

Chapter 4

An ethical approach to
children's involvement in
research

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Chapter 4 overview

Diversity of childhood

We identify three scenarios in which a child’s or young person’s potential for input into a decision about research raises distinct ethical questions:

- **Case One:** children who are not able to contribute their own view as to whether they should take part in research, such as babies and very young children, or children who are temporarily unable to contribute because they are very unwell or are unconscious.
- **Case Two:** children who are able to form views and express wishes, but who are clearly not yet able to make their own independent decisions about research.
- **Case Three:** children and young people who potentially have the capacity and maturity to make their own decisions about taking part in a particular research study, but who are still considered minors in their domestic legal system.

Role of parents

Ethical considerations that parents should take into account when making decisions with or on behalf of their children include:

- **Respect for children as individuals**, regardless of their age or capacity, expressed, for example, through consideration of children’s wishes.
- **Recognition of children’s developing capacity** for autonomous agency, and parents’ supportive role in helping their child to develop decision-making skills and confidence.
- **Concern for children’s immediate and longer-term welfare.** Longer-term welfare is concerned with children’s and young people’s future ‘good’ including, but not limited to, what is best for them in terms of their physical health or personal interests. Parents also have a responsibility to seek to influence the values that their child acquires as they grow up, and to ‘shape’ the adult they become.

How different parents balance these considerations will depend on many contextual factors including the situation of their child at the time (which of the three cases is applicable), the nature of the decision, and the nature of family relationships.

Understanding welfare

- An understanding of a child’s longer-term welfare should encompass the possibility of contributing to wider social goods, such as participation in properly regulated clinical research.
- The language of ‘best interests’ is often used to capture this general concern for children’s welfare, but is misleading in the context of research. Parental consent to research should be based on their confidence that participation in the proposed research is *compatible* with their child’s immediate and longer term interests.

Challenging vulnerability

- Concerns about the potential vulnerability of children and young people in research should be treated as an alert, and not as an automatic brake on research: a prompt to researchers to ask themselves: ‘Does this research raise particular ethical challenges and what can I do about them?’ Researchers need to work in partnership with children, young people and parents throughout the whole endeavour of research.

Introduction: scope and methodology

- 4.1 In Chapter 1 of this report, we set out the ethos that has underpinned the Working Party's consideration of these issues, both in terms of our approach to the value of research (see paragraph 1.19), and in our emphasis on children's and young people's capacity to engage with the research process and the wider world (see paragraphs 1.20–1.26). In Chapter 2, we looked at how, in practice, children and young people, their families, and professionals approach the option of research involvement, and at the approaches taken by law to the role of children and young people in such decision-making. We then, in Chapter 3, analysed the factors underpinning the initial prioritisation and selection of research topics, the 'threshold requirements' governing clinical research set by international ethical conventions to protect potential participants, and the various means of scrutiny through which research proposals pass in order to ensure the quality of a research study, before researchers are permitted to recruit children and young people to take part in it.
- 4.2 In this chapter, we now draw on our underpinning ethos, on the available empirical evidence, and on our overview of existing regulatory approaches, to analyse the ethical issues at stake in seeking to involve children and young people in clinical research. We will then go on, in the final chapters, to consider the implications of this analysis for ethical conduct by research professionals. As we discussed in our Introduction, our approach has been to root our analysis in the reality of children's and young people's lives, aiming to understand how they and their parents experience the 'offer' of taking part in research in the context of their day-to-day lives. To achieve this, we have drawn both on the published literature, and on the direct contribution of children, young people and their parents to the Working Party's considerations: in stakeholder meetings, through our open consultation in the UK and beyond, and in school workshops in the UK and Kenya (see Introduction and Appendices 2-4).
- 4.3 Thus, rather than beginning with the values and principles set out in international ethical or legal conventions on research and considering how these fit with children's and young people's experiences, we have taken the opposite approach: that of starting with the experiences, concerns, and implicit values, arising out of families' practical experience of research involvement, and considering the extent to which these correlate with, or challenge, traditional thinking about the ethical acceptability of research with children and young people. In particular, we have resisted starting from the assumption that an ethical approach to research with children and young people will necessarily be an adapted version of an ethical approach to research with adults. Children and young people are not simply 'small adults', and we should start our consideration with *their* experiences and concerns.
- 4.4 Inevitably, our consideration of 'what matters' ethically to children and young people, families, and research professionals will touch on issues of wider research governance, applicable to all forms of research involving human participants, whatever their age. However, our central focus of concern, both in this chapter, and in the practical policy recommendations that follow, will be on the specific ethical challenges that arise out of the involvement of children and young people in research. We therefore begin with a consideration of what it is that is ethically different about involving children and young people in clinical research.

What is (ethically) different about children and young people?

Who do we mean by ‘children’?

4.5 As we noted in Chapter 1, the terms ‘children’ or ‘minors’ are used in research guidelines and conventions to refer to a far from homogenous group: from newborn babies to adolescents approaching young adulthood (see paragraphs 1.14–1.15). In order to consider what it is that is potentially different, ethically speaking, about children and young people in research, it is necessary to make some further distinctions within this broad concept of ‘childhood’. The use of simple age categorisations is problematic because of the diversity of children’s intellectual abilities and speed of development, maturity, and experience, including experience of illness (see paragraph 2.30). We therefore suggest the use of three ‘paradigm’ or ‘example’ cases of childhood which raise distinct ethical issues with respect to decision-making in research. These draw not only on the capacities associated with particular stages of childhood development, but also on the complexity of the decision to be made, and on situational and temporal factors (such as emotional turmoil or ill-health) which may affect how children and young people experience, and are able to engage with, the research process.

- **Case One:** children and young people who are not able at this time to contribute their own view as to whether they should take part in research. This case covers all babies and very young children, but may also apply on a temporary basis to older children or young people if they are unconscious, or very unwell. Children in Case One may, of course, express physical and emotional reactions to the *procedures* involved in research, but cannot actively participate in an initial decision as to whether they should undertake them.
- **Case Two:** children and young people who *are* able at this time to form views and express wishes, but who are clearly not yet able to make their own decisions about research involvement without assistance. Many children will be able to express wishes and preferences in this way from a relatively young age. The sophistication of their views will vary significantly.
- **Case Three:** children and young people who potentially have the intellectual capacity and maturity to make their own decisions about taking part in a particular research study, but who are still considered to be ‘minors’ in their domestic legal system. ‘Capacity’ to make a particular decision should be understood both in terms of the intellectual capacity to understand what is involved and the emotional maturity and experience to understand the wider picture – for example, the likely impact on their future life.

4.6 All children, at the beginning of their lives, will fall into Case One, and most (although not all) will progress over time through Case Two to Case Three. Some children with learning disabilities, for example, may not reach Case Three, although this should never be assumed simply on the basis of a diagnostic label. Although the developmental aspect of childhood means that most children, most of the time, will progress in a linear way through these three paradigm cases, it is nevertheless impossible to suggest meaningful age ranges for each case. This is because the case that is relevant to the situation of a particular child or young person will depend not only on their own maturity and development (combined with other factors such as temporary diminution of capacity), but also, critically, on the *nature* of the proposed research, and hence the nature of the decision to be taken. Thus, Case One might potentially cover

an unconscious 14 year old whose parents are asked to consent to involvement in emergency research; or a frightened seven year old in severe pain whose parents need to make an immediate decision about commencing participation in cancer research on the day of diagnosis; as well as all babies. Case Two might cover a three year old who is a potential participant in a vaccine trial; a 12 year old who is not used to being trusted with his own decisions in a study about his levels of physical activity; or a 15 year old with a life-limiting condition faced with the prospect of participating in a phase 1 trial.⁴⁵⁰ Finally, Case Three might cover a confident and articulate eight year old invited to participate in research about her experiences of using a particular health service; a 13 year old taking part in a study concerned with use of tobacco and alcohol; or a 14 year old used to accepting responsibility to take part in a cognitive study including brain scans.

- 4.7 The primary purpose of these paradigm cases is thus not to provide simple answers to how children at particular ages should be treated in clinical research, but rather to indicate three quite distinct *situations* in which a child's or young person's potential for input into a decision about research raises distinct ethical questions, both for their parents and for professionals involved in research. We return to these cases at different points throughout this chapter.

The role of parents

- 4.8 This **developmental** aspect of childhood, from the complete helplessness of a baby in Case One to the relative self-sufficiency of a young person in Case Three, provides a pointer in identifying what it is that is distinct or 'special' about childhood. A factor that unites all three cases, correlating directly with this developmental nature of childhood, is that children have **parents** (understood in the broadest possible sense of one or more adults taking on a role of parental responsibility whether or not they have a biological connection with their child) who play an important role, from both legal and ethical perspectives, with respect to making decisions on their behalf.⁴⁵¹ While it is certainly the case that some children, such as those in child-headed households,⁴⁵² or street children, do not have any such adult taking a protective interest in their welfare, we suggest that such circumstances should be regarded as exceptional (in the sense of being problematic, even if not necessarily rare) and deserving of separate analysis (see paragraphs 6.37–6.41 for a discussion of researchers' responsibilities in such circumstances).⁴⁵³ We therefore suggest that these two factors – the developmental nature of childhood, and the complementary role of the parent – help explain why it is important to consider the ethical challenges that arise in research with children

⁴⁵⁰ For an illustration of children's capacity to understand and engage, see Myra Bluebond-Langner's work with dying children: "[all] of the leukemic children whom I studied faced death with a great deal of understanding about the world of the seriously ill and their place in it. They knew the institution and disease as well as any lay adult." See: Bluebond-Langner M (1978) *The private worlds of dying children* (Princeton: Princeton University Press), at page 135.

⁴⁵¹ As we noted in Chapter 1, we use the term 'parent' in this report to cover all those with 'parental responsibility' for a child: that is, those who are legally entitled to make decisions for and with the child. In the UK context, for example, this will include legally appointed guardians and also many others, such as grandparents, who have acquired parental responsibility through a parental responsibility order or residence order.

⁴⁵² It was reported at the Global Health Bioethics Network summer school in Malawi (July 2014) that in Malawi alone over a million children live in such households.

⁴⁵³ See: Clacherty G and Walker J (2011) *Including street children: a situational analysis of street children in Durban, South Africa*, available at: <http://www.streetchildrenresources.org/wp-content/uploads/2013/01/including-street-children-south-africa.pdf> who highlight the ethical imperative of ensuring that these particularly excluded groups of children and young people are appropriately included in research, especially given that the distinct threats to their health and safety posed by their living conditions.

separately from those challenges that may arise in research with others considered as vulnerable in some way, such as adults who lack capacity.

4.9 The nature of the parenting role is in a constant state of change and evolution throughout children’s development, from the starting point of children’s complete vulnerability and dependence on others, until the points when in practice and/or in law they are regarded as sufficiently mature to take responsibility for their own actions in particular spheres (see paragraph 2.64). Even when children formally reach the age of majority in their own jurisdiction, parents do not stop being parents: young adults may depend on their parents (both practically and emotionally) long into adult life, and in most cases emotional ties between parent and child will continue to evolve during the lifetime of both parties.⁴⁵⁴ However, at the point when children become legally adult, the powers and responsibilities inherent in the parenting role alter fundamentally. We therefore suggest that a starting point for considering what is *ethically* distinct about children is a consideration of the role of the parent towards their minor child (legally defined), both in general, and in specific application to decision-making in research. Such an analysis will also help us understand the role of others who may, in particular contexts and at particular times, have recognised responsibilities towards children: for example, teachers, health professionals and researchers.

4.10 Drawing on the input the Working Party received directly from children, parents and professionals in consultation responses, the published literature on decision-making in research with children (see Chapter 2), and ethical analysis of ‘good’ parenting decisions,⁴⁵⁵ we identified at least three distinct ethical considerations that parents should take into account when making decisions with or on behalf of their children:

- respect for children as **individuals**, regardless of their age or capacity;
- recognition of children’s **developing capacity for autonomous agency** and the supportive or educational role of parents in helping their child develop and ‘practise’ decision-making skills and confidence; and
- concern for children’s immediate and longer-term **welfare**.

In addition to ethical considerations that will inform the way parents make decisions on behalf of, or with, their children, parents need also to take account of any **practical constraints** that might influence what options are genuinely open to them with respect to a particular decision. These practical constraints may also at times have ethical importance. We consider the three ethical considerations, and the issue of practical constraints, in more detail below.

Children as individuals

“Well, you should let your parents maybe give an opinion but it is your choice!”⁴⁵⁶

⁴⁵⁴ See, for example, Arnett J (2004) *Emerging adulthood: the winding road from the late teens through the twenties* (Oxford: Oxford University Press). See also: Kuther TL, and Posada M (2004) Children and adolescents’ capacity to provide informed consent for participation in research *Advances in Psychology Research* **32**: 163-73, at page 168 where they note: “parents remain influential through young adulthood. It appears that the voluntary element of consent is complex.”

⁴⁵⁵ See, in particular, Rosati C (2006) Preference-formation and personal good *Royal Institute of Philosophy Supplement* **59**: 33-64.

⁴⁵⁶ Comment by year four child (aged 8-9), reported in Nuffield Council on Bioethics (25 November 2013) *Blog: what do you mean - ask children?!*, available at: <http://blog.nuffieldbioethics.org/?p=907>.

“You’re your own person and you don’t have to do something if you don’t want to.”⁴⁵⁷

“Children [taking] part in research should be treated as research participants and not just a means to research findings.”⁴⁵⁸

- 4.11 The notion of respecting children as individuals, regardless of their age or capacity, is described by the philosopher Connie Rosati as “regard for the child as the distinct individual that she is”.⁴⁵⁹ This regard for children as distinct individuals was expressed by consultation respondents both in terms of consideration of children’s wishes, and respect for their bodily integrity. One parent, for example, commented that “even at five my child knows what he will and won’t do”,⁴⁶⁰ while a young person put the view forcefully that “it’s your body and you shouldn’t be forced to agree to doing something you don’t want to or aren’t comfortable with.”⁴⁶¹ Such consideration of children’s preferences does not, however, necessarily entail giving children a *veto*, whether in connection with research participation or with respect to other aspects of parental decision-making.⁴⁶² As we discuss below (see paragraphs 4.18–4.33), parents must also take into account questions of their child’s welfare which may, at times, run directly counter to their immediate preferences. The preferences of a very young child with respect to participation in research elements of cancer treatment, for example, are unlikely to be the only factor in parental decision-making. Moreover, as we saw in Chapter 2, there is considerable evidence of the value placed by many children and young people (including those approaching adulthood) on shared decision-making with their parents (see paragraphs 2.30–2.32). However, regard for children and young people as individuals and respect for their sense of self provides a powerful reason for ensuring that they are *involved* in any decision that affects them.
- 4.12 Regard for children and young people as individuals should not, however, be understood as respect for ‘partial capacity’. Clearly, as children develop and mature, their ability to make decisions on their own also evolves, and part of the parental role is to support that process (see paragraph 4.13). Decisions, whether about research participation or anything else, vary in complexity, and children will have the capacity to make some decisions long before they have the capacity to make others. The role of parents where their minor children *do* have capacity to make a particular decision about research involvement is discussed below (see paragraphs 4.42–4.50). However, where children make a choice or express a preference *without* that capacity and maturity, it is not meaningful to regard their choice as ‘partially capacitous’ but rather as

⁴⁵⁷ Fifteen year old, responding to the Survey Monkey questionnaire for young people. See: Nuffield Council on Bioethics (2015) *Survey Monkey questionnaire: analysis of young people’s responses*, available at: <http://nuffieldbioethics.org/project/children-research/evidence-gathering-activities/>.

⁴⁵⁸ Fasela Emmanuel, NIMR, Lagos, Nigeria, responding to the Working Party’s call for evidence.

⁴⁵⁹ Rosati C (2006) Preference-formation and personal good *Royal Institute of Philosophy Supplement* 59: 33-64, at page 38.

⁴⁶⁰ Nuffield Council on Bioethics (2015) *Survey Monkey questionnaire: analysis of parents’ responses*, available at: <http://nuffieldbioethics.org/project/children-research/evidence-gathering-activities/>.

⁴⁶¹ Nuffield Council on Bioethics (2015) *Survey Monkey questionnaire: analysis of young people’s responses*, available at: <http://nuffieldbioethics.org/project/children-research/evidence-gathering-activities/>.

⁴⁶² See, for example, Uniacke S (2013) Respect for autonomy in medical ethics, in *Reading Onora O’Neill*, Archard D, Deveaux M, Manson N, and Weinstock D (Editors) (London: Routledge), pp94-110.

an expression of will or value that should be given appropriate consideration because of their intrinsic value as an individual (see paragraphs 4.39–4.40).⁴⁶³

Developing capacity

“I would always ensure my child was involved in decision-making processes, recognising her level of maturity and development.”⁴⁶⁴

“... those from eleven onward, aah, those should make their own decision... Ours as parents is to try to help them...”⁴⁶⁵

- 4.13 An important part of the parenting role, as children mature, is to support them in their development into increasingly autonomous decision-makers. As young participants at the Working Party’s stakeholder day told us, children need the “*chance* to learn, and to make their own mistakes”.⁴⁶⁶ At the same time, it is clearly not the role of responsible parents to abandon children to the consequences of their own decision-making if they lack the understanding or experience to recognise the likelihood or gravity of adverse consequences. As we emphasised in our description of the three paradigm cases (see paragraph 4.5), capacity to make a decision independently includes not only the intellectual ability to understand what is involved, but also the maturity and experience necessary to foresee how the implications of what is involved might affect one’s future life (or indeed that of others), and to feel confident in asking others for help in thinking things through.⁴⁶⁷
- 4.14 This role of parents in supporting their children’s emergent ability to make their own decisions and direct their own lives, while ensuring that this exploration of autonomous agency takes place in a relatively safe environment, has been described as one of ‘mediation’ between children’s wishes and what is practically feasible, socially acceptable, or safe in the wider world. The family lawyer, John Eekelaar, for example, suggests that “a primary role of parenting is, indeed, to mediate between the developing personality of the child and the social world”.⁴⁶⁸ The philosopher Garrath Williams similarly describes the “breadth and depth of institutional experience” required to understand the “terms of cooperation” inherent in the social world, and argues that “above all [children] gain this experience under the authority of their parents, who guide them into the fraught world of adult institutions”.⁴⁶⁹ Parents who responded to the Working Party’s consultation made similar claims in connection with their role in guiding

⁴⁶³ See, for example, Williams G (2012) Children as means and ends in large-scale medical research *Bioethics* **26(8)**: 422-30, which argues for the importance of seeing children as ‘ends in themselves’, and the compatibility of this approach with children’s participation in research.

⁴⁶⁴ Nuffield Council on Bioethics (2015) *Survey Monkey questionnaire: analysis of parents’ responses*, available at: <http://nuffieldbioethics.org/project/children-research/evidence-gathering-activities/>.

⁴⁶⁵ 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).

⁴⁶⁶ Nuffield Council on Bioethics (2014) *Note of stakeholder group meeting*, available at: <http://nuffieldbioethics.org/wp-content/uploads/Stakeholder-meeting-note.pdf>.

⁴⁶⁷ See, for example, the discussion in Nedelsky J (1989) Reconceiving autonomy: sources, thoughts and possibilities *Yale Journal of Law and Feminism* **1**: 7-36, at page 11, where Nedelsky argues that “the capacity to find one’s own law can develop only in the context of relations with others (both intimate and more broadly social) that nurture this capacity”.

⁴⁶⁸ Eekelaar J (1994) The interests of the child and the child’s wishes: the role of dynamic self-determinism *International Journal of Law, Policy and the Family* **8(1)**: 42-61, at page 52.

⁴⁶⁹ Williams G (2012) Children as means and ends in large-scale medical research *Bioethics* **26(8)**: 422-30.

and sharing decision-making with their children with respect to research, suggesting: "It should be [an] informed choice and all must be involved to achieve this".⁴⁷⁰

- 4.15 Families will, of course, take a wide range of approaches to the question of how much their children should be encouraged to 'practise' making decisions for themselves and how much opportunity they should have to make their own mistakes. There will be great diversity of approach both between and within different cultural traditions with respect to parenting, and the extent to which children expect to have their voices heard within their families will differ widely around the world.⁴⁷¹ However, we suggest that an inevitable part of any child's development towards adulthood involves increasing responsibility and agency; and that part of the parental role is to support their capacity to handle those responsibilities. The *form* this support may take will vary considerably: it may be highly verbalised, encouraging children to express views and make choices from an early age; or it may be indirect, in placing children in a position where they are expected to take responsibility for themselves or others, such as younger siblings. Whatever form the parental influence may take, children in any culture will be aware of different expectations placed upon them in terms of accepting and managing responsibility between their early childhood and their adolescence.
- 4.16 In general, it is hard to see why any individual child or young person should be treated as *less* responsible in the context of research decisions than he or she is in their daily life.⁴⁷² There are, of course, exceptions to this claim – for example, where children are simply too ill or distressed at the time a research decision is required, or where the responsibilities that they are normally expected to bear are already excessive. We return to these points later (see paragraphs 6.21 and 6.37–6.41).
- 4.17 Recognition of developing capacity includes, by implication, the recognition that the point will come where children can, and will, 'take over' from adults, in the sense of being able to provide their own legally valid consent to proposed research involvement.⁴⁷³ As we discuss below (see paragraph 4.42), this does not necessarily mean that parents will be excluded from a part in decision-making if the young person wishes to involve them, just as adults may find it supportive for a partner or friend to be

⁴⁷⁰ Nuffield Council on Bioethics (2015) *Survey Monkey questionnaire: analysis of parents' responses*, available at: <http://nuffieldbioethics.org/project/children-research/evidence-gathering-activities/>.

⁴⁷¹ 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, which discusses challenges to research in rural Ethiopia where children are not necessarily seen as having 'private views' as subordinate members of the household. The complexity of the picture, however, is demonstrated by Twum-Danso A (2010) The construction of childhood and the socialisation of children in Ghana: implications for the implementation of Article 12 of the CRC, in *A handbook of children and young people's participation: perspectives from theory and practice*, Percy-Smith B, and Thomas N (Editors) (Abingdon: Routledge), pp130-40, who found in her work in Ghana that children commented in group discussions that it was better not to express opinions, but in practice expressed their views privately to their mothers. Family dynamics may also affect parents' decision-making: see, for example, Sun L, and Lin Y (2015) Homogenous mothers-in-law, different daughters-in-law: in-law relationship comparison between Vietnamese and Taiwanese daughters-in-law *Asian Social Science* **11(4)**: 252-8, which notes how, in Vietnam, "the position of the mother-in-law is supreme, and she can dominate over, demand, force and even scold the daughter-in-law."

⁴⁷² Cheah PY, and Parker M (2015) Research consent from young people in resource-poor settings *Archives of Disease in Childhood* **100(5)**: 438-40; 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/>, at page 16.

⁴⁷³ See, for example, Ross LF (1998) *Children, families and healthcare decision-making* (New York: Oxford University Press); Manson N (2014) Transitional paternalism: how shared normative powers give rise to the asymmetry of adolescent consent and refusal *Bioethics* **29(2)**: 66-73.

involved.⁴⁷⁴ However, in such circumstances, the role of a parent will cease to be that of a ‘mediator’ between their child and the world, and become more like that of an equal; offering support, as needed. This shift into capacitous decision-making should not, of course, be seen as a single transition point but as a series of such points, depending on the complexity of the decision: a young person may be capable of making their own decisions in some, but not all, areas and may value more or less support at different times and in different circumstances.

Welfare: moving on from ‘best interests’

“Best interests are helpful when a child has an obvious need. Does a particular child ‘need’ to participate in research? Certainly all children need research to be done.”⁴⁷⁵

“It... offers flexibility in that there can be a number of legitimate views as to what is in the best interests of a child.”⁴⁷⁶

“[‘Best interests’] is not helpful at all. Even for therapeutic trials, the treatments are given not primarily that the child should get well, but to objectively evaluate if the medicine works.”⁴⁷⁷

“‘Best interests’ in the research context are difficult to define given that the inherent nature of research, and the rationale for undertaking it, will inherently mean that outcomes are difficult to predict.”⁴⁷⁸

4.18 A crucial part of the parents’ role is to promote their child’s welfare: taking care of their child both in terms of protecting them from possible harms and in doing what is ‘good’ for them. This role is often captured in the language of ‘acting in a child’s best interests’ although, as we argue below, the use of the word ‘best’ may, at times, create more confusion than clarity. Concern for a child’s welfare may usefully be separated into concern for their *immediate* welfare at the time of the research (such as any pain, anxiety, distress, or enjoyment associated with participation in research) and for their *longer-term* welfare (their future ‘good’, including, but not limited to, questions of what is ‘best’ for them in terms of their physical health or personal interests – see paragraph 4.27). Parents who responded to the Working Party’s survey highlighted factors such as the burden of invasive procedures and discomfort as examples of immediate concerns they might have in connection with research, along with anxiety about the risks of more permanent physical and emotional harm, or invasions of privacy. They also noted possible ways in which participation could be good for their child: for example, in terms of their child’s own health (“better care from their medical team” or “potential to get access to an innovative treatment”); enjoyment (“children like to take part in new things, and might enjoy the experience”); and more broadly in terms of inculcating the value of benefitting others (“encouraging my child to help others”).⁴⁷⁹

⁴⁷⁴ 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) which found that mothers play a supporting role in treatment decisions well into their children’s early adulthood.

⁴⁷⁵ Anonymous respondent to the Working Party’s call for evidence.

⁴⁷⁶ Professor Jo Bridgeman, responding to the Working Party’s call for evidence.

⁴⁷⁷ Roma Chilengi, responding to the Working Party’s call for evidence.

⁴⁷⁸ Health Research Authority, responding to the Working Party’s call for evidence.

⁴⁷⁹ Nuffield Council on Bioethics (2015) *Survey Monkey questionnaire: analysis of parents’ responses*, available at: <http://nuffieldbioethics.org/project/children-research/evidence-gathering-activities/>.

Children and young people raised a similar range of possible benefits and concerns with respect to taking part in research (see paragraphs 2.20–2.23).

- 4.19 While individual children and young people may have very different feelings about particular procedures, such as the prospect of a blood sampling, judgments about whether their immediate welfare is affected by the proposed research are likely to be relatively uncontested. Something that distresses children or makes them anxious will be a matter of concern with respect to their welfare. Conversely, if children show interest or enjoyment in taking part, parents will be reassured that participation is having a positive effect on their short-term welfare.
- 4.20 What constitutes children's or young people's longer term welfare, on the other hand, may be more hotly contested. As we noted at the beginning of this report (see paragraph 1.10), the primary purpose of research is an attempt to derive generalisable new knowledge that may benefit others in the future. While a research protocol may include elements of treatment such as a novel medicine or intervention, procedures undertaken for research purposes (whether these are additional tests to collect data, or the randomisation of patients to one or another arm of a comparative study) do not directly aim to *benefit* participants. On the other hand, one of the most important tasks of the peer and ethical review processes described earlier is that of protecting potential participants from unjustified *harm* by ensuring that any risks and burdens involved in these research-related procedures are reduced to an acceptable minimum, and the risks involved in any therapeutic element are proportionate to the hoped-for benefits (see paragraphs 3.48–Box 3.1).
- 4.21 Thus, in considering how children's longer term welfare might be understood, we have to confront directly the question of whether parents may, ethically or legally, consent to something 'being done' to their child that does not have the primary aim of benefiting them (even if, in the event, their child happens to derive some benefit from it, whether emotional or physical). Children, like adults, may of course be *willing* to take part in research for altruistic reasons (see paragraphs 2.20–2.21), but if it is the case that parents can only consent to what is 'best' for their child, it is difficult to see how such a requirement would permit, for example, invasive procedures that are not directly associated with their child's healthcare. Indeed, legal advice given to the Medical Research Council (MRC) in the 1960s suggested that no 'non-therapeutic' medical research with children under the age of 12 could be lawful precisely because such research could not be in their best interests.⁴⁸⁰
- 4.22 We suggest that these concerns as to the scope of parental decision-making are misplaced for two reasons. First, in the specific legal context of the UK, we argue that parents are not obliged (and could not practically or ethically *be* obliged) to act at all times in the 'best' interests of their children, since interests within families will often compete, and will have to be balanced. Second, from a broader ethical perspective, we suggest that the notion of *promoting* children's longer-term welfare should be understood in a more holistic way than that implied by the terminology of 'best' interests.

⁴⁸⁰ See: Kennedy I (2001) *Treat me right: essays in medical law and ethics* (Oxford: Clarendon Press), at page 5. Kennedy traces how this approach has shifted to a focus on the importance of limiting the degree of risk to which children are potentially exposed.

- 4.23 The language of ‘best’ interests is widely deployed in the context of children’s research⁴⁸¹ for at least two reasons. For clinicians, there is an inevitable crossover between research and treatment, and despite the central ethical and legal importance of parental consent for the care of children (see paragraph 4.25), clinicians treating children will always *recommend* the care that they believe to be ‘best’ for a particular child in light of his or her medical condition and the treatment options available. Moreover, the legal and ethical requirement in the UK for health professionals to treat *adult* patients who lack capacity in their own best interests is well established.⁴⁸²
- 4.24 The term ‘best interests’ is also commonly used in a legal context, when courts are called upon (for example, by health authorities) to determine what action will best promote the welfare of a child when this is contested.⁴⁸³ Disagreements leading to court determinations may arise either between parents (for example, in the family courts when determining the living arrangements of children whose parents are divorcing), or between parents and health or social care professionals (if significant disagreement exists between what parents want, and what professionals believe to be the best course of action for a child). There are many cases where the opportunity for a court to consider, independently, what course of action would be ‘best’ for a child has been highly valuable in finding a way forward in areas where there are genuine and sincerely-held differences of opinion. Such differences may particularly arise in connection with decisions about treatment near the end of a child’s life.⁴⁸⁴ Similar considerations might also arise in cases where access is desired to unlicensed treatment that is only available in the context of research, and where there is no consensus on its appropriateness.⁴⁸⁵ In such cases, however, the decisions as to what is ‘best’ for a child would relate first and foremost to his or her own *treatment* needs, and not to procedures undertaken for research purposes, even though at times the treatment might only be available within the ‘package’ of research.
- 4.25 Although such legal procedures exist to resolve parental and professional differences of opinion, it is important to note that challenges of this kind will only be brought to court where parents’ actions are believed to fall *outside* a wide spectrum of acceptable decision-making by parents. They will not be brought simply because a health professional takes a different view from that held by a parent. Nor, other than in emergency, may a health professional simply ignore parental decisions and act in what they believe to be a child’s best interests without first seeking court authorisation.⁴⁸⁶
- 4.26 The breadth of this spectrum of ‘acceptable’ parental decision-making derives both from an understanding that what is ‘good’ for children extends well beyond their physical well-being (a point to which we return in more detail below), and also from the impossibility, on a practical level, of the interests of one person in a family always

⁴⁸¹ See, for example, use of the term by respondents to our call for evidence: 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/>, pp38-43.

⁴⁸² Mental Capacity Act 2005, and formerly in case law.

⁴⁸³ See section 1(1) of the Children Act 1989. ‘Best interests’ and ‘welfare’ are regularly used interchangeably in the case law: see, for example, *Re Wyatt (a child) (medical treatment: continuation of order)* [2005] EWCA Civ 1181 at 79 and 87; and *Re A (children) (conjoined twins: surgical separation)* [2001] 2WLR 480 at 512.

⁴⁸⁴ See, for example, the case of *NHS Trust v. Baby X and others* [2012] EWHC 2188. Ian Kennedy, however, has criticised the use of the language of ‘best interests’ also in this context, on the basis that it simply serves to legitimise decisions based on instinct (a form of ‘*ad hocery*’) with the “empty rhetoric of best interests”: Kennedy I (2001) *Treat me right: essays in medical law and ethics* (Oxford: Clarendon Press), at page 395.

⁴⁸⁵ See, for example, the case of *Simms v. Simms and another*; *PA v. JA and another* [2002] EWHC 2734, although it should be noted that in this case the proposed intervention was described as “pioneering treatment”, rather than treatment provided in the context of research.

⁴⁸⁶ English judges are able to hear urgent applications concerning medical treatment at very short notice: see *Glass v. United Kingdom* [2004] 1 FLR 1019.

taking precedence (see paragraph 4.34). Parents also have responsibilities to take into account the interests of other children in their family, of adult family members for whom they may have caring responsibilities, and indeed of each other and themselves.⁴⁸⁷ On a mundane level, this may mean children being unwillingly 'dragged along' to their sibling's sporting or other leisure activities; on a more serious level, parents may exceptionally be forced to confront the question of whether they should consent to one child being a bone marrow donor for a sibling. At times, children's immediate interests may need to be subordinated to adult or wider family interests, such as where adult illness or other difficulties in the family temporarily dominate family decision-making.

- 4.27 While this constraint on parents' ability to act always in their child's 'best' interests may seem, at first sight, primarily a *practical* one, the practical demands placed on parents by others also serve to illuminate our second claim in paragraph 4.22: that what is 'good' for a child *must* extend beyond what is easy or enjoyable or nice for them, or that which is needed to promote their physical or emotional well-being. As we argued in Chapter 1, children are able, and expected, to begin to take their place in the social world around them from an early age (see paragraphs 1.21–1.25). While one part of the parental role, as we suggest, is to have regard to the unique individual that their child is (see paragraphs 4.11–4.12), this parental function is complemented by a responsibility to seek to influence the values that their child acquires as they grow up: that is, to shape the kind of person their child becomes. This 'shaping' includes influencing how children understand their responsibilities to others, as social beings.⁴⁸⁸ Thus, as Garrath Williams argues: "first... each of us is duty-bound to contribute to social goods in *some* ways, and second... this duty is one that we are duty-bound to lead our children into. We do so partly by our own example, and partly by requiring them to undertake it."⁴⁸⁹
- 4.28 **We therefore suggest that an understanding of children's long-term welfare should encompass the possibility of contributing to wider social goods. Such a contribution could take the form of participation in properly regulated clinical research in order to contribute to the knowledge base necessary to improve healthcare for all children in the future.** Any desire to make such a social contribution may, of course, go alongside many other factors also relevant to the welfare of particular children, such as the prospect of improvements in healthcare that could directly benefit them in future; or indirect benefits such as greater attention from clinicians and researchers; or enjoyment in taking part. However, such prospect of (or belief in) personal benefit for child participants should not be regarded as an ethical prerequisite for parents to consent to participation.
- 4.29 This is not, of course, to say that either adults or children have a specific *duty* to take part in research; rather that, in determining what is good for their children, parents are not only permitted but *required* to take into account the fact that their children are

⁴⁸⁷ See, for example, Ross LF (1998) *Children, families and healthcare decision-making* (New York: Oxford University Press) for a description of families as having 'group goals' which are distinct from the individual goals of family members; and Buchanan A, and Brock D (1990) *Deciding for others: the ethics of surrogate decision making* (Cambridge: Cambridge University Press) for a justification of why parents may take into account both their own self-interests and their obligations to their other children. For an overview of ethical arguments in this field, see: McDougall RJ, and Notini L (2014) Overriding parents' medical decisions for their children: a systematic review of normative literature *Journal of Medical Ethics* **40(7)**: 448–52.

⁴⁸⁸ See, for example, Herring J, and Foster C (2012) Welfare means relationality, virtue and altruism *Legal Studies* **32(3)**: 480–98.

⁴⁸⁹ Williams G (2012) Children as means and ends in large-scale medical research *Bioethics* **26(8)**: 422–30, at page 426.

growing up in a particular social context, and need to learn to take their adult place in that society. Participation in properly regulated research offers one possible opportunity for expressing social solidarity, and hence may be regarded as ‘good’ for the child.⁴⁹⁰

- 4.30 Returning, then, to the question of terminology: in the context of court proceedings in the UK concerned with children’s welfare, the courts’ focus on what is ‘best’ for one child is understandable, given that such proceedings arise precisely because of significant levels of disagreement over the right course of action in a particular case.⁴⁹¹ It is also important to note that the terminology of ‘best’ interests has, in fact, increasingly been interpreted by judges in the broader way described above, with many factors other than a child’s physical well-being taken into account in judging what is best for that child, both in cases relating to medical care,⁴⁹² and those relating to wider aspects of a child’s upbringing.⁴⁹³ However, it was clear from our consultation responses that, in the very different context of day-to-day parental and clinical decision-making with respect to children’s participation in research, the language of ‘best’ interests was deeply problematic. Indeed respondents used the term in directly conflicting ways. Some saw it as clearly objective, suggesting an understanding based on children’s personal medical needs. Others argued it was entirely subjective, by implication recognising the very disparate attitudes different parents might take to what constituted their children’s welfare, and equally the diversity of children’s and young people’s *own* attitudes.
- 4.31 Other respondents suggested that the term should be understood with reference to the needs of *all* children and young people to receive evidence-based healthcare, thus eliding the interests of individual child participants and the interests of all potential beneficiaries of the research.⁴⁹⁴ There is clearly an important distinction to be made between what is ‘good’ or ‘best’ for children as a class, and what is ‘good’ or ‘best’ for a *particular* child. The bioethicist Seema Shah, for example, highlights how vaccination programmes are ‘good’ for children, because the benefit/risk ratio is highly favourable for children as a group, but that nevertheless it may be in the ‘best interests’ of some particular children *not* to be vaccinated, because of their particular health conditions. In such examples, describing vaccination as being in ‘children’s best interests’ may in fact be dangerous because of the risk that the particular needs of children for whom vaccination is contraindicated may be overlooked.⁴⁹⁵ One way of avoiding this confusion may be to avoid the term ‘best interests’ altogether when considering the interests of a group, and to use instead the language of likely ‘benefits and harms’ of a procedure.
- 4.32 Given the various difficulties described above, the Working Party does not believe that, in the specific context of participation in research, the terminology of children’s or

⁴⁹⁰ See also: Lyons B (2012) Solidarity, children and research *Bioethics* **26(7)**: 369-75 for a discussion of research participation by children as an example of social solidarity.

⁴⁹¹ Note, however, that where courts are asked to consider the interests of siblings, they have explicitly considered the sets of interests together, rather than making two separate ‘best interests’ judgments: see, for example, *Re T and E* (proceedings: conflicting interests) [1995] 1 FLR 581, a case involving care and adoption proceedings, where the court took both children’s welfare into account and balanced them against each other. If an order would greatly benefit one child and slightly disadvantage the other, then the order should be made.

⁴⁹² See, for example, *Re Wyatt* (a child) (medical treatment: continuation of order) [2005] EWCA Civ 1181.

⁴⁹³ See, for example, *Re G* (children) [2012] EWCA Civ 1233 at 29 where Munby LJ took the view that a child’s happiness “can include such things as the cultivation of virtues and the achievement of worthwhile goals, and all the other aims which parents routinely seek to inculcate in their children”, and should not be understood as “pure hedonism”.

⁴⁹⁴ 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/>.

⁴⁹⁵ Shah S (2013) Does research with children violate the best interests standard: an empirical and conceptual analysis *Northwestern Journal of Law & Social Policy* **8(2)**: 121-73. See also: Huxtable R (2004) *Re C* (A Child) (immunisation: parental rights) [2003] EWCA Civ 1148 *Journal of Social Welfare and Family Law* **26(1)**: 69-77.

young people's 'best' interests is particularly helpful either to those responsible for making decisions about their research participation, or those responsible for designing or reviewing research protocols. We note that research guidance issued by bodies such as the MRC and the Royal College of Paediatrics and Child Health (RCPCH) already avoids its use: in its 2004 guidance, the MRC requires that research should not be "contrary to the child participant's interests";⁴⁹⁶ while the RCPCH, in its 2014 update to its earlier guidance, uses the terminology of children's 'interests' only in the context of the collective interests of all children to be able to receive healthcare "assured by research".⁴⁹⁷

- 4.33 However, in inviting children and parents to contribute to the social goods of research, researchers must, of course, be confident that the study protocol does not pose undue risks or burdens for children and young people. Thus, alongside participation in research understood as "an act of care for others", as characterised by one of our consultation respondents, there must, of course, be concern for the physical and emotional well-being of every child participant. **We therefore suggest that parental consent to research should be based on their confidence that participation in the proposed research is compatible with their child's immediate and longer term interests.** An emphasis on the compatibility of children's interests with the demands of research participation both maintains the interests of the individual participant rightly at the forefront of consideration, while avoiding the misleading implication that participation may only be acceptable if it is the 'best' (which may be understood as the 'only') option for a particular child or young person. We return later to the associated responsibilities of both researchers and those responsible for the review of research proposals in this respect (see Chapters 5 and 6).

The relevance of practical constraints

- 4.34 Finally, in addition to these three ethical considerations (that is, respect for children's individuality, respect for their developing autonomy, and concern for their welfare), consultation respondents also echoed the findings of our literature survey in emphasising the *practical* constraints that may hinder participation (see paragraphs 2.14–2.15). Parents who responded to the Working Party's online survey highlighted factors such as the convenience of the location; whether travel, parking and accommodation expenses were covered; and the extent to which participation coincided with treatment schedules, as important logistical constraints that might prevent children taking part in research even if they and their parents actively wished to participate. While such constraints are essentially practical in nature, they do, nevertheless, illustrate further an ethical factor influencing decision-making within a family that emerged in our earlier discussion of best interests: the fact that other family members will also have legitimate needs that at times will take precedence (see paragraphs 4.26–4.27). In the context of research participation, these familial considerations are, primarily, likely to be relevant in *refusing* participation that might otherwise have been accepted. These considerations also raise the issue of the extent of research professionals' responsibilities to seek to keep these constraints to a

⁴⁹⁶ Medical Research Council (2004) *MRC ethics guide: medical research involving children*, available at: <http://www.mrc.ac.uk/documents/pdf/medical-research-involving-children/>, at paragraph 4.3.

⁴⁹⁷ Modi N, Vohra J, Preston J *et al.* (2014) Guidance on clinical research involving infants, children and young people: an update for researchers and research ethics committees *Archives of Disease in Childhood* **99(10)**: 887-91, at page 887. The guidance uses the concept of what is "important for the individual child" when considering whether risks that are more than minimal or low can be justified.

minimum. We return to the wider question of professionals' responsibilities in Chapter 5.

Decision-making in the paradigm cases

4.35 We have emphasised earlier in this report that clinical research covers a wide range of possible activity (see paragraphs 1.5–1.9 and 3.48). Children, young people and their families also differ significantly. We were reminded by our stakeholder group that “families operate in very different ways, and researchers need to be aware of that”.⁴⁹⁸ Thus, the way in which these three ethical factors, along with any practical constraints, will be weighed in practice will be different – depending, for example, on the individual child or young person, their parents, the context of the research, and the circumstances of the family. No ethical guidance or regulation with respect to the involvement of children in research can hope to specify precisely the ‘right’ weight to be given to respecting a child’s worth as an individual, encouraging their developing capacity, and protecting and promoting their welfare in any individual case. However, a consideration of how the balance is likely to *shift* as children progress through the three cases described in paragraphs 4.5–4.7 casts light on some of the most contested areas of ethical debate described in earlier chapters of this report: those of children’s own ‘say’ in research decisions, and the question of how parents may justify exposing their children to potential discomfort, if not risk, through research participation.⁴⁹⁹ In turn, this will help us to clarify the ethical basis of *researchers’* responsibilities to the children whom they seek to recruit into research.

4.36 In **Case One**, the feature that distinguishes a child’s position from that of children and young people in Cases Two and Three, and from adults, is the inability of the child or young person to take part in a decision about whether they should participate in the research (as opposed, for example, to indicating physical or emotional responses to any procedures involved in that research). Hence the sole focus is on the role of *others* (first and foremost children’s parents) in making decisions on behalf of their child. We discuss later in this chapter some of the problems that arise when children are automatically assumed to be ‘vulnerable’ in research in a way that adults are not (see paragraphs 4.53–4.61). However, the babies, children, and young people falling within this case, whether on the basis of their stage of development or because of temporary incapacity, are very clearly ‘vulnerable’ in a way that children in Cases Two and Three may not be, in that at this point they are entirely dependent on others to make decisions for them.⁵⁰⁰

4.37 Parents’ primary concern in such circumstances will be for the *welfare* of their children. However, this will not be a question with a single right answer: parents of children in similar positions may come to different conclusions about the acceptability of particular procedures. Such differences in judgment will arise because of the diversity of parental views as to what constitutes their child’s welfare, both in the immediate present, and in the longer term. There may be particular diversity with respect to the value placed on

⁴⁹⁸ Nuffield Council on Bioethics (2014) *Note of stakeholder group meeting*, available at: <http://nuffieldbioethics.org/wp-content/uploads/Stakeholder-meeting-note.pdf>.

⁴⁹⁹ In recognising this as an important concern for many of those involved in research with children and young people, the Working Party is also alert to the evidence that, in practice, many parents give consent to research at least partially because of a belief or hope that it will be of direct benefit to their own child: see paragraph 2.22.

⁵⁰⁰ See, for example, 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), where very young children’s “fragility”, dependency and inability to express or defend themselves was felt to raise very different questions with respect to research participation, compared with those arising in connection with the participation of older children.

contributing to wider social goods, such as the knowledge obtained through research (see paragraph 2.21). Differences in judgment will also arise out of respect for their child as an *individual*, however young: for example, in terms of the potential for distress caused by the research interventions to *this* particular child. Such considerations are clearly also encompassed under the banner of concern for their child's immediate welfare interests – but the fact that children can and do have quite disparate reactions to the same procedures highlights the personal and individual nature of such responses and needs.⁵⁰¹

4.38 Finally, as we discussed above (see paragraphs 4.26–4.27), parents may legitimately take into account their *own* needs and values in making a decision about research participation, or indeed may simply be unable to make a decision because of the stress of the situation. As the quotations in Box 4.1 illustrate, in some cases being asked to take part in research that is unlikely to be of direct benefit to their own child may simply be one burden too many for parents to bear at a difficult time. Much is assumed about the 'vulnerability' of children: but parents too may be placed in impossible circumstances where they may feel highly anxious and unsupported.⁵⁰² We return to the implications of the difficult, sometimes impossible, situations in which parents may find themselves in our analysis of the concept of vulnerability (see paragraph 4.61) and in our consideration of the implications for professional responsibilities (see paragraph 6.26 and Box 6.4).

Box 4.1: Examples of decision-making in Case One

"You just think 'Oh God, something else, another thing to have to think about' when you've got this little baby and all you can think about is if he's going to be ok."⁵⁰³

"I was thinking, the longer I take to make this decision, the longer [he] has to wait for something to help him. You know if I took like twenty four hours to decide... he might have deteriorated so much that the nitric oxide might not have [worked] on him."⁵⁰⁴

"Would I want to go on an in-depth interview during that period [after premature birth]? No, I don't think so. I don't think I'd have the sanity or patience to do something like that."⁵⁰⁵

"My son has recently been diagnosed with an incurable and life-limiting condition and one that will result in profound physical disabilities, so taking part in clinical research into a treatment or cure could be hugely significant for him."⁵⁰⁶

"She is a small child, under five years, she cannot tell you where she hurts. She can tell you the hand is hurting only to find that it's hurting inside there, so expressing herself becomes a problem."⁵⁰⁷

⁵⁰¹ See, for example, Alderson P, Hawthorne J, and Killen M (2005) The participation rights of premature babies *The International Journal of Children's Rights* 13: 31-50.

⁵⁰² See, for example, Kodish ED, Pentz RD, Noll RB *et al.* (1998) Informed consent in the children's cancer group *Cancer* 82(12): 2467-81.

⁵⁰³ Jollye S (2009) An exploratory study to determine how parents decide whether to enrol their infants into neonatal clinical trials *Journal of Neonatal Nursing* 15(1): 18-24, at page 20.

⁵⁰⁴ Snowden 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, at page 2286.

⁵⁰⁵ Ward FR (2010) Parents' views of involvement in concurrent research with their neonates *Journal of Empirical Research on Human Research Ethics: JERHRE* 5(2): 47-55, at page 50.

⁵⁰⁶ Nuffield Council on Bioethics (2015) *Survey Monkey questionnaire: analysis of parents' responses*, available at: <http://nuffieldbioethics.org/project/children-research/evidence-gathering-activities/>.

4.39 In **Case Two**, the feature that distinguishes the position of children or young people (and potential parental response) from the other two cases is their ability to form and express views about the invitation to take part in research, or particular aspects of the research. However, this ability falls short of the intellectual capacity and emotional maturity required to make the decision about research participation on their own.⁵⁰⁸ In this case, in addition to making judgments about their child's immediate and longer term welfare, parents will need to determine how these factors should be balanced both against the respect due to their child's own views and feelings on taking part in the research, and their general educational obligation to develop their child's decision-making capacity. As we note above (see paragraph 4.35), there can be no simple calculus as to *how* these factors should be weighed in the balance against each other where they are in potential conflict. Relevant considerations for parents who are making decisions with children or young people in Case Two include:

- the potential for their child to derive direct or indirect benefit from the proposed research, and the likelihood and severity of any associated risks;
- the burden of research participation for their child – for example, whether they have particular anxieties about any of the procedures involved;
- their child's own views and feelings about the proposed research;
- the maturity and understanding of their child;
- the value placed by the parents on the role of participation for their child's longer term welfare;
- the relative strength of their views with respect to the various welfare considerations listed above, and their child's feelings; and
- the likely impact on their child's immediate and longer term welfare of overriding their preferences: for example, the degree of immediate distress and the risk of future lack of trust in clinicians or researchers if they are required to take part against their will.

4.40 The way in which these factors will be balanced will depend on the particular parents, the individual children/young people, and the nature of the decision to be made. As we saw in our review of the evidence, in many circumstances, parents and children will come to a shared decision as to whether or not to participate in a particular study (see paragraphs 2.30–2.33). Where, for example, the research involves no prospect of direct benefit, such as survey-based research about health behaviours or experiences of health services, parents may adopt a 'gate-keeping' role: they may first make their own judgment on whether the burdens involved are acceptable and the research worthwhile, and then, if that judgment is positive, may allow a relatively young child to decide for themselves whether or not to take part.⁵⁰⁹ Alternatively, they may take a view

⁵⁰⁷ 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).

⁵⁰⁸ Note Williams' discussion of research involvement as a form of social contribution, where he emphasises the relevance of children's emotional maturity (experience of "the game" of social relations), rather than intellectual capacity: Williams G (2012) Children as means and ends in large-scale medical research *Bioethics* **26(8)**: 422-30.

⁵⁰⁹ Such an approach could be compared to giving a young child a 'choice' between alternatives that are all acceptable to the parent, such as choices relating to (already approved) meal options, or activities.

that the research is a 'good thing to do', and more actively encourage their child to participate, even if there is initial resistance. In contrast, if the study in question relates to their child's care, such as the prospect of a clinical trial of a new intervention, parents' dominant concern will be for the welfare of their child, their perception of what will be 'best' for them, and their assessment of any additional burdens imposed by procedures related to the research. However, even in these cases, the other factors cited above will be important. Given that, by definition, there will *always* be a degree of uncertainty as to whether an intervention that is the subject of research will be better than any alternatives, then the enthusiasm, or reticence, of children or young people with respect to the proposed study should always play some part in the decision, to a greater or lesser extent depending on all of the other factors in play.

- 4.41 Where parents and their child initially disagree, then, as in other areas of family life, there is likely to be some degree of negotiation within the family. Parents who believe that there are good reasons for their child to participate in research may engage with an initially hesitant or reluctant child in a variety of ways: these may include encouraging, persuading, cajoling, distracting or indeed bribing them to take part. As Garrath Williams notes in his justification of the involvement of children in research: "As children we learn very early that we have to do things we dislike or did not expect as part of acting together with others."⁵¹⁰ Children's *anxieties* about taking part in research, particularly with respect to pain or discomfort, should, however, always be taken very seriously (see case study of vaccine research in Box 6.2 on page 154). If a child remains clearly opposed to participation, then there would have to be strong reasons relating to welfare (longer-term good) in order to justify overriding their preferences and sense of self-worth.

⁵¹⁰ Williams G (2012) Children as means and ends in large-scale medical research *Bioethics* **26(8)**: 422-30. See also: John T, Hope T, Savulescu J, Stein A, and Pollard AJ (2008) Children's consent and paediatric research: is it appropriate for healthy children to be the decision-makers in clinical research? *Archives of Disease in Childhood* **93(5)**: 379-83, at page 380, where children were invited to take part in a follow-up to a vaccine study which involved blood tests. When asked whether they would respect their child's decision not to participate, the majority of parents said they would, but half would use a variety of methods in persuasion first.

Box 4.2: Examples of decision-making in Case Two

“We should talk about it and decide, but because I am 13 I should have a lot of say.”⁵¹¹

“I’m not really a fan of having blood taken.”⁵¹²

“Usually when they want me to know something they usually tell my mom, and if she thinks that I should know then she tells me. Because I get overwhelmed with things really easy, she doesn’t tell me until the last minute so I don’t have any other choice. That makes me mad. But I think she... she knows that now, and I don’t think she’ll do that anymore... I think she was afraid that I would refuse to go through with it.”⁵¹³

“Yeah. We told her what was going on. You really can’t hide too much from her. She was seven going on 14.”⁵¹⁴

“I always think it’s best to be upfront with your kids, no matter what, to a level of their understanding... I mean, at nine, he’s old... he is old enough to say, well, you know, I don’t really fancy it.”⁵¹⁵

“I think that if the child is over the age of 11 or they have a long-term condition, they should be able to voice that they wish to be a part of the research regardless of what their parents or guardians may say.”⁵¹⁶

“I believe that my child has a right to be part of any decisions regarding his treatment and the risks they may be exposing themselves to.”⁵¹⁷

“... you’re working towards adulthood and I think if you are not comfortable with the decision, you are going to, not going to have the best psyche with your treatment and if your parents say ok this is what we are doing you’re going to get this treatment, you are already so out of control. I mean this cancer is coming and taking control of your body.”⁵¹⁸

“The 9, 10 year olds there they just understand, somehow they do understand themselves, so they should also, if the parents have agreed they should go for that research, they also should be asked if they want to, and then they should be told the benefits of having this kind of research, they should be educated somehow. Somehow they will end up understanding and making a decision also.”⁵¹⁹

⁵¹¹ Nuffield Council on Bioethics (2015) *Survey Monkey questionnaire: analysis of young people’s responses*, available at: <http://nuffieldbioethics.org/project/children-research/evidence-gathering-activities/>.

⁵¹² Ibid.

⁵¹³ Snethen JA, Broome ME, Knafel K, Deatrck JA, and Angst DB (2006) Family patterns of decision-making in pediatric clinical trials *Research in Nursing & Health* **29(3)**: 223-32, at 227.

⁵¹⁴ Ibid., at 228.

⁵¹⁵ Woolfall K, Shilling V, Hickey H *et al.* (2013) Parents’ agendas in paediatric clinical trial recruitment are different from researchers’ and often remain unvoiced: a qualitative study *PLoS ONE* **8(7)**: e67352.

⁵¹⁶ Nuffield Council on Bioethics (2015) *Survey Monkey questionnaire: analysis of young people’s responses*, available at: <http://nuffieldbioethics.org/project/children-research/evidence-gathering-activities/>.

⁵¹⁷ Nuffield Council on Bioethics (2015) *Survey Monkey questionnaire: analysis of parents’ responses*, available at: <http://nuffieldbioethics.org/project/children-research/evidence-gathering-activities/>. See also: paragraph 2.20.

⁵¹⁸ Snethen JA, Broome ME, Knafel K, Deatrck JA, and Angst DB (2006) Family patterns of decision-making in pediatric clinical trials *Research in Nursing & Health* **29(3)**: 223-32, at page 228.

⁵¹⁹ 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).

- 4.42 In **Case Three**, by contrast, the distinctive feature is children's or young people's potential capacity to make the decision for themselves whether to participate in research. Thus, the particular challenges faced by both families and researchers in this case arise first with respect to the judgment as to whether children or young people in fact have the capacity to make this particular decision; and second with the question of how the potential for any conflict with the views of their parents may be managed. As we note in Chapter 2 (see paragraphs 2.51–2.57), the legal position in the UK with respect to children's decision-making powers in the context of research involvement is highly complicated, and in some cases uncertain. However, our primary focus here is on an *ethical* analysis of the respective roles of children and their parents in making decisions about research participation in circumstances where children or young people arguably have the intellectual capacity to make the decision in question (for example, by reference to the 'capacity test' for adults in the English Mental Capacity Act 2005⁵²⁰), but where the society in which they live does not grant them full 'adult' decision-making powers. We return in Chapters 5 and 6 to the legal and professional implications of our analysis.
- 4.43 We set out clearly in Chapter 1 (as part of the ethos of this report) two critical attitudes to children and young people that have underpinned the Working Party's approach throughout to the difficult issues that arise when contemplating clinical research with children and young people. First, we argued that children should be regarded as active participants in research from a very early age. Second, we took the view that it is always essential to consider children in the context of their family and the life they share with that family (see paragraph 1.23). Similarly, we saw in our review of the empirical evidence in Chapter 2 that the way in which decisions about research participation are made is heavily influenced by family circumstances and by the nature of family relationships. This ethos, supported by the empirical evidence available, provides the basis for our ethical analysis of the role of competent young people and children in making decisions about research involvement.
- 4.44 We therefore suggest that, instead of seeking primarily to identify *who* (children or their parents) are entitled to provide a legally effective consent or veto on research participation in Case Three, the ethical focus should be on obtaining agreement within the family unit concerned. Thus, the starting assumption in any discussion as to whether children or young people in Case Three should take part in a research study should be that this should normally be a shared family decision. Such an approach both reflects the experiences of supportive family decision-making described in the literature, and obviates the need for anxious calculations as to whether or not the young person in question meets a competence threshold – which itself is often likely to be contested. Clearly, however, such an approach will not always be possible: there will be cases where meaningful research results may only be obtainable without parental involvement (for example, where research relates to sexual behaviour or illegal drug use). There will also be cases where young people and their parents take opposing views on the appropriateness of participation. Young people, parents and professionals all need guidance on how to handle such cases, and we return to this below (see paragraphs 6.24–6.25). Similarly, we consider later the very specific challenges that face children and young people in all our cases who do not have any form of parental support, whether from an actual parent, or from other adults taking on this role (see paragraphs 6.31–6.41). However, we argue that, in the majority of cases,

⁵²⁰ Broadly the ability to understand the relevant information, and retain it long enough to make a decision.

a consensual or negotiated approach will reflect the reality of family life, and the way that young people and their parents make decisions in many other domains.

- 4.45 This claim – that the default approach within Case Three should be for consensus decisions within the family with respect to research participation – is implicitly built on a further claim about the *nature* of parental responsibility. It is uncontroversial to argue that parents continue to have an interest in the welfare of their children, even when those children are competent to make their own decisions. As we note in paragraph 4.9, emotional and caring relationships between parents and their children continue into adulthood, and a parent’s concern for the welfare of their child does not simply evaporate at the point when their child is able to take on decision-making responsibility for themselves. However, it is far from self-evident to claim that these parental interests in their children’s welfare should continue to have an effect in the public, as well as in the private, sphere once children are competent to make their own decisions. Indeed, if parental responsibility and power to make decisions on behalf of their minor children is understood as deriving *only* from children’s inability to make those decisions for themselves, then it follows quite straightforwardly that those responsibilities and powers fall away as soon as children are capable of making the decision in question.
- 4.46 We argue, however, that this is too ‘thin’ an account of parental responsibility. Drawing on our earlier analysis of what is special about childhood, we suggest that parental responsibilities do not derive solely from children’s initial inability to make their own decisions. Rather they derive from the particular developmental character of childhood (see paragraphs 4.8–4.9) which, we have suggested, underpins the threefold responsibilities of parents to respect their child as an individual; help them to develop as independent decision-makers; and promote their immediate and longer-term welfare. In particular, we have argued that parents’ role in promoting their child’s welfare includes seeking to influence and steer the kind of adult their child becomes (see paragraphs 4.18–4.28). These responsibilities are certainly connected with the inability of younger children to make decisions for themselves, but even a brief consideration of the relationship between parents and teenagers illustrates how this is only a partial picture. Teenagers are commonly required by their parents to do many things that they may not want to do, often in connection with the way they treat others (for example, with respect to particular standards of courtesy, or giving up time to visit older family members). On the whole we think it appropriate for parents to have a role in influencing the kind of behaviour they believe to be acceptable in their family: not because their child is unable to understand the consequences of behaving otherwise, but because it is a parent’s job to promote what they see as desirable attitudes and behaviours.
- 4.47 In other words, **we are making the claim that there *is* a morally significant difference between ‘competent children’ and ‘adults’, which may potentially justify differential treatment. Children, however intellectually capable, do not have full adult powers – and the corollary of that is that they also do not have full adult responsibilities.**⁵²¹ Parents are there, both ethically and legally, to share

⁵²¹ See, for example, the discussion in Manson N (2014) Transitional paternalism: how shared normative powers give rise to the asymmetry of adolescent consent and refusal *Bioethics* **29(2)**: 66-73: Manson uses the concept of a child’s acquisition of “unshared, unconstrained, adult power” as the point at which parental powers should fall away, and argues that parents and children up to that point should have a “joint bank account” approach to decision-making where either can ‘make withdrawals’ (i.e. consent), and hence neither can veto. A statutory example of the distinction between an adult and a competent child in England is found in the Care Act 2014 where ‘adults’ are defined as those aged 18 and above (section 2(8)), but where section 58(3) makes provision for children who have “capacity or [are] competent to consent” to make decisions for themselves about an assessment in connection with transition to adult services. Section 58(4) goes on to state that if a competent child refuses, the local authority is still empowered to go ahead “if the child is experiencing, or is at risk of,

that responsibility until the agreed threshold of adulthood is reached. In making this claim, it is crucial to acknowledge that childhood is, at least in part, a social characterisation that will vary from society to society. The law in each country will set a norm judged appropriate for this parental power and responsibility to end: that is, the age of majority. It will vary around the world, and move over time; some jurisdictions may also choose to specify different ages for particular aspects of parental power to end.⁵²² However, it is always drawn *somewhere*. In practice, the question of when parental power really ends will depend on the nature of a family's relationship: in some cases parental influence (or even active control) over behaviour will persist well past the legal age of majority. Thus, 'house rules' may apply to young people over the age of 18 who still live at home, and parents may continue to seek to influence their children throughout their life. In other families, parental powers may, in practice, cease to be effective long before the age defined by law.

- 4.48 This approach to parental responsibility in childhood helps explain why, intuitively, it may seem right for parents to be able to override the wishes of an apparently competent child or young person where major risks are at stake. Such cases may arise, for example, where parents consent to medical treatment that their child has refused but which is believed to be critical for their healthcare, or even life-saving. In these difficult cases, it is sometimes claimed that particular children or young people are not competent to make such important decisions. However, in practice, this justification may disguise the real rationale for intervention: that of care for that particular child's welfare. That is certainly not to say that children's wishes are unimportant – but that in some (exceptional) cases these may be trumped by concerns over welfare.
- 4.49 We argue then, that our threefold analysis of parental responsibilities is also applicable where children and young people fall into Case Three – but that the *balance* of those responsibilities will be exercised differently from Case Two. The parental role in helping their child to develop capacity begins to fall away, but has not yet become redundant, given that different decisions demand different levels of competence. Thus, encouraging children to make up their own minds with respect to very low risk activities (for example, contributing to interview-based research) might be regarded as practice for making later research decisions, where more might be at stake. Respect for their children as individuals who are able to make their own decisions will increasingly be the dominant feature of the parental role, but concerns about welfare will still be significant. In Case Three though, by contrast with the other cases, such concerns will primarily be expressed in the form of *advice and support*, rather than through exercising the role of substitute decision-maker. The exception may arise where parents have strong reasons to believe that participation could have serious implications for their child's welfare that are significant enough to outweigh other considerations. In the context of research, such exceptions are primarily likely to arise in connection with treatment that is only available in the context of a research study (where parents strongly believe that participation is essential for their child's welfare); or in connection with a research study that they believe poses too *high* a risk for their child to participate (and hence where they wish to veto involvement).

abuse or neglect": in other words the local authority retains protective powers with respect to competent children, despite their competence.

⁵²² As, for example, the UK Clinical Trials Regulations do, in defining 'minors' as under the age of 16, even though in many other areas of law in England and Wales parental powers *coexist* with those of children up to the age of 18.

4.50 As the above examples make clear, an important aspect of this analysis of parental powers and responsibilities lies in their *discretionary* nature. A key aspect of parenting rests in the gradual yielding of responsibility, accompanied by appropriate levels of support, from parent to child.⁵²³ Thus, for many decisions relating to research involvement, it is likely to be appropriate that children or young people will be the primary decision-makers, with the support of their parents. While we make the claim that parents continue to have a role with respect to their children's decision-making until they have full adult powers, an important aspect of that role is found in the *discretionary manner* in which it should be exercised. We return in Chapters 5 and 6 to consider how professionals should respond where they have concerns over how that discretion might be, or is being, exercised (see paragraphs 6.19–6.25). We also discuss how, depending on circumstances, parents too may need support in how they exercise their parenting role in this paradigm case just as much as in others (see paragraph 4.61).

⁵²³ See, for example, the discussion in Taylor R (2007) Reversing the retreat from Gillick? R (Axon) v. Secretary of State for Health *Child and Family Law Quarterly* **19(1)**: 81-97, where it is argued that the Axon case demonstrates a growing respect for the rights and autonomy of children, with parental rights and authority diminishing or yielding to children as they mature.

Box 4.3: Examples of decision-making in case 3

"No, I think they say 16 is when you can sign the things in here but I still think it's good to have your parents there just as the extra person, because if you're on your own like making decisions and all this paper-work then you don't know what, you want to read all this stuff and just leave it to them to do and you don't know what you're... like sometimes when you have to sign something or and you're saying 'Should I sign this or not?' there's no one else to help you, it's kind of hard."⁵²⁴

"Mainly it was him more than me... He's almost 17 years old. That was his decision and ours, but we didn't tell him that. We let him decide."⁵²⁵

"I don't want to leave him out since he's 17. I try to give him the opportunity to make his own decision, but I will have the final say so of what's best for him, but I'll try to include him in it."⁵²⁶

"Personally if my parents told me I wasn't allowed to take part in the trial, I think that I would listen to them cos I would kind of trust their judgment on whether they think it is safe or not."⁵²⁷

"I don't think it's 18 and above or less than 18, if you are going to participate in the research right now you have to use your intelligence, if you consider the advantages and think it is going to help, it's you who will make the decision you don't have to quote the age or something."⁵²⁸

"If he can answer question, let him just answer. Sometimes they do things which the parents themselves get surprised, because they know how to do things [*other group participant: 'Nowadays!'*]. Now if at 13 years he goes to Mombasa, Malindi, and back, by himself, if you ask him silly questions, won't he surprise you with his answers?"⁵²⁹

"... my younger brother [aged 13 years] was involved in a pneumonia study and was given a diary to fill in for three days. Now when they came home they found me and him, I'm not his parent, the parents are not there, but the boy is big... he can explain everything. Now they involved me, if I can agree and I told them even he himself can agree because there's nothing there, it's just talking and filling. He himself said "I will do it". You see? He is a child, but can express himself."⁵³⁰

Additional factors influencing decision-making

4.51 Two further issues arise that fall outside the immediate parent-child relationship, but are still very important in influencing the decision that is eventually made in connection with children's or young people's participation in research. First, in coming to a decision

⁵²⁴ Coyne I, Amory A, Kiernan G, Gibson F and Breatnach F (2010) *Children with cancer: children, parents, and health professionals' perspectives on children's participation in shared decision making* (Dublin: Cancer Research Ireland), at page 101.

⁵²⁵ Olechnowicz JQ, Eder M, Simon C, Zyzanski S, and Kodish E (2002) Assent observed: children's involvement in leukemia treatment and research discussions *Pediatrics* **109**(5): 806-14, at page 811.

⁵²⁶ Ibid.

⁵²⁷ Nuffield Council on Bioethics (2014) *Be a part of it: what young people think of clinical research*, available at: <http://www.youtube.com/watch?v=e2k6eA0dn9Q>; see also paragraph 2.19.

⁵²⁸ 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).

⁵²⁹ Ibid.

⁵³⁰ Ibid.

about whether it is ‘good’ for a child or young person to take part in a particular research procedure, the perceived value of research (including the question of to whom that value accrues) will be highly relevant. If parents perceive no, or very limited, value in the proposed research, they will have little reason for considering the trade-offs involved in participation. We return to this question of value below (see paragraphs 5.2 and 5.32).

- 4.52 Second, it is crucial to return to the point that there are many adults in the lives of children and young people who, in particular contexts and at particular times, have recognised responsibilities towards them (see paragraph 4.9). In the context of clinical research, the professionals with whom children, young people and their families come into contact clearly play a critical role in determining the involvement of children or young people in research. They may, for example, influence the decisions of parents and young people through the manner of their approach; they may decide *not* to approach a particular family regarding a research opportunity; or they may choose not to act on parental consent where a child is unwilling to participate. Where children and young people do proceed to take part in a particular study, then their experience of that study, and their attitudes to research more generally, will be affected by the interactions they and their parents have with the professionals concerned with that study. We turn to the responsibilities of this group of professionals in Chapter 6, after consideration in Chapter 5 of professional responsibility with respect to the prior questions of the development, design and review of research protocols that will ultimately be ‘offered’ to children and parents. Before we do so, however, we need first to examine one of the concepts most often cited in the context of professional responsibilities with respect to research with children: that of vulnerability.

Challenging vulnerability

“The term vulnerable can’t be used in isolation; we are always vulnerable to something specific, and the things that we are vulnerable to change over time.”⁵³¹

“In principle, we consider that only adults are sufficiently mature to agree willingly to risk their own health or well-being for altruistic reasons. Children are too vulnerable to all forms of coercion, especially emotional coercion.”⁵³²

- 4.53 We note in Chapter 1 that much of the general approach to the regulation of clinical research involving children – from international ethical declarations, to national law – is underpinned by the idea that children, in contrast to ‘autonomous’ adults, are inherently vulnerable.⁵³³ This assumption has, in turn, influenced how the responsibilities of professionals involved in research (whether as researchers, clinicians, or those responsible for reviewing research) have been viewed. However, this straightforward association between childhood and vulnerability was strongly challenged throughout the Working Party’s consultative activities.

⁵³¹ Nuffield Council on Bioethics (2014) *Note of stakeholder group meeting*, available at: <http://nuffieldbioethics.org/wp-content/uploads/Stakeholder-meeting-note.pdf>, at page 8.

⁵³² Christian Medical Fellowship, responding to the Working Party’s call for evidence.

⁵³³ See, for example, 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 19: “Some groups and individuals are particularly vulnerable and may have an increased likelihood of being wronged or of incurring additional harm.”

- 4.54 In a factfinding meeting exploring the concept of vulnerability, it was argued that while a 'folk' or dictionary account of vulnerability as an indication that a person is 'at an increased risk of harm' may be relatively unproblematic, difficulties arise when trying to use the concept as a guide when making moral decisions.⁵³⁴ Use of the label of vulnerability for particular groups, such as children, or adults without capacity, or prisoners, inevitably fails to capture the diversity and richness of any group, and does not help identify particular members of that group who are, or are not, a subject of particular ethical concern. Similarly, a 'group approach' to vulnerability may lead to particular vulnerabilities being missed, because the person in question does not apparently belong to any of the identified groups.⁵³⁵ Even, however, where a person is appropriately identified as 'vulnerable', the use of this label does not necessarily provide an ethical steer to action, because the *reasons* for which they might be at increased risk of harm are not explained in any way by the label of vulnerability. Thus while, for example, the Declaration of Helsinki states that "some groups and individuals are particularly vulnerable and may have an increased likelihood of being wronged or of incurring additional harm", it is silent on the (potentially very variable) *reasons* why particular individuals or groups might be at greater risk of being wronged or of incurring additional harm.⁵³⁶ On the other hand, it was suggested at the meeting that an awareness that particular groups, or people in particular circumstances, *may* be vulnerable can provide a useful alert: an indication that there is something of additional ethical concern at stake.
- 4.55 Children and young people participating in our stakeholder event similarly argued that, while some children in some circumstances could certainly be vulnerable, it was wrong to assume that children are *necessarily* so.⁵³⁷ Even young children can make decisions for themselves "if things are properly explained", and the point was made strongly that children living with particular conditions or disabilities (who are often seen as 'more vulnerable' than their contemporaries) do not want to be treated any differently from their friends.⁵³⁸ Concern was expressed that describing children as 'vulnerable' can simply 'stop the conversation' about whether children should participate in research; however, as in the discussion at the factfinding meeting, it was agreed that the label might still have value as a 'flag' to make sure that appropriate protections are in place.
- 4.56 The young people present at the stakeholder event also identified a number of ways in which they might feel more or less vulnerable in the context of research. "Being prepared" or "being empowered" were both cited as ways in which any sense of vulnerability might be lessened: and hence having information, or knowing how to go about obtaining information, was seen as an important factor in 'arming' children

⁵³⁴ Nuffield Council on Bioethics (2014) *Factfinding meeting: vulnerability* (London, 21 May: Nuffield Council on Bioethics). Note also the Oxford English Dictionary's definition of vulnerable as "exposed to the risk of being attacked or harmed, either physically or emotionally".

⁵³⁵ We note, in the very different context of childhood 'grooming', how the plight of teenage girls has been ignored because of the way they had been 'classified': in court, for example, they were described as prostitutes, rather than as abused children. See, for example, The Guardian (6 January 2015) *End use of outdated term 'child prostitution', says MP*, available at: <http://www.theguardian.com/society/2015/jan/06/child-prostitution-term-outdated-mp-ann-coffey>.

⁵³⁶ 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 19.

⁵³⁷ Nuffield Council on Bioethics (2014) *Note of stakeholder group meeting*, available at: <http://nuffieldbioethics.org/wp-content/uploads/Stakeholder-meeting-note.pdf>.

⁵³⁸ One participant described how teachers constantly tried to protect her, for example by suggesting that she did not participate in sports lessons - while she felt able to take part and make her own decisions about when to stop. The difficulties that arise when identifying particular subgroups of children as more vulnerable than others is explored in detail in Frankenberg R, Robinson I, and Delahooke A (2000) Countering essentialism in behavioural social science: the example of 'the vulnerable child' ethnographically examined *The Sociological Review* **48(4)**: 586-611.

against vulnerability. The support of parents was also described as an important factor. It was noted that they would know how their child handled difficult situations and, hence, would be best placed to help them; and also that it was reassuring for children to know that they and their parents had access to the same information.⁵³⁹ Teachers having access to information was similarly seen as a source of reassurance. In contrast, poor relationships with researchers, poor communication or “being put on the spot in front of strangers” could make young people feel more vulnerable, as could being given too *much* responsibility.

- 4.57 As these examples demonstrate, in many (though not all) cases, the factors that may potentially make children feel, or be, vulnerable in the context of clinical research do not arise *inevitably* because of the nature of childhood; and nor are they necessary features of research. Rather, they arise in the context of the developmental nature of childhood – experienced, for example, in a young child’s need for practical and emotional support in understanding what is proposed; or an older child’s anxiety about the impact of research participation on their school life. Once the relevance of this context is recognised, there will often be scope to modify aspects of the research in response. The extent, for example, to which children’s vulnerability may derive either from a lack of control over what is happening to them, or, conversely, from feeling that too much is being expected of them, is something that those responsible for research with children can largely control – both through the way they design the study itself, and in the way that they communicate with and support children and their families. (Such modification will not, of course, always be possible, a point to which we return in paragraph 4.60.)
- 4.58 The Working Party shares the concern, expressed by children, parents and professionals, that an unthinking use of the notion of vulnerability may be used as a ‘conversation-stopper’ with respect to children’s involvement in research. Indeed, there is a real risk that this apparently protective response to perceived or actual vulnerability may not only exclude children and young people from opportunities to participate in activities that are inherently worthwhile (see paragraphs 5.2 and 5.32), but could also harm the interests of many children in the future by preventing potentially valuable research from taking place. We further agree that an awareness that children may *potentially* be vulnerable in research may nonetheless provide a useful alert to those professionally concerned with research to ask themselves: ‘Does this research raise particular ethical challenges and what can I do about them?’ The real challenge for those professionals is thus the nature of the *response* they make to the alert, and their own sensitivity to the need to avoid taking advantage of a potentially unequal relationship.
- 4.59 At the beginning of this report, we set out our understanding of children as people who, from an early age, can take an active role in determining the direction of their lives, in the context of a shared life with others. We suggest now that **an appropriate response by professionals to concerns about children’s potential vulnerability in research is to ensure that they work in partnership with children, young people and parents throughout the whole endeavour of research.** Such a partnership approach will ensure that, whenever children and young people are invited to take part in research, the procedures to which they are being invited to consent have been developed with the input of others in a similar situation to themselves. Where it is not

⁵³⁹ Similar points were raised by students from a secondary school who took part in the Working Party’s Youth REC project, who emphasised how important it was for parents to have information so that they can meet their own responsibilities in caring for their child.

feasible to seek direct input from children in similar situations (that is, for some of the children and young people in Case One), then this engagement will be carried out on their behalf by parents; but, as we discussed earlier in this chapter, parents will also continue to play a role as their children develop through Case Two to Case Three. Such an approach implies a fundamental shift from seeking to protect children 'from' research, to protecting them through their own active engagement with how research with children and young people is designed and carried out.

- 4.60 Alongside this focus on a partnership with children, young people and parents in the design of studies, it is, however, crucial to recognise that it will not always be possible to achieve the desired end. Sometimes changes that might be needed to a research protocol to avoid putting children in a vulnerable position (for example, where the proposed procedure would be too distressing for a young child unable to understand what was happening), or over-burdening those who are already in a vulnerable situation (for example, because of the severity of their existing illness), cannot be achieved without compromising the ability of the research to produce meaningful results.⁵⁴⁰ In such cases, the proposed research cannot go ahead. Similarly, a proposal that has been developed with the input of children and families in the way described above, might still render particular children vulnerable (for example, in connection with the distress that some children feel in connection with hyperdermic needles). Again, in such cases, it would be inappropriate to recruit those particular children to the study.
- 4.61 In our consideration of the extent to which children may potentially be vulnerable in research, it is also important to be alert to the fact that **parents, too, may often need support in the context of their child's research involvement.** A necessary part of any parent's role in any context (not just that of research), is that of making decisions with and on behalf of their minor child. However, this day-to-day responsibility is inevitably more challenging to exercise if the decision to be taken involves potential burden or risk for their child, or arises in highly emotional and difficult situations (see paragraphs 2.6–2.11).⁵⁴¹ In some situations, such as in the immediate aftermath of a diagnosis of a life-threatening or life-changing illness, relatively few parents may be able to make decisions (or support their child in making a decision) without support themselves. This is an important recognition but, as with our analysis above with respect to children's potential vulnerabilities, it should not be seen as placing an automatic brake on certain kinds of research. Rather it acts as a prompt to consider how research studies may be developed and carried out, and how professionals can appropriately support parents in a way that does not make unreasonable demands on either parents or children.
- 4.62 In the following two chapters, we explore further what our analysis of vulnerability might mean for children, young people and their families: both in the development and design of research; and in the relationship between researchers and families when children and young people are invited to take part in a particular study.

⁵⁴⁰ See, for example, the justification for the use of "naturalistic experiments" regarding the effects of long-term cannabis use in Nordentoft M (2014) Adolescent cannabis use and adverse sequelae in adulthood *The Lancet Psychiatry* **1(4)**: 249-51, given the inevitable difficulties in carrying out a controlled study giving children cannabis and monitoring the effects.

⁵⁴¹ There is some (limited) evidence that compared to adult patients with cancer, parents of children with cancer struggle to absorb information about trials: see: Simon CM, Siminoff LA, Kodish ED, and Burant C (2004) Comparison of the informed consent process for randomized clinical trials in pediatric and adult oncology *Journal of Clinical Oncology* **22(13)**: 2708-17.