being sensitive to the importance of maintaining family harmony with respect to research participation); and
- act in accordance with the professional virtues outlined in Chapter 5: trustworthiness, openness and courage.

We discuss further below how these responsibilities might be exercised in practice, first with respect to researchers' direct obligations to children and young people, and second in the context of researchers' interactions with parents and their children together. We then look at the particular challenges that may arise where children and young people do not have parents to support them, whether on a temporary or permanent basis.

Responsibilities to children and young people

> *"I think that they really shouldn't think of all the participants as a whole group of people but more as individuals because everyone has different lives and it could affect them in different ways."*[574]

Involvement in research decisions

6.4 We start with the first requirement: that of treating children and young people as distinct individuals, of value in themselves, and the implication this has for the ways researchers engage with them when considering research participation. While this requirement clearly applies to *all* children and young people, regardless of their age and stage of development, we suggest that the ensuing responsibilities for researchers in the way they interact with children and young people are distinct for each of the cases we describe in Chapter 4 (see paragraph 4.5). Where children fall into Case One (such as babies, or children experiencing temporary incapacity, who are unable to contribute their own view with respect to research involvement), researchers' responsibility to respect them as individuals overlaps almost entirely with their responsibility to consider their immediate and longer-term welfare. The primary focus of researchers, along with parents, will be on whether or not the research procedures involved will be a cause of distress, or potential harm, for this particular child (as indicated, for example, by his or her responses). Where children and young people fall into Cases Two or Three, however, responsibilities for researchers arise that are quite distinct from, and additional to, these welfare concerns. We consider first children and young people in Case Three: those who are intellectually and emotionally able to make their own decision about research involvement.

Children and young people in Case Three

6.5 Children and young people fall within Case Three where they are capable of understanding what is involved in taking part in a particular piece of research and of deciding for themselves whether or not to take part, but are not as yet given full decision-making power under national legislation (see paragraphs 4.42–4.50).[575] **We take the view that, where children and young people have this level of**

[574] Participant in the Youth REC film. See: Spencer G, Boddy J, and Rees R (2014) *"What we think about what adults think": children and young people's perspectives on ethics review of clinical research with children* (London: Nuffield Council on Bioethics).

[575] In England and Wales, this would apply to children and young people under 18 for most research, given general coexistence of parental powers with children's powers, but under 16 in the specific context of clinical trials, since minors there are specifically defined as under 16.

understanding, professionals have an ethical obligation actively to seek their consent, not their 'assent', regardless of any additional requirements of national legislation. At the same time, parents continue to have a legitimate interest in their children's decisions until they are formally recognised as an adult within their national jurisdiction. We therefore suggest that, wherever possible, professionals should seek consent both from the children and young people concerned, and from their parents. Such an approach is respectful of children and young people, and of the continuing role of their parents, and provides a practical focus for encouraging a genuinely shared decision.[576] A focus on shared family decision-making is particularly helpful in this context as it obviates the need for fine judgments to be made as to whether or not a particular child or young person really does have the capacity to make a particular decision.

Recommendation 13

We recommend that, where children and young people have sufficient maturity and understanding, but are not yet treated as fully 'adult' by the law of their country, professionals should, wherever possible, seek consent from both the children or young people concerned, and from their parents.

6.6 As we discuss in more detail below, it is crucial that the *process* of seeking consent from children and young people and their parents should not be confused with the *manner* in which that consent is documented. For children and young people and their parents to provide meaningful consent (or equally, for them to decide to refuse the invitation to participate), they must have access to high quality information, opportunities to discuss the project with professionals able to answer their questions, and assurance that their decision will not affect the provision of standard care (see paragraphs 6.17–6.18 and 6.28). The consent, once given, should be recorded in a way that is culturally appropriate. In a UK context, this is likely to involve both the young person and parents signing the consent form; but other methods of documenting the consent process, such as audio or video recordings, or a note by the researcher, should be equally acceptable, particularly where these methods have been chosen as a result of local community engagement in the development of the study.[577] A signature on a consent form is only a means of *recording* a decision; it is the decision itself, and the (ongoing) process that enables that decision, that is the ethically significant part of the 'consent'.[578]

[576] See, for example, Hart RI, Foster HE, McDonagh JE *et al.* (2015) Young people's decisions about biologic therapies: who influences them and how? *Rheumatology*: Published online first (5 February 2015) for an account of how young people in their early 20s continue to play considerable value on parental support, particularly from their mothers. See also: Morrow V, and Richards M (1996) *Young people's transition to adulthood* (York: Joseph Rowntree Foundation), which notes that "there is no sharp distinction between childhood and adulthood: it is a complex mixture of continuing dependency on parents stretching into the twenties and beyond".

[577] See, for example, The University of Nottingham (2015) *REACH: Rojiroti Evaluation Assessing Children's Health - pilot project*, available at: http://www.nottingham.ac.uk/reach/pilot-project.aspx. See also: Shenk K and Williamson J (2005) *Ethical approaches to gathering information from children and adolescents in international settings: guidelines and resources* (Washington, DC: Population Council) for further discussion of the importance of community engagement.

[578] See, for example, the discussion in Harston GWJ, Sheehan M, and Kennedy J (2014) Emergency medicine research: rites, rituals and consent *Emergency Medicine Journal* **31(2)**: 90-1.

Box 6.1: Case study: taking a shared approach to consent

Lucy is a 15 year old who is asked if she would like to participate in a study of her relapsing nephrotic syndrome, a chronic condition where the kidneys become inflamed and lose protein. The study will look at a short course of daily prednisolone (an anti-inflammatory medicine) in response to upper respiratory tract infection. Two weeks before her regular outpatient appointment, Lucy's usual doctor posts an information sheet for both Lucy and her parents. The information sheet describes the study and explains its aims. At the appointment, her doctor asks Lucy and her mother if they have read the information sheets and would like to talk further about the study. When they say yes, the research nurse for the study is asked to join them.

The doctor and research nurse ask Lucy if she would like to speak to them on her own about the study, which she agrees to. During this time, they discuss what the study involves and that Lucy will have to have a pregnancy test before taking part in the study. Her mother is then asked to join them again and they talk through the different treatment arms in the study, and the hospital visits involved. The team check that both Lucy and her mother understand what they have been told. They ask Lucy's mother if she has any extra questions she wants to ask. The team then give Lucy and her mother time together to discuss the decision, which they had also previously discussed in the car on the way to the appointment. They jointly decide to proceed, and so both Lucy and her mother sign the consent form for the study.[579]

6.7 There will, of course, always be cases where a shared decision-making model will not work: because of the nature of the research; because of disagreement within the family; or in cases where children and young people do not have the kind of family support envisaged above. We return to the latter two cases below (see paragraphs 6.19–6.27 and 6.31–6.41). **Where the nature of the *research* is such that parental involvement is believed to be inappropriate, or might undermine the research objective or even threaten a young person's well-being, we take the view that it may be ethically acceptable to approach children and young people in Case Three without parental knowledge or involvement. However, such approaches should be subject to specific review by a REC**. It would thus be open for a REC to approve a proposal that children and young people in Case Three be invited to participate in research where there was good reason to believe that parental involvement in the decision would compromise the accuracy of the information received. This might, for example, include research exploring young people's drug use or sexual activity.[580] In coming to such a decision, the REC would take into account both the likely value of the research (for example, with respect to informing health service provision within the area), and the sensitivity of planned recruitment processes. Depending on the circumstances, such an approach to research might need, or benefit from, wider community engagement at the design and development stage: openness towards the wider community at this early stage will do much to promote trust in the

[579] With thanks to Helen Sammons, Working Party member.

[580] See, for example, Kenyan guidelines on HIV testing in clinical treatment and applicable to research, where young people "engaged in behaviour that puts them at risk" may be treated as mature minors and hence able to give consent without parental involvement: Republic of Kenya Ministry of Health (2006) *Guidelines for HIV testing in clinical settings: 3rd edition*, available at: http://www.who.int/hiv/topics/vct/KENYA_HIV_Guidelines_2006.pdf.pdf.

value of the proposed study, and in the robustness of the scrutiny to which it will be subject.[581]

Children and young people in Case Two: what do we really mean by 'assent'?

6.8 We have characterised Case Two as applying to children and young people who are able to form views and express wishes about research involvement, but without the capacity to make an independent decision. We have also suggested that quite young children, in some cases from the ages of two or three, may be able to understand that they are being asked to do something to help other people, rather than for their own benefit (see paragraph 4.6). We argue that as soon as children have the ability, even at this most basic level, to express views and wishes about the research, researchers have an obligation to *involve* them in a way that is appropriate to their understanding and development. This involvement must also be compatible with respect for the parenting approaches of particular parents (see paragraph 6.16). For young children, this might involve talking directly to children – *after* discussing the proposal with their parents – to describe what the research involves, using pictures or other means to explain what might happen, and responding appropriately to their reactions (see box 6.2). For older children, it might be more appropriate to discuss the possibility of research involvement with children and their parents together, again with appropriate information materials to support understanding.

[581] For a helpful discussion of this approach in Nigeria, see: Folayan MO, Haire B, Harrison A *et al.* (2014) Ethical issues in adolescents' sexual and reproductive health research in Nigeria *Developing World Bioethics*: Published online first (9 June 2014).

Box 6.2: Case study: involving young children in vaccine trials

Thoughts from a paediatric research nurse:[582]

"For a vaccine research study, we prepare age-appropriate information, including sticker charts, and bring age-appropriate toys. Though these are used as a means of distraction and as a reward system, they also help to guide children through the process using what is familiar to them.

An experienced paediatric health professional can easily assess the parent-child relationship, and children's and parents' past experiences of medical interventions, and medical conditions, in a short time. It is important to be aware of these factors and to allow both parties chance to talk about them.

We ask parents what they have told their child and what they feel their child has taken on board. We also ask parents what they think will help their child. We introduce ourselves to children and establish their understanding of our visit. We may use pictures on the adapted information sheets for this purpose. Generally, it is not children's lack of comprehension of the process and the rationale behind the basic purpose of the study that causes difficulties, but rather the health professional's inability to communicate this. Children's own experience can help with this and parents are essential in helping their child to remember. For example: 'Some children get very poorly – have you been poorly? We need to check new medicines to see if they stop children getting poorly – do you remember having medicine?'

When undertaking invasive procedures, the process should be explained, again with parents' assistance, in recalling past experiences, such as 'watching Mummy having her blood test'. It is essential that it is acknowledged that it may hurt, and that if it does we can stop (anaesthetic cream is used for blood tests). It is important that those undertaking the study acknowledge children's non-verbal communication, and adapt to ensure that children have a sense of control in this situation. This means asking children things like where they want to sit, and what they would like to play with. An experienced health professional is adept at doing so.

For follow-on visits, if children don't want to continue, they need to be allowed to voice this and withdraw. Researchers and parents need to let this happen. Often it is fear of pain, and when you talk to them, they say that as long as it doesn't hurt they would like to help. There is a genuine sense of this. I have worked with children in these circumstances. We agree that if it hurts, we'll stop. I have been have hugged afterwards by a child who was so pleased they had done it, both for themselves and their parents. A three year old when asked by a parent why they had let me do the blood test said, "because I trusted her". Another three year old said I could have one attempt at a blood test. Having not got blood, I stopped. The parents wanted another attempt, but the boy said: "She will not do it again because we agreed," and he was right. Parents sometimes need to be reminded of their child's informed decisions, and to feel assured that they have not 'wasted our time', which is often the overriding concern. The experienced paediatric professional is the advocate for this agreement with each child. This may be the first established relationship with a non-familiar adult, and it is empowering.

In a hospital setting, when pre-school children have experience of both invasive and non-invasive therapies needed to ensure they stay healthy, and have an established understanding of procedures and their conditions, they are far more informed when approached for a study than a child who doesn't have this experience. These children are even better equipped to voice logical and rational arguments regarding taking part or not taking part. Again they have a right for this to be respected."

[582] With thanks to Liz Davis, Working Party member.

6.9 The term 'assent' is often used to describe these interactions with children who do not, as yet, have the capacity to make independent decisions about research participation. As we saw in Chapter 2, however, the various guidelines that refer to assent paint a highly confusing picture. At one extreme, assent is presented as encompassing a three year old's "emergent capacity to agree", while at the other, it is limited to the "knowing agreement" of children fully able to understand what is involved but prevented by domestic law from providing researchers with a legally effective consent (see Box 2.3 on pages 60-1). Moreover, the focus in some guidelines on obtaining assent in writing seems to confuse assent with the process of obtaining legally-effective consent that will enable the research to proceed. A requirement for written assent also risks focusing researchers' and parents' attention primarily on the *act* of obtaining a signature, and away from the ethically-significant *process* of involving children and young people that should be an essential prerequisite to such an act.

6.10 We thus suggest that much greater clarity with respect to the assent of children and young people to take part in research would be obtained by distinguishing clearly between the process of involving children in participation decisions, and any act by which this is documented.[583] Researchers' direct responsibilities to children, arising out of respect for them as distinct individuals, make it an ethical imperative that children who have any ability to engage with the question of research participation are appropriately involved in that decision (see paragraphs 6.23-6.24, and Box 6.5). Indeed, failure to take this responsibility seriously constitutes a breach of trust between researchers and the children they are seeking to recruit. *How* the process of involving children is then documented is very much a secondary concern.

Recommendation 14

We recommend that requirements in guidance and regulation to 'seek' or 'obtain' assent from children who are being invited to take part in research should be understood as requirements to involve children, as much as they wish and are able, in the decision about participation. In devising assent processes, researchers should primarily be concerned with how best to develop trusting relationships with children and communicate information appropriately throughout the research.

6.11 The ways in which this involvement may be achieved will clearly vary significantly, depending on the nature of the research, the participants, and the context in which the research takes place. Information material appropriate to the children and young people's level of understanding, and to the cultural environment in which the research is taking place, is important; but even more important is the emphasis to be placed on sensitive and skilled communication. Researchers seeking ethical approval of their studies with children and young people should be able to demonstrate that all those who will be interacting directly with children and families as part of the proposed research have the necessary communication skills. Researchers and other staff involved in research who do not routinely work with children should have access to relevant training *before* the research begins.

[583] See, for example, Baines P (2011) Assent for children's participation in research is incoherent and wrong *Archives of Disease in Childhood* **96(10)**: 960-2; Sibley A, Sheehan M, and Pollard AJ (2012) Assent is not consent *Journal of Medical Ethics* **38(1)**: 3; Wilkinson D (2012) Dissent about assent in paediatric research *Journal of Medical Ethics* **38(1)**: 2.

6.12 **The fact that children have been appropriately involved in the participation decision should be recorded for future reference. However, this record must not be perceived as the main point of the process**. Assent forms constitute one possible form of documentation: they may act as a prompt for the researcher, and some children may see an invitation to sign a form as recognition of their value as an individual. They are not, however, the only (or necessarily the best) way of recording children's involvement. Alternative forms of documentation might include inviting children and young people to co-sign the consent form with their parents, or for parents to note on the consent form that their child has been involved in the decision. Increasingly, though, it may become more appropriate to use interactive online technologies, both as a means of sharing information about the research and recording children's involvement.[584] The record of the way in which children have been involved in the decision must also, crucially, be culturally appropriate. In some contexts, signing a form may be perceived as threatening, rather than empowering. In such cases, alternative methods of documenting both assent and consent, such as voice or video records, drawing pictures, or making a note in children's health records, should be employed.[585]

6.13 This focus on the *way* in which children and young people in Case Two are properly involved in research participation decisions highlights again the important part played by the professional virtues of trustworthiness, openness and courage (see paragraphs 5.8–5.11). Research professionals need to build a trusting relationship with the children and young people whom they are inviting to participate in their studies, and with their parents; they need to be open with them, explaining clearly what the research will involve and the choices available to them; and they need to have the courage to cede control appropriately to children taking part, as described in Box 6.2 above.

6.14 These virtues are similarly important in the way REC members review research proposals involving children and young people. We recommended above that, when devising assent processes, researchers should primarily be concerned with how best to develop trusting relationships with children, and communicate information appropriately throughout the research (see Recommendation 14). Similarly, the focus of REC scrutiny should be on the appropriateness of the processes that the researchers intend to use to involve children and young people in decision-making, the information resources they will use in these processes, and the communication skills of those who will be directly responsible for interacting with potential participants. This flexible approach to the engagement of children and young people in research decisions has been described as a form of "personalized assent" that depends on trust in "the moral responsibility and integrity of the researcher."[586] Trusting researchers with flexible approaches to assent takes courage on the part of those responsible for REC scrutiny. As we note at paragraph 5.35, recognition by researchers of the responsibility held by

[584] For a discussion of how digital technologies such as laptops, smartphones, and tablet devices can be used to offer support for conveying information about research, and to facilitate children's and young people's decision-making in the context of research, see: Parsons S, and Abbott C (2013) *Digital technologies for supporting the informed consent of children and young people in research: the potential for transforming current research ethics practice*, available at: http://responsible-innovation.org.uk/torrii/sites/default/files/Parsons%20%26%20Abbott%20Digital%20technologies%20for%20informed%20consent%20FINAL_0.pdf.

[585] See, for example, the techniques used by the Young Lives research teams in Peru, Vietnam, Ethiopia and India: Morrow V (2009) *The ethics of social research with children and families, in Young Lives: practical experiences - working paper no. 53* (Oxford: Young Lives). See also the 2013 policy change in India, which requires that "in all clinical trials, in addition to the requirement of obtaining written informed consent, audio-visual recording of the informed consent process… is required to be done while adhering to the principles of confidentiality": Central Drugs Standard Control Organization (India) (2013) *Order: 19 November*, available at: http://cdsco.nic.in/writereaddata/Office%20Order%20dated%2019.11.2013.pdf.

[586] Giesbertz NA, Bredenoord AL, and van Delden JJ (2014) Clarifying assent in pediatric research *European Journal of Human Genetics* **22(2)**: 266-9.

RECs for scrutinising their capacity to exercise such discretion is an essential part of the process.

6.15 We recognise that the approach to consent and assent advocated in this chapter represents a significant shift in current practice, in emphasising how context-specific and child-specific these processes need to be. Such an approach imposes additional challenges both for the researchers and for those responsible for the scrutiny of research proposals. Practical guidance on realising these aims in practice is urgently needed.

Recommendation 15

We recommend that research funders encourage or commission good quality research proposals exploring how the approaches to consent and assent put forward in this report might best operate in practice. Such research would provide a secure foundation for future good practice guidelines, tools and resources that are sensitive to a range of contexts.

Responsibilities to children and parents together

6.16 Having explored professionals' *direct* responsibilities to children and young people in the context of research, we now turn to the responsibilities that arise out of the recognition that children should always be seen in the context of their families: that is, professionals' responsibilities to children and parents together.[587] Approaches to parenting are many and diverse, even within apparently homogenous communities. An exploration of how children with chronic illnesses and their parents individually understood consent processes in the context of a US-based paediatric trial, for example, identified four distinct parental approaches to their child's decision making, characterised as exclusionary, informative, collaborative, and delegated approaches.[588] Researchers will need to be sensitive to these differences, while still remaining alert to the responsibilities they owe directly to children and young people themselves.

Extending the fair offer: communication

6.17 We have argued that partnerships between professionals, children, young people, and their parents in the development of research will minimise the risk of children and young people being placed in a vulnerable position through research participation. We have further suggested that the role of RECs is to ensure that any invitation to children or young people to take part in research is a 'fair offer' that they can trust. Professionals subsequently responsible for *extending* that offer to children, young people and their parents have a critical part to play in maintaining that partnership, and ensuring that an invitation to take part in research is genuinely 'fair'.

6.18 Good communication is an essential element of this process – both in terms of the clarity and accessibility of the information provided (whatever the format), and,

[587] See, for example, the discussion of the "dynamic triad with multiple relationships formed between the researcher, the youth, and the youth's parent(s) or guardian(s) in Trussell DE (2008) Unique ethical complexities and empowering youth in the research process *Journal of Park and Recreation Administration* **26(2)**: 163-76, at page 167.

[588] Snethen JA, Broome ME, Knafl K, Deatrick JA, and Angst DB (2006) Family patterns of decision-making in pediatric clinical trials *Research in Nursing & Health* **29(3)**: 223-32.

critically, in terms of the quality of face-to-face communication (see Box 6.5). In addition to what has been noted above with respect to age-appropriate information for children and young people themselves, it is crucial that their parents feel well-informed about what the study involves, and that information about burdens, risks and benefits is presented as openly and clearly as possible. As part of that process, professionals need to be alert to wider environmental influences on children, young people and their parents; for example, with respect to a 'pro-science' climate that could exacerbate risks of therapeutic misconception (see paragraph 1.17). Particular challenges in communication arise where researchers are also providing direct care to children or young people (see paragraph 6.28).

Facilitating shared decision making

6.19 The language of 'partnership' highlights the importance of the tripartite relationship between professionals, parents, and children and young people. It also raises the issue of how professionals should respond to the diverse approaches that parents may take with respect to involving their children in decision-making. We suggest that the starting point for professionals should always be one of *respect* for parents' role in determining how, and at what speed, their child develops towards being an independent decision-maker. As we suggested in Chapter 1, children and young people do not function in isolation, but rather in the context of their particular family and social environment. When approaching children and young people about the prospect of research participation, professionals must be sensitive to the variable forms of family dynamic that may be in play. However, this respect for individual parental approaches must run alongside and, where necessary, be constrained by professionals' own direct responsibilities to children and young people: to respect them as individuals and to have regard for their welfare. **Thus, while professionals should respect parents' views with respect to their child's participation in decisions about research, parental preferences cannot act to cancel out professionals' own responsibilities. While parental consent renders their child's participation in research legally permissible, it does not make it mandatory, thus leaving an important area for professional discretion and judgment**.

6.20 The need for such discretion could arise in a number of circumstances, including where parents wish to exclude their child altogether from a decision (for example, out of a desire to protect them from knowledge of their diagnosis), or where parents wish their child to take part in research, but he or she disagrees. In the first case, if parents remain adamant that their child cannot be part of the decision at all, even though they are clearly able to form and express their own preferences, professionals may take the view that it is not possible to include them in the study, unless there are strong welfare reasons for inclusion that trump all other considerations.[589] In cases like these, however, researchers have a strong professional obligation to endeavour first to encourage and support parents in enabling their children's voices to be heard.[590]

6.21 Such cases, however, should be distinguished from those that arise where children or young people are in Case One because of a temporary inability to engage at all: for example, because of severe pain, distress, or emotional confusion at the point at which

[589] See, for example, Spriggs M, and Gillam L (2013) Deception of children in research *Journal of Medical Ethics* **41(2)**: 179-82.
[590] Such situations may arise, for example, as a result of perceptions of appropriate gender roles: in some cases, girls and young women may need particular support from researchers to enable their voices to be heard: see Jao I, Mwangome N, Davies A, Molyneux CS and Marsh V (2014) *Nuffield Council on Bioethics Working Party on ethical issues for research involving children: report on consultations with community representatives and secondary school students in Kilifi, Kenya* (Kilifi, Kenya: KEMRI Wellcome Trust Research Programme).

the decision must be made. Such circumstances may arise, for example, where decisions about research protocols are closely interwoven with treatment decisions and need to be made urgently at the time of diagnosis (such as with the diagnosis of some cancers, as described in paragraph 1.9 and Box 6.3 below), or where children are unconscious and questions of research relating to emergency care arise. In such cases, where even sharing brief information with a child may not be possible, it may be appropriate for professionals to act solely on parental consent at this point of initial recruitment.[591] However, professionals' direct responsibilities to respect children or young people as individuals underpin a duty to ensure that children and young people are *subsequently* engaged in explanations about the research, including any choices about their involvement, as soon as they are able to be so.

6.22 As we noted above, children's assent and engagement in decision-making about research is a process, not a one-off event. Children and young people who are unable to engage at the start of the process must be encouraged and enabled to do so as soon as they are able. Similar issues may arise in longitudinal research where children are recruited as babies, but continue taking part in the study as they grow older, at which point it becomes essential to involve them appropriately in ongoing decision-making. This process of engagement is important not only because of the respect it confers on young research participants, but also because it provides the opportunity for them to understand the contribution they are making, an issue that young people were repeatedly keen to stress to the Working Party. It is important to avoid the illusion of choice where none really exists; however, a child who is part of a trial because it is inextricably linked to treatment considered essential for their welfare can still be afforded a sense of agency by giving them with an understanding of the contribution they are making.

[591] Health Research Authority (2015) *Principles of consent: emergency research (England and Wales) - children / young people in other emergency research*, available at: http://www.hra-decisiontools.org.uk/consent/principles-emergency-EnglandandWales.html.

Box 6.3: Case study: young children with cancer

Parents from the Paediatric Oncology Reference Team (PORT)[592] highlight the situation of young children who are seriously ill with a life-threatening cancer, such as leukaemia or a brain tumour, where all focus may be on starting treatment as quickly as possible. That treatment may, however, potentially include research elements such as randomisation to different treatment options. In such cases, decisions about these research elements may need to be made, at least on an initial basis, immediately after diagnosis. If children are emotionally and physically unable to deal with any information about the study at that particular point, requiring them to read or listen to an information sheet describing the research aspects of the protocol may neither promote their welfare, nor be respectful of them as individuals. It may also be a distraction from helping them to understand that they have a serious illness that requires treatment. In some families, there may be an understandable desire not to share the full gravity of the situation with children, and to keep information sharing to a minimum, particularly in the early days of what could be a long treatment process.

Where children have no genuine choice about whether or not to take part in research (because it is so closely interwoven with their treatment, and parents / professionals believe that treatment within this particular research context is best for their welfare) it is disingenuous to imply that they have a free choice about participation or withdrawal. This is in contrast to non-interventional studies going *alongside* treatment, such as research about their experiences of cancer care, where choices about participation, and the possibility of future withdrawal, should genuinely exist.

In cases like these, children are likely to move over time from Case One to Case Two as they respond to initial treatment. They will then be able to absorb appropriately communicated information about the research aspects of their treatment protocols, and to express their views on these.

PORT are currently working on patient information sheet templates that are concise, use simple language, and clearly explain the trial questions, as opposed to standard treatment (for example explaining the relevant side-effects of the trial medicines as opposed to medicines used in standard treatment). It is PORT's hope that parents' improved understanding of the trial will allow them to better engage with their child regarding trial questions, as this becomes appropriate.

6.23 Where disagreement about research participation arises *within* families, professionals have a responsibility to engage both with parents, and with children and young people, with the aim of negotiating an acceptable solution that is respectful of all parties. As we discussed in Chapter 4, young children's wishes cannot always be determinative, particularly where researchers and parents reasonably believe that they might obtain significant benefit from participation (see paragraph 4.11), and it may well be appropriate to persuade them. Parents who have sought to convince their child that participating in research to benefit others is a 'good thing to do' might legitimately feel that if, for example, the researcher simply accepts their child's 'no' at a point of minor discomfort, their own parenting role has been undermined. However, professionals' own responsibilities towards children, and in particular the importance of their creating a trusting relationship with them (see Box 6.2 above) place strict limitations on how far they should proceed in the absence of consensus.

[592] Paediatric Oncology Reference Team (PORT) (2015) *Homepage*, available at: https://sites.google.com/site/ukportgroup/home.

6.24 **Where children (even young children with limited understanding of what is proposed) explicitly and consistently dissent, there will generally be both ethical and practical reasons why it would be right for professionals to accept that dissent, despite parental willingness to proceed. The more children are able to understand what is involved in a research proposal, the greater the justification needed to act against their clearly expressed wishes. The multiple factors in play in such cases, however, make simple 'yes' or 'no' answers as to how professionals should approach these difficult decisions impossible to offer**. Rather, they reinforce the fundamental importance of reflexive professional practice, directed towards creating and sustaining open trusting relationships with children, young people, and their parents.

6.25 **Similar issues may arise where children or young people in Case Three wish to participate in a research study, but their parents do not agree. In such cases, professionals have an important role in seeking to inform and encourage parents. However, if these attempts prove unsuccessful, then in most cases participation in research should not go ahead**. Even in countries where the law recognises coexisting powers of children/young people and their parents to consent (hence providing for a legally effective consent from a minor), professionals must take into account the position of children and young people within their families, and cannot simply ignore the realities of family hierarchies and the consequences for those involved of overriding them.[593] We have discussed the specific situation where research may be permissible with children and young people in Case Three *without* parental involvement (see paragraph 6.7) and we discuss below cases where parents are temporarily or permanently absent (see paragraphs 6.31–6.41). However, where parents have been involved in the process of their child being invited to take part in research, and have consistently taken the view that their child should *not* take part, then strong justification would be required to warrant participation on the basis of children's or young people's consent alone.

6.26 In the very different circumstances of babies and very young children in Case One, clearly parents' decisions about whether or not they should participate in research will be determinative. However, depending on the context in which the possibility of research involvement arises, such as during neonatal care, parents may be particularly in need of sensitive support from professionals (see paragraph 4.61).

[593] See, for example, Hart R, and Lansdown G (2002) Changing world opens door to children *CRIN News* **16**: 9-11 who discuss "the damaging impact of creating a struggle of values at home" in the context of failures of communication, cited in Alderson P, and Morrow V (2011) *The ethics of research with children and young people: a practical handbook* (London: SAGE Publications), pp107-8. Note, similarly, the emphasis placed by both young people and adults in the Working Party's consultation in Kilifi, Kenya on the importance of family discussions and willingness on the part of both young people and parents to listen to, and learn from, each other: Jao I, Mwangome N, Davies A, Molyneux CS and Marsh V (2014) *Nuffield Council on Bioethics Working Party on ethical issues for research involving children: report on consultations with community representatives and secondary school students in Kilifi, Kenya* (Kilifi, Kenya: KEMRI Wellcome Trust Research Programme).

Box 6.4: Case study: support for parents

"Where the clinicians offering a trial took a leisurely approach, parents could feel that they too could take time to reflect.

'They said I could take as much time as I wanted… [within] a certain time as [the baby] did need something to be done. They didn't rush me into a decision. [The doctor] said "I'll leave [the form] with you… I'll leave you to talk and you come down to me when you're ready." So there was no pressure on the doctor's part. He was really good… sitting talking to us for a good half hour, forty-five minutes explaining everything.'"

'Tessa' describing her experience of being invited to enrol her baby in a randomised control trial shortly after birth.[594]

6.27 Parents of children of any age may, of course, disagree with each other with respect to whether or not it is appropriate for their child to participate in research. In such cases, it will again be the professional responsibility of researchers to seek to negotiate a solution that will be acceptable both to the children and to the adults concerned.[595] While, depending on the jurisdiction, the law may only require consent from one parent to permit research to go ahead, there is an important difference between one parent being silent or absent, and active disagreement between parents. As in cases where disagreement arises between children and their parents, irreconcilable disagreement between parents may in practice mean that children or young people cannot be included in the study. Slightly different issues arise where one parent is absent, and the other is uncertain of their authority to consent.[596] In such cases, if national legislation permits one parent to authorise participation, professionals will need to exercise their discretion in determining whether or not to seek that consent, taking into account the reality of family dynamics and power relationships. In areas where this issue is known to arise repeatedly (for example, where many fathers live and work away from their families), proactive community consultation could help create wider community acceptance of consent by one parent only.

Particular challenges for professional judgment

Clinicians and researchers: professionals' dual roles

6.28 Questions of professional judgment may become particularly acute in circumstances where professionals have dual roles, both as researchers, and as clinicians providing care to children and young people who might potentially participate in their studies. In such cases, professionals must ensure that their own, legitimate, interests in the success of their research are not permitted to compromise the interests of children and young people under their care.[597] On the one hand, they must be alert to how families

[594] Snowdon C, Elbourne D, and Garcia J (2006) "It was a snap decision": parental and professional perspectives on the speed of decisions about participation in perinatal randomised controlled trials *Social Science & Medicine* **62(9)**: 2279-90, pp2285-6.

[595] Similar issues may arise where children live between two or more households, or there are disputed guardianship arrangements: see, for example, Abebe T (2009) Multiple methods, complex dilemmas: negotiating socio-ethical spaces in participatory research with disadvantaged children *Children's Geographies* **7(4)**: 451-65, at page 456.

[596] This may often be the mother. See, for example, Nuffield Council on Bioethics (2015) *Children and clinical research: ethical issues - summary of consultation responses*, available at: http://nuffieldbioethics.org/project/children-research/evidence-gathering-activities/, pp17-8.

[597] de Vries M, Houtlosser M, Wit J *et al.* (2011) Ethical issues at the interface of clinical care and research practice in pediatric oncology: a narrative review of parents' and physicians' experiences *BMC Medical Ethics* **12(1)**: 18. See also: Caldwell PHY, Dans L, de Vries MC *et al.* (2012) Standard 1: consent and recruitment *Pediatrics* **129 (supplement 3)**: S118-S23 who

may be influenced by existing trusting clinical relationships and may find it hard to say 'no' (see paragraph 2.27). On the other hand, concerns about undue influence may prompt professionals in such circumstances to be so non-directive that children, young people and parents can feel abandoned in their decision-making (see paragraph 2.26). Professional judgment is required to strike the right balance, ensuring that potential participants and their parents understand what is involved in the study (and their clinician's own involvement in it), and are clear that their decision about research participation will not affect their care in any way. Families may also welcome the possibility of discussing the proposed research with another professional who is not directly involved in caring for their child. Similar concerns may arise in the context of longitudinal research, both because of children's developing ability for engagement over the research period (see also paragraph 6.22), and because the sense of obligation engendered by long-term involvement in a study may make it harder for both parents and children to say 'no' at any given point.[598]

Recommendation 16

We recommend that, where a protocol indicates that children and young people may be recruited by a health professional responsible for their care, research ethics committees should explore with researchers the justification for this approach. Where such recruitment procedures are appropriate, research ethics committees may wish to assure themselves that there are support arrangements in place, such as access to another member of the research team to whom families can turn for additional information if they wish.

Innovative treatment outside research

6.29 As we noted in Chapter 1, innovative or experimental treatments may occasionally be provided outside the context of research (see paragraph 1.6). Such use is permitted by the Declaration of Helsinki within the professional discretion of clinicians,[599] but is controversial because of the potential lack of scrutiny and associated safeguards that are required for research. A necessary corollary of the licence to exercise such discretion is found in the expected virtues or characteristics of professional practice. As we discuss above (see paragraphs 5.5–5.12), in the specific context of research with children, we suggest that the virtues of trustworthiness, openness and courage are particularly important.

6.30 We take the view that, wherever possible, novel therapies of any kind should be subject to properly evaluated research. Where, exceptionally, novel treatment outside the context of research is appropriate (for example, in some cases of "compassionate

argue, at S121, that this is a key issue in cases where research is seen as an integral part of good care (i.e., in oncology), rather than as an extra activity.

[598] Williams G (2012) Children as means and ends in large-scale medical research *Bioethics* **26(8)**: 422-30.

[599] World Medical Association (2013) *WMA Declaration of Helsinki - ethical principles for medical research involving human subjects*, available at: http://www.wma.net/en/30publications/10policies/b3/index.html, paragraph 37: "In the treatment of an individual patient, where proven interventions do not exist or other known interventions have been ineffective, the physician, after seeking expert advice, with informed consent from the patient or a legally authorised representative, may use an unproven intervention if in the physician's judgement it offers hope of saving life, re-establishing health or alleviating suffering. This intervention should subsequently be made the object of research, designed to evaluate its safety and efficacy. In all cases, new information must be recorded and, where appropriate, made publicly available."

use"[600]), it should be regarded as a professional obligation of the health professional concerned to ensure that information about treatment outcomes and the clinical course of the patient's condition is collected and made publicly available; for example, through a registry or publication. Such a commitment to openness is necessary both to maintain trust, and to ensure that any significant information (for example, relating to adverse effects) is available to other clinicians with patients in similar situations.

Recommendation 17

We recommend that the Royal College of Paediatrics and Child Health takes the lead with other Royal Colleges and relevant professional bodies in exploring how best to ensure that information as to the outcomes of 'innovative' or 'experimental' treatment given to children or young people outside the context of research is properly documented and made available to others concerned.

Responsibilities in the absence of parents

Temporary absence of parents

6.31 The temporary absence of parents who would usually expect to be involved in decisions affecting their child may arise either in the form of actual physical absence, or as 'situational incapacity', where parents are present but too shocked or distressed to make a decision. In such cases, the responsibilities of professionals towards children and young people summarised at the start of this chapter (see paragraph 6.3) take on an added importance, as they will be exercising these responsibilities alone rather than in support of the parental decision-making role.

6.32 If it is reasonable for research decisions to be delayed until a parent is present and able to make a decision, clearly there is no justification for proceeding in their absence. However, there will inevitably be some health-related situations where the question of enrolling a child or young person in research without the support of their parent will arise. These may include research linked with the emergency care of children and young people.[601] Distinct issues may also arise in the temporary absence of parents of young people in Case Three who have the capacity to consent for themselves but where, ordinarily, joint consent would be sought from the young person and their parent (see paragraph 6.5 and Recommendation 13).

6.33 In the case of emergency research in the absence of a parent able to make a decision, the role of the REC in scrutinising the risks, burdens and benefits of the research will become even more important. We argued in Chapter 5 that the primary responsibility of a REC was to decide whether a research protocol would represent a 'fair offer' to children, young people and parents (see paragraph 5.28). In circumstances where, at least initially, parents will have no role, there is an added burden on RECs to be confident that the proposal is fair. Such confidence on the part of RECs is likely to be

[600] See the discussion in Brierley J, and Larcher V (2009) Compassionate and innovative treatments in children: a proposal for an ethical framework *Archives of Disease in Childhood* **94(9)**: 651-4.

[601] Health Research Authority (2015) *Principles of consent: emergency research (England and Wales) - children / young people in other emergency research*, available at: http://www.hra-decisiontools.org.uk/consent/principles-emergency-EnglandandWales.html. See also: Davies H, Shakur H, Padkin A *et al.* (2014) Guide to the design and review of emergency research when it is proposed that consent and consultation be waived *Emergency Medicine Journal*: Published online first (31 July 2014); Schreiner MS, Feltman D, Wiswell T *et al.* (2014) When is waiver of consent appropriate in a neonatal clinical trial? *Pediatrics*: Published online first (6 October 2014).

boosted by the active involvement in the design process of children, young people and parents – for example, those who have in the past had some experience of emergency research (see Box 6.5). Trust in the research proposal and its objectives may also be enhanced through local public engagement when the study is being developed, mirroring our approach to research with young people in Case Three where parents have been explicitly excluded because of the nature of issues addressed (see paragraph 6.7).

6.34 The question then arises as to the scope for children or young people to be involved in participation decisions. In many cases of emergency research, children or young people, regardless of their age or maturity, will be in Case One because they are unconscious, or severely incapacitated by pain or emotional distress. In such cases, no engagement will be possible at the time the initial decision is taken. Where, however, children and young people are in Case Two and able to contribute their view, then all means (appropriate to the urgency of the situation) should be used to encourage them to do so. Unless there are very strong welfare reasons to the contrary, any hesitancy on the part of children and young people to participate should be respected. If children and young people are in Case Three then their decision to consent or refuse should similarly be respected. Depending on the nature of the research, it may also be appropriate for a third party – such as a nurse not directly involved in the research – to witness the discussion between the researcher and potential participant.[602] Where a parent is present, but too shocked or distressed to take a decision, they should be encouraged to be as involved in the discussions as they can be, but not forced into a decision-making role.[603]

6.35 Where a study involving emergency research in the absence of parental consent is approved by a REC, it will be critical to inform and involve parents as soon as possible after the research begins. While sometimes described as 'deferred' or 'retrospective' consent by parents, this is misleading as, by definition, parents are not in a position at that point to refuse. Rather, **the process should be understood, first, as the provision of information about what has happened, and then as an invitation to consent for future procedures (where appropriate) and for the use of any data gathered as a result of the earlier procedures**. Similarly, where children and young people were in Case One when the research began because they were unconscious or in too much pain or distress, they should be invited to engage in discussion and participate in future decision-making as soon as they have recovered sufficiently to do so.

Non-emergency research

6.36 For children or young people in Case Three, the absence of a parent raises different issues from those in Cases One and Two (see paragraph 6.32). By definition, they are thought to have the capacity to make decisions for themselves, even though their parents may still also retain the *authority* to make those same decisions. Thus, for

[602] This model is being developed, for example, for emergency research with adults in the John Radcliffe hospital in Oxford, where over 50 professionals, such as nurses and radiographers, have come forward to be trained: Mark Sheehan, personal communication, 16 April 2015.

[603] See, for example, the approach used in the FEAST trial in Africa where parents were invited to 'assent' rather than 'consent' because of the emergency circumstances in which the research arose: Molyneux S, Njue M, Boga M *et al.* (2013) 'The words will pass with the blowing wind': staff and parent views of the deferred consent process, with prior assent, used in an emergency fluids trial in two African hospitals *PLoS ONE* **8(2)**: e54894.

children or young people in Case Three, clinical research that may be permitted in the absence of parents might relate not only to emergency research (where a decision cannot be delayed) but also to non-emergency circumstances where parents are not present, such as where young people seek medical care on their own. As we suggest in the context of research with young people that might be directly undermined by parental involvement (see paragraph 6.7), RECs will need to consider whether it is reasonable, in the circumstances, for researchers to seek a shared decision or accept a young person's consent alone.

Permanent absence of parents

6.37 Some children may simply not have parents, or other adults with a parental role, to support them at all. This situation may arise more often in low income countries, where a high number of children may be orphaned, living in child-headed households, on the periphery of wider family groups without the regular support of a meaningful 'parent-child' relationship, or on the streets. However, permanent absence of parents may also occur in high income countries, where teenagers live away from their immediate family because of relationship breakdowns, or where parental responsibility is exercised through institutional means (for example, where a local authority has parental responsibility for a child in care). Where children live in foster care, for example, foster parents do not have parental responsibility, and may only exercise responsibilities that have been explicitly delegated to them.[604] In practice, children and young people in these situations tend to be excluded from research, regardless of their own wishes with respect to participation. Where particular treatments are only available in the context of research (which may arise in high as well as low income countries: see paragraph 1.11), then children and young people not living with their parents are similarly excluded from treatment that might potentially be of benefit to them.

6.38 In the UK context, although the difficulties involved in seeking consent where parental responsibility is held at institutional level should not be underestimated, there will still always be *someone* who has the authority to give consent for 'looked-after' children and young people[605] to take part in research. The Medicines for Children Research Network (now 'CRN: Children') has published an account of how, with persistence, a looked-after child who was eligible to take part in a study concerned with impaired sleep in children with neuro-developmental disorders was finally able to participate after six months of negotiation by a study nurse with the local authority social services department, and the active support of her foster mother.[606] The success achieved by researchers in this case demonstrates the crucial role played by individual research professionals in facilitating access to research; and also the importance of developing good working relationships with local social service departments, and raising their awareness of the potential value of such research participation.

6.39 While in the UK context consent from a person (or institution) with parental authority will always be necessary for children and young people in Case One or Case Two,

[604] See, for example, guidance by the Fostering Network on this issue, which cites how young people in foster care often miss out on day-to-day activities such as sleepovers or school trips, because the authority to agree has not been delegated to their foster parents, and obtaining permission from the local authority is too cumbersome or slow: The Fostering Network (2015) *Parental responsibility and delegated authority*, available at: https://www.fostering.net/all-about-fostering/foster-carers/looking-after-child/delegated-authority#.VL0_d9KsW5K. For an account of the particular difficulties, see also: Hopkins P (2008) Ethical issues in research with unaccompanied asylum-seeking children *Children's Geographies* **6(1)**: 37-48.

[605] Children and young people in the care of a local authority.

[606] Medicines for Children Research Network (2010) *Widening participation for all children*, available at: http://www.crn.nihr.ac.uk/wp-content/uploads//neurological/Widening%20participation%20for%20children-AUG2010.pdf.

somewhat different issues arise in the context of children and young people in Case Three. As we noted earlier in this chapter, for some forms of research it may be appropriate for RECs to agree for consent to be sought from young people in Case Three alone, without the knowledge or involvement of their parents (see paragraphs 6.7 and 6.36). Where research has been approved in this way, clearly looked-after young people in Case Three could similarly participate without the need to seek local authority permission. In other cases, particularly where researchers have reason to believe that those eligible for their study may include looked-after young people, and the burden and risk of the research is low, RECs could be asked to consider whether exceptions to the need for parental consent could be agreed (see Box 6.5).

Recommendation 18

We recommend that the UK children's research networks (Clinical Research Network: Children and the Scottish Children's Research Network) work with the Children and Family Court Advisory and Support Service (Cafcass) to develop good practice guidance for social services departments and researchers to facilitate the opportunities for looked-after children and young people to participate in research.

6.40 In low income settings, it may sometimes be the case that there is no one at all who is able to give or withhold consent on behalf of children without parents: children may be orphans, living with older siblings or being cared for by a number of adults with little emotional attachment.[607] In such circumstances, the ethical challenges for involving children and young people in Case One or Case Two in research bear similarities to those arising in emergency research (see paragraphs 6.33–6.34). Where professionals have reason to believe that participation in research includes the prospect of direct benefit for children and young people, then there may be good welfare reasons why they should attempt to facilitate their access to research that has been judged to be both of value and a 'fair offer'. Judgments like these, however, require confidence and reflexivity on the part of both the researchers responsible for the study, and the REC members responsible for scrutinising it. Local stakeholder involvement will play an important point in helping RECs to determine whether research in these circumstances would indeed constitute a fair offer for these children and young people.[608] The challenges faced by professionals in these circumstances highlight the critical importance both of researchers' access to training in ethical considerations and of capacity building for RECs. Where it can be foreseen at the planning stage that children without parental support are likely to be eligible to participate, additional protections, such as an independent advocate able to witness the recruitment process, could be considered (see paragraph 6.34). Ensuring that Case Two children in these

[607] See, for example, Kruger M, Ndebele P and Horn L (2014) *Research ethics in Africa: a resource for research ethics committees* (Stellenbosch, South Africa: SUN MeDIA), at page 96. See also an account of the work of Maureen Kelley who highlights how orphans and vulnerable children may have multiple caregivers, and notes how the consequent lack of continuity, and frequent lack of emotional attachment between child and caregiver, can undermine the meaningfulness of surrogate decision-making: Cheah PY (1 October 2014) *Blog: consent and assent in paediatric research - panel discussion at the World Congress of Bioethics, June 2014, Mexico City*, available at: http://www.ethox.ox.ac.uk/ethox-blog/consent-and-assent-in-paediatric-research-panel-discussion-at-the-world-congress-of-bioethics-june-2014-mexico-city. Parents may also be simply inaccessible, for example because they are working away from home. See: Clacherty G, and Donald D (2007) Child participation in research: reflections on ethical challenges in the southern African context *African Journal of AIDS Research* **6(2)**: 147-56.

[608] See, for example, Bwakura-Dangarembizi M, Musesengwa R, Nathoo K *et al.* (2012) Ethical and legal constraints to children's participation in research in Zimbabwe: experiences from the multicenter pediatric HIV ARROW trial *BMC Medical Ethics* **13(1)**: 17.

circumstances are appropriately involved in the decision about taking part in research poses further significant challenges to researchers.

6.41 Finally, we consider the question of young people in Case Three: those who are still considered 'minors' in their own jurisdiction but have the ability and maturity to make their own decision about participation in research. In the absence of any adults who are able to give a legally effective consent, we again suggest that young people's own consent, or decision not to participate, should be determinative, as in the situation of the temporary absence of parents described above (see paragraphs 6.34 and 6.36). In making a judgment as to whether children or young people have this degree of maturity, researchers may legitimately take into account the degree of control and responsibility that an individual child or young person is used to exercising in other areas of their life.[609] However, in so doing it is critical to take into account whether they really are able to take on this responsibility without finding it an undue burden.[610] The role of professional discretion is therefore crucial in ensuring that children and young people are not inappropriately excluded from worthwhile research, while avoiding burdening an already over-burdened child.

[609] Vakaoti P (2009) Researching street-frequenting young people in Suva: ethical considerations and their impacts *Children's Geographies* **7(4)**: 435-50; Cheah PY, and Parker M (2015) Research consent from young people in resource-poor settings *Archives of Disease in Childhood* **100(5)**: 438-40.

[610] Cheah PY (1 October 2014) *Blog: consent and assent in paediatric research - panel discussion at the World Congress of Bioethics, June 2014, Mexico City*, available at: http://www.ethox.ox.ac.uk/ethox-blog/consent-and-assent-in-paediatric-research-panel-discussion-at-the-world-congress-of-bioethics-june-2014-mexico-city.

Box 6.5: Points to consider when carrying out clinical research with children and young people

- Have you involved children, young people and parents in the development of your study?
  - In the design of the study itself? (e.g. the number of appointments or interventions required)
  - In the development of easy-to-understand information about the study?
- Does your study represent a fair offer to prospective participants? Are you confident that the value of the study, and its likely risks, burdens and benefits, have been carefully weighed up from the perspective of potential participants? Have children, young people and parents been involved in identifying possible benefits, risks and burdens?
- Is expertise in a particular area of children's healthcare important in order for the REC to understand the approach taken in this study? Has this been communicated to the REC, so that it is well placed to obtain advice if necessary?
- Are you able to demonstrate how you will communicate, and discuss, information about the study appropriately and sensitively with potential participants and their parents, so that they are able to make free and informed choices about whether to take part? Does everyone in your team who will be interacting with children, young people and parents have the necessary communication skills?
- Good assent practice is about the *process* of involving children and young people meaningfully in decisions about research. Are the particular methods you have chosen for involving children and young people in decisions about taking part the most appropriate ones?
- Children and young people who have the capacity and maturity to make their own decision about your study should be invited to give consent (not assent), even if the law additionally requires parental consent. Does your consent process and documentation allow for this?
- Decisions about research participation should, wherever possible, represent a shared decision between parents and children/young people. How will you encourage shared decision-making?
- Is the subject matter of your research such that it may be appropriate or necessary to recruit children and young people *without* the involvement of their parents? If so, can you justify the approach you have chosen?
- What arrangements have you made to support children and young people who do not have a parent, or another adult exercising a parental role, so that they are not excluded from your study?
- Will clinicians be responsible for recruiting children and young people, for whom they are providing care, to take part in research? If so, is this the most appropriate approach? Have you considered alternative approaches?
- Does the information provided for children, young people and parents explain how and when they can find out about the outcomes of the research? Will those outcomes also be explained in accessible language?