

# **“What we think about what adults think”**

Children and young people’s perspectives on ethics  
review of clinical research with children

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## Chapter 1: Introduction

- 1.1 Much has been written about the ethics of clinical and social research with children and young people,<sup>1</sup> but there remains a dearth of research which has considered *children's* views of ethics considerations in research that involves them. The work reported here was conducted as part of a larger project being undertaken by the Nuffield Council on Bioethics, which has established a working party titled *Children and clinical research: ethical issues*.<sup>2</sup> Our research aimed to help inform the discussions of that working party, and specifically by learning directly from children and young people's perspectives. Students from three schools – a junior school, a secondary school and a sixth form college – took part in workshop discussions, on which this report is based. Two films were produced, along with a range of web resources that can be used in discussions with students in other schools, colleges or universities, and also by members of research ethics committees for training purposes.<sup>3</sup>

### The ethics of research involving children: background

- 1.2 To understand the specific ethics considerations entailed in clinical research ethics with children and young people, it is necessary to begin with a broader consideration of ethical practice in research with children and young people. Not least, it might be assumed that research involving children and young people would entail the same ethics principles that have been derived for research with adults. Principles that are set out, for example, in the 1947 Nuremberg Code and the 1964 Declaration of Helsinki include ensuring freely given and fully informed consent and the right to withdraw from research participation. Morrow has written that there are provisos that apply more specifically to research involving children, but these are in addition to core ethics principles which apply to adults and children alike. The additional considerations highlighted by Morrow include:

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<sup>1</sup> See, for example, Gill D (2004) Ethical principles and operational guidelines for good clinical practice in paediatric research. Recommendations of the Ethics Working Group of the Confederation of European Specialists in Paediatrics (CESP) *European Journal of Pediatrics* **163**(2): 53-7; Piercy H, and Hargate M (2004) Social research on the under-16s: a consideration of the issues from a UK perspective *Journal of Child Health Care* **8**(4): 253-63; Edwards SD, and McNamee MJ (2005) Ethical concerns regarding guidelines for the conduct of clinical research on children *Journal of Medical Ethics* **31**(6): 351-4; Alderson P (2007) Competent children? Minors' consent to health care treatment and research *Social Science & Medicine* **65**(11): 2272-83; Morrow V (2008) Ethical dilemmas in research with children and young people about their social environments *Children's Geographies* **6**(1): 49-61; Munro ER (2008) Research governance, ethics and access: a case study illustrating the new challenges facing social researchers *International Journal of Social Research Methodology* **11**(5): 429-39; Chabot C, Shoveller JA, Spencer G, and Johnson JL (2012) Ethical and epistemological insights: a case study of participatory action research with young people *Journal of Empirical Research on Human Research Ethics: An International Journal* **7**(2): 20-33; Boddy J (2014) Research across cultures, within countries: hidden ethics tensions in research with children and families? *Progress in Development Studies* **14**(1): 91-103.

<sup>2</sup> For more information on the Nuffield Council's project, see: <http://nuffieldbioethics.org/children-and-research>.

<sup>3</sup> Ibid.

- children’s competencies, perceptions and frameworks of reference, which may differ according to factors including – but not only – their age, are different from those of adults;
- children’s potential vulnerability to exploitation in interaction with adults, and adults’ specific responsibilities towards children;
- the differential power relationships between adult researcher and child participant; and
- the role of adult ‘gatekeepers’ in mediating access to children, with concomitant ethical implications in relation to informed consent.<sup>4</sup>

1.3 However, there is evidence that core ethics principles may not be automatically (or universally) applied to research with children and young people. Rees and colleagues conducted a systematic review of approximately 500 studies involving children and young people in educational contexts; just 13 per cent reported that consent had been sought from children and young people themselves.<sup>5</sup> There is some disagreement in the academic literature over children’s competence to consent, whether in clinical research or in other contexts. Some have argued strongly that children do not have the capacity to understand research well enough to consent or even assent “in a meaningful way”.<sup>6</sup> The conclusions of this study are undoubtedly questionable, based on a questionnaire study of just 18 young people aged between five and 18 years. However, the perception that children are unable to consent persists. For example, Burke *et al.* interviewed 251 children aged between six and 15 years, and concluded that “even young children” could understand risks and benefits associated with medical procedures in their study. However, these authors add a cautionary note that understanding risks and benefits of a study “is not the same as suggesting that young children can ultimately consent to the research”.<sup>7</sup>

1.4 Debates in the academic literature about children’s competency and autonomy to make decisions about whether to participate in research sit alongside legal requirements, including frameworks such as the Fraser guidelines, based on the judgment in *Gillick vs West Norfolk and Wisbech Health Authority*.<sup>8</sup> However, the Fraser guidelines (which apply specifically to contraceptive advice) and the assessment of ‘Gillick competency’ apply to medical treatment, and not to medical research. Gillick competency holds that “parental right yields to the child’s right to make his own decisions when he reaches a sufficient understanding and intelligence to be capable of making up his own mind on the matter requiring decision,” and that a child’s ability to consent should be judged

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<sup>4</sup> Morrow V (2008) Ethical dilemmas in research with children and young people about their social environments *Children’s Geographies* **6(1)**: 49-61, at page 52.

<sup>5</sup> Rees R, Garcia J, and Oakley A (2007) Consent in school-based research involving children and young people: a survey of research from systematic reviews *Research Ethics Review* **3(2)**: 35-9.

<sup>6</sup> See, for example, Ondrusek N, Abramovitch R, Pencharz P, and Koren G (1998) Empirical examination of the ability of children to consent to clinical research *Journal of Medical Ethics* **24(3)**: 158-65, at page 164.

<sup>7</sup> Burke T, Abramovitch R, and Zlotkin S (2005) Children’s understanding of the risks and benefits associated with research *Journal of Medical Ethics* **31(12)**: 715-20, at page 719.

<sup>8</sup> *Gillick vs West Norfolk and Wisbech Health Authority* [1985] 3 All ER 423.

on an individual basis.<sup>9</sup> However, there is evidence that the Fraser guidelines are (mis)applied to research with children and young people.<sup>10</sup> Boddy and Oliver report a lack of clarity and consistency in the interpretation and application of the Fraser guidelines and assessment of Gillick competence to the governance of research with children and young people in local authorities in England,<sup>11</sup> and Wheeler argues for the need to “retain Gillick competence as the central doctrine with which to judge capacity in children”.<sup>12</sup> Piercy and Hargate, discussing the impact of the Fraser guidelines on research, comment that:

“It appears that there is an increasing separation between the ability of a young person to consent to treatment and to consent to research. In consequence, the age at which a young person is deemed capable to consent to participate in research is rising, not falling.”<sup>13</sup>

- 1.5 Regulatory requirements that emphasise the need to secure consent from adult gatekeepers can do so at the expense of children’s perspectives. For example, Alderson comments that the introduction of the idea of child ‘assent’ overrides legal traditions of consent. Consequently, children’s agreement to participate may be elided, or based on passive assent, rather than freely given and fully informed consent.<sup>14</sup> Writing in 2007, she observes that debates about minors’ consent or assent can appear to be “less concerned with children’s rights than with adults’ freedoms”.<sup>15</sup>
- 1.6 There is a well-established tension in discussions of research ethics – especially when concerning children – between protection and participation.<sup>16</sup> The United

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<sup>9</sup> See: Wheeler R (2006) Gillick or Fraser? A plea for consistency over competence in children *BMJ* **332(7545)**: 807.

<sup>10</sup> See, for example, Piercy H, and Hargate M (2004) Social research on the under-16s: a consideration of the issues from a UK perspective *Journal of Child Health Care* **8(4)**: 253-63; Wheeler R (2006) Gillick or Fraser? A plea for consistency over competence in children *BMJ* **332(7545)**: 807; Boddy J and Oliver C (2010) *Research governance in children’s services: the scope for new advice*, available at: <https://www.gov.uk/government/publications/research-governance-in-childrens-services-the-scope-for-new-advice>.

<sup>11</sup> Boddy J and Oliver C (2010) *Research governance in children’s services: the scope for new advice*, available at: <https://www.gov.uk/government/publications/research-governance-in-childrens-services-the-scope-for-new-advice>.

<sup>12</sup> Wheeler R (2006) Gillick or Fraser? A plea for consistency over competence in children *BMJ* **332(7545)**: 807.

<sup>13</sup> Piercy H, and Hargate M (2004) Social research on the under-16s: a consideration of the issues from a UK perspective *Journal of Child Health Care* **8(4)**: 253-63, at page 260.

<sup>14</sup> Alderson P (2012) Children’s consent and ‘assent’ to healthcare research, in *Law and childhood studies: current legal issues (Volume 14)*, Freeman M (Editor) (Oxford: Oxford University Press).

<sup>15</sup> Alderson P (2007) Competent children? Minors’ consent to health care treatment and research *Social Science & Medicine* **65(11)**: 2272-83, at page 2273.

<sup>16</sup> See, for example, Spencer G (2000) Children’s competency to consent: an ethical dilemma *Journal of Child Health Care* **4(3)**: 117-22; Alderson P (2007) Competent children? Minors’ consent to health care treatment and research *Social Science & Medicine* **65(11)**: 2272-83; Boddy J and Oliver C (2010) *Research governance in children’s services: the scope for new advice*, available at: <https://www.gov.uk/government/publications/research-governance-in-childrens-services-the-scope->

Nations Convention on the Rights of the Child (UNCRC) specifies rights to both participation and protection in all areas of children's lives – rights that therefore extend to involvement in research. Article 19, for example, sets out the right to protection from all forms of physical or mental violence, injury or abuse, neglect or negligent treatment, maltreatment or exploitation, including sexual abuse; whilst Articles 12 and 13 relate to participatory rights: for the child who is capable of forming his or her own views, the right to express those views freely in all matters affecting the child (Article 12); and the right to freedom of expression, including freedom to seek, receive and impart information and ideas of all kinds (Article 13).

- 1.7 As Powell *et al.* argue, there is no essential conflict between children's right to be protected and their right to have a say on matters that affect them; rather, it is a question of balance.<sup>17</sup> Thus the challenge is to consider how best to recognise and address these additional considerations for research with children, ensuring their rights to participate be protected.
- 1.8 Over recent decades, there have been major theoretical and methodological developments in the sociology of childhood and in participatory research with children and young people.<sup>18</sup> This body of work endeavours to recognise and accommodate young people's specific concerns and competencies, as well as their potential vulnerabilities in unequal power relationships with adults. Of critical concern is the importance of recognising – and attending to – the socially constructed and politically mediated nature of 'childhood' and of the presumed 'innocence' and immaturity of children.<sup>19</sup> Powell and Smith, for example, highlight:

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for-new-advice; Powell MA, Graham A, Taylor NJ, Newell S and Fitzgerald R (2011) *Building capacity for ethical research with children and young people: an international research project to examine the ethical issues and challenges in undertaking research with and for children in different majority and minority world contexts - report prepared for the Childwatch International Research Network, Oslo, Norway*, available at: [http://epubs.scu.edu.au/ccyp\\_pubs/32/](http://epubs.scu.edu.au/ccyp_pubs/32/); Boddy J (2014) Research across cultures, within countries: hidden ethics tensions in research with children and families? *Progress in Development Studies* **14(1)**: 91-103.

<sup>17</sup> Powell MA, Graham A, Taylor NJ, Newell S and Fitzgerald R (2011) *Building capacity for ethical research with children and young people: an international research project to examine the ethical issues and challenges in undertaking research with and for children in different majority and minority world contexts - report prepared for the Childwatch International Research Network, Oslo, Norway*, available at: [http://epubs.scu.edu.au/ccyp\\_pubs/32/](http://epubs.scu.edu.au/ccyp_pubs/32/).

<sup>18</sup> Mayall B (2002) *Towards a sociology for childhood: thinking from children's lives* (Buckingham: Open University Press); Tisdall K, Davis J, and Gallagher M (2008) *Researching with children and young people: research design, methods and analysis* (London: Sage); Groundwater-Smith S, Dockett S, and Bottrell D (2014) *Participatory research with children and young people* (London: Sage).

<sup>19</sup> James A, and Prout A (1988) *Constructing and reconstructing childhood: contemporary issues in the sociological study of childhood* (London: Falmer Press); Kehily M (2004) Understanding childhood: an introduction to some key themes and issues, in *An introduction to childhood studies*, Kehily M (Editor) (Maidenhead: Open University Press/McGraw Hill); Jenks C (2005) *Childhood (second edition)* (Abingdon: Routledge).

“The structural vulnerability of children, which is not a biological reality, but rather children’s lack of power and status within our societal structures.”<sup>20</sup>

- 1.9 Such concerns can be addressed by recognising and enabling children’s competencies and expertise in their own lives. Kellett argues that it is untenable to suggest that children have lesser knowledge than adults but rather that their knowledge is different.<sup>21</sup> There has been a growing interest in developing child-centred research methodologies,<sup>22</sup> and a concomitant increase in the involvement of children as researchers.<sup>23</sup> This wider context highlights the importance of ethics regulation and review being informed by children’s perspectives. As Kellett observes:

“Children are party to the subculture of childhood which gives them a unique “insider” perspective critical to our understanding of their worlds.”<sup>24</sup>

Adults often make decisions that affect children. For adults who scrutinise child research on RECs, these decisions are intended to ‘protect’ children and children’s interests. They might well benefit from the ‘insider’ perspective that Kellett describes.

## Aims

- 1.10 The research reported here builds on the cross-disciplinary developments discussed above, with the aim of learning from young people’s ‘insider perspectives’ on childhood through exploring their views of ethical considerations in clinical research with children. The research explores areas of (dis)connection between adult and child perspectives, particularly in relation to risks or ethics concerns that are perceived by children but not by adults, or vice versa.
- 1.11 In doing so, the project aims to inform research ethics training and education, delivering a resource that can support engagement with research ethics in clinical research with children and young people. This resource can be used in the future by schools or in clinical contexts, as well as by adult professionals engaged in clinical research with children, or indeed its associated ethical review.

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<sup>20</sup> Powell MA, and Smith AB (2006) Ethical guidelines for research with children: a review of current research ethics documentation in New Zealand *Kōtuitui: New Zealand Journal of Social Sciences Online* **1(2)**: 125-38, at page 135.

<sup>21</sup> Kellett M (2010) Small shoes, big steps! Empowering children as active researchers *American Journal of Community Psychology* **46(1)**: 195-203.

<sup>22</sup> Mayall B (2002) *Towards a sociology for childhood: thinking from children's lives* (Buckingham: Open University Press).

<sup>23</sup> See, for example, Open University (2014) The Children’s Research Centre, available at: <http://www.open.ac.uk/researchprojects/childrens-research-centre/>.

<sup>24</sup> Kellett M (2010) Small shoes, big steps! Empowering children as active researchers *American Journal of Community Psychology* **46(1)**: 195-203, at page 195.

1.12 Lundy sets a challenge to work with children's 'voice' with regard to the UNCRC. She notes that Article 12 has two key elements: (i) the right to express a view, and (ii) the right to have the view given due weight; and on this basis sets out four criteria, as follows:

- Space: children must be given the opportunity to express a view
- Voice: children must be facilitated to express their views
- Audience: the view must be listened to
- Influence: the view must be acted upon as appropriate.<sup>25</sup>

1.13 Responding to this imperative, the research reported here has not only focused on creating a space within which we have sought the views of children and young people, facilitating their expression through discussion. The project also seeks to ensure that their views reach a relevant audience, through the production of film and training resources. It remains for those who watch the film – members of ethics committees or other stakeholders involved in commissioning, designing, reviewing or using research with children – to listen to, and act upon, the expertise of the student participants in this research project.

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<sup>25</sup> Lundy L (2007) 'Voice' is not enough: conceptualising Article 12 of the United Nations Convention on the Rights of the Child *British Educational Research Journal* **33(6)**: 927-42, at page 933.

## Chapter 2: Methods

- 2.1 The research involved workshops with children and young people in three schools – a junior school, a secondary school and a sixth form college. Participants in workshop discussions were presented with a film (see below) presenting a hypothetical case of clinical research, and asked to discuss the key ethics considerations from their point of view. Mid-way through the workshops, they were presented with a film of an adult Research Ethics Committee (REC) discussing the research. This aimed to prompt further discussion, and so to illuminate (dis)connections between adults and young people’s concerns.
- 2.2 The project was conducted in **three stages** over a period of six months. **Stage one** developed a 15-minute film (Film 1) of a hypothetical case study about a child asthma patient. This film is comprised of three components: the first depicts a role play between a child asthma patient and her consultant, including scenes from a ‘usual’ family morning for a child with serious asthma, and their visit to hospital for a routine check-up with their consultant. The second component shows the consultant explaining his plans for a clinical research study of a new potential treatment for childhood asthma; and the third component portrays the discussions of a mock research ethics committee (REC) of the consultant’s study, ethics application, and related materials.
- 2.3 The proposed clinical trial presented during Film 1 was hypothetical, constructed for the purposes of the study to address a health issue that is likely to be familiar to children, and to encompass ethics considerations including risk, privacy/confidentiality, and child consent. Likewise, the REC was constructed for the purposes of this project and drew upon existing professional contacts to include up to five people with relevant experience in research ethics. The committee was constructed to include a mix of expertise, including perspectives from research ethics committee chairs, a clinician, a student representative, experts in research governance, and a ‘lay’ member with particular expertise in work with vulnerable children and young people. The research did not seek to judge the quality of ethics committee decision-making; rather, the film of the REC discussion was used as a prompt for workshop participants to consider the match between the discussions held by the mock REC to their own perspectives.
- 2.4 **Stage two** involved a series of filmed, half-day workshops with students from three schools (a junior school, a secondary school, and a sixth form college) in the Brighton area. The workshops were structured so that children and young people participating in the sessions would undertake the series of activities set out in Box 2.1.

### Box 2.1: Structure of school workshops

- i.) Inviting students to consider definitions and approaches to (clinical) research

and research ethics;

- ii.) Watching part one of Film 1 (part 1) (see paragraph 2.2 above for further information about the contents of Film 1);
- iii.) Facilitated discussion with students, using a number of participatory techniques in order to elicit the key concerns and ethics questions that children and young people identify. Techniques included:

- Creating posters
- Editing/redesigning study information sheets
- Simulating processes of randomisation by organising participants into 'control' and 'intervention' groups

The consultant's ethics application, including study information sheets, assent forms and parental letters and consent forms were also presented during the workshops to stimulate discussions;

- iv.) Watching part two of Film 1 (focusing on the views of the mock adult REC), followed by a facilitated discussion of the ethics considerations raised by the mock adult REC.

2.5 The three half-day workshops were filmed by VH and the footage informs the analysis presented in this report. The footage was also used to create Film 2, which captures and synthesises the key themes from the workshop discussions. The key aim of Film 2 is to help to produce guidance for researchers and adult RECs about children and young people's perspectives on ethics review in clinical research with children.

2.6 **Stage three** marks the formal end of the project in the form of a launch event held at Brighton and Sussex Medical School at the end of March 2014 with an invited audience including young people who participated in the study and other representatives of their schools, as well as key adult stakeholders, including the adult REC and other participants from Film 1. The launch event included a screening of both films from the project, and a discussion with the research team, members of the Nuffield Council on Bioethics, children and young people who took part in the workshops, and invited guests. The project films are available from the Nuffield Council on Bioethics' website, and will be used by the Council's Education Advisory Group.<sup>26</sup>

## Recruitment and ethical considerations

2.7 Following the decision to focus on asthma as an exemplar clinical condition, a clinician specialising in asthma treatment for children was recruited through existing working relationships (BF) to take part in Film 1. The clinician's contacts

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<sup>26</sup> Nuffield Council on Bioethics (2014) *Children and clinical research: ethical issues*, available at: <http://nuffieldbioethics.org/children-and-research>

were used to identify a child with asthma and their family, and they were invited by the clinician to take part in the introductory section of Film 1. Subsequently, professional contacts across the research team were used to draw together a mock adult REC for the purposes of the second section of Film 1.<sup>27</sup> All contributors to Film 1 completed a consent form prior to filming.

- 2.8 As previously described (see paragraph 1.1 above), the research was conducted in three schools in the Brighton area – a junior school, a secondary school, and a sixth form college – to encompass three age groups (9-11 years; 11-16 years; and 16-18 years). Schools were sampled (insofar as was possible within the study timeframe and location) to include socio-economically mixed catchment areas. Initial contact was made with the schools by the one member of the research team (JB), who also visited two of the participating schools (junior and secondary) prior to the workshops to discuss the project in more detail.
- 2.9 Following initial contact, each participating school was asked to identify a volunteer sample of six to eight young people, who (with individual child *and* parent/guardian consent) took part in the half-day workshops. Information sheets and consent forms were circulated to potential participants and their parents/guardians prior to the school workshops. The workshops were held between November 2013 and January 2014. Ethical approval for this project was granted by the Institute of Education, University of London.<sup>28</sup>

## Data collection and analysis

- 2.10 One member of the research team (GS) facilitated all three school workshops; workshops were also attended by KH (representing the Nuffield Council on Bioethics) and by the film-maker (Vivianne Howard) and a sound technician.
- 2.11 Workshop activities were tailored to match the three different age groups and included facilitated group discussions, reading and reviewing ethics materials such as consent forms and study information sheets, and watching and discussing Film 1. A variety of participatory techniques were used to engage workshop participants and to encourage discussions about the proposed clinical research and ethics considerations children and young people identify. These included making posters, drawings, editing/re-designing study information sheets, and simulating processes of randomisation by organising workshop participants into 'control' and 'intervention' groups. The consultant's ethics application, including study information sheets, assent forms and parental letters and consent forms were also presented during the workshops to stimulate discussions.

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<sup>27</sup> For further details about the content of Film 1, including a description of the research study and mock REC discussions, please see Appendix A.

<sup>28</sup> Approval number FCL 558.

2.12 The workshops were filmed and footage (including transcripts of the workshops) were analysed thematically in relation to the aims of the research. The first stage of analysis included viewing the film footage from the three workshops, with a whole team discussion that included the film-maker, followed by further (re)reading of the transcripts by the whole study team. Discussions were then held by the team to identify key themes. Subsequent analysis stages involved two members of the team (JB, GS) independently analysing transcripts to produce analytical categories. Consistency of interpretations across these independent analyses were checked and confirmed by a third member of the team (RR). The analysis period also involved the development of a 'storyboard' and script for the purposes of producing Film 2. This stage involved close collaboration with the director of both films (VH) to identify footage that best captured the key themes identified from the close-focused analysis of the workshop transcripts.

## Chapter 3: Findings from the workshops

- 3.1 The aim of the three school-based workshops was to explore children and young people's views of ethical considerations in clinical research with children, and the extent to which the considerations they raised were captured by an adult REC.
- 3.2 The findings presented here take forward this aim through analysing and identifying areas of (dis)connection between adult and child perspectives, particularly in relation to risks or ethics concerns that are perceived by children but not by adults, or vice versa. The analysis foregrounds children's perspectives and frames of reference when discussing the study and related ethical concerns. Where relevant, comparisons are made with the discussions held by the adult REC meeting – highlighting too when workshop participants appeared to take-up and accommodate, or further contested the perspectives and discussions held during the adult REC meeting.

The findings are organised under seven main themes:

- What are research ethics?
  - Helping others: benefits of the study
  - A child-centred approach
  - What's it all about? The importance of being fully informed
  - Putting children at risk: health and social harms
  - Valuing children's contributions: incentives and rewards
  - It can be too personal: privacy, confidentiality and data management
- 3.3 As this chapter will demonstrate, the young people who took part in the research provided a thorough and insightful account of ethical issues in the research proposal. They highlighted many of the points raised by the adult REC, but also others that were *not* addressed by the adult REC in Film 1. The fact that they were able to do this so well – with no formal training in research ethics, and (especially for younger children participating in the sessions) starting the workshop with very little (if any) formal knowledge of research ethics – highlights children's expertise in their own lives, and what adults can (and should) learn from their nuanced understanding of the particular risks that might be encountered in clinical research with children. We thus begin our presentation of findings from the workshops with participants' broader discussions about research ethics to illuminate their detailed knowledge and understanding of the emergent issues. The youngest children who took part – in year 6 at junior school – summed up eloquently our project's aims:

GIRL: You're asking us questions about what we think about what the adults think... questions.

GS: That is exactly right – it sounds very complicated!

GIRL: You're asking us questions about what we think about what you think about what we think!

*Junior school student*

- 3.4 Especially in the context of ethics debates about the recognition of children's competences, as well as their potential vulnerability, this skilful summary of the 'meta' nature of our project is striking. These discussions also serve to illustrate the importance of accounting for young people's perspectives on ethical research practice.

### **What are 'research ethics'?**

- 3.5 At the beginning of the workshops, participants were asked about their understandings of research (and of clinical research), and also what they understood by the term 'ethics'.

- 3.6 Students at the sixth form college gave an account of what they understand by the term 'ethics':

GS: So if said to you what are ethics – what do you think ethics are about?

GIRL: What's right or wrong in a situation.

*Sixth form college student*

One participant in the junior school workshop summed up succinctly the task of reviewing research ethics:

GS: So if the research committee decided that the study was ethically okay, what do you think that might mean?

BOY: Would it mean like it's a good idea and they can't see much that's going to go wrong with it?

*Junior school student*

Young people also commented that the adult REC picked up similar issues – although there were some differences in perspective. For example:

GIRL: It was fairly similar to the conversations we have been having.

GS: Yes did you essentially agree with much of the conversation though they were having?

GIRL: Yeah we said a lot of the same things, I agreed with a lot of things that they were saying and they said a lot of things we were saying but in more detail which I agree with.

*Sixth form college student*

## Helping others: benefits of the study

- 3.7 The children and young people who took part in the workshops gave considerable emphasis to the possible range of risks connected with the study (see paragraph 3.18 below). However, the participants also highlighted some of the possible benefits, including the improvement of asthma for those children affected by the condition (both those in the trial, and others), but also the positive impacts of improved health on daily lives, and benefits for society. Workshop participants expressed their concern for others in the scenarios they discussed, and described a need to act benevolently (also see paragraphs 3.26 to 3.30 below).

GIRL: It could cut down on the amount of medication the children are taking each day so it will be better for them.

*Sixth form college student*

GIRL: If you only had to take one or two tablets instead of a lot it would make morning routines quicker and easier.

BOY: We also thought of helping to cure children – it might not be anytime soon but maybe they will find a cure to stop asthma attacks.

GIRL: We also found helping like to cure children because we don't know but in the future... Maybe in the future we will be able to help cure asthma and stop asthma attacks and stuff.

*Secondary school students*

GIRL: It will cost the NHS less money as well cos if they only have to have one or two drugs then they don't have to waste money on these things that aren't really working for them.

*Sixth form college student*

## A child-centred approach

- 3.8 Throughout the discussions, workshop participants signalled their preference for a child-centred approach to the research and its conduct. Specifically, young people who participated in the project highlighted the importance of adding a personal element to the clinical trial.

## Making it personal

- 3.9 Across all three school workshops, young people frequently framed their responses to the clinical trial in terms of the child participant. They expressed the importance of ensuring the proposed study was attentive to the circumstances of the individual child and considerate of their feelings. Workshop participants emphasised that children should feel part of the study and they underscored the responsibility of the research team to build a relationship with participants.

GIRL: Researchers need to think about the children in this situation cos it could really affect these children's benefits and their future.

*Secondary school student*

GIRL: ... It is a lot of time given from the children side of things and you know they are taking a risk in taking part – so they should be knowing and feeling personal and feeling like a part of it.

*Secondary school student*

- 3.10 The discussions amongst members of the adult REC meeting emphasised the importance of referring to children as participants rather than subjects of the research. After watching these discussions in the second part of the film, the children and young people in the workshops reiterated the idea of the child being at the centre of the research and more firmly expressed the importance of 'keeping it personal'. After viewing the REC discussions, some workshop participants appeared to take up the frames of reference used by the adult REC in order to (re)emphasise their own views on the same issues.

GIRL: I think they said...that they referred to the participants as subjects. I think that is a good point. Because it kind of makes it, they are not, I don't know it just doesn't feel like they are caring about the people that are doing it, it's more like there are things to be tested as opposed to people that have issues or that need to be helped.

*Sixth form college student*

BOY: They just need to make sure that they consider all the young people's feelings – what they might be thinking...

GIRL: I think they should work really closely with the doctors so that they know the children more and they have a close relationship...

*Sixth form college student*

GIRL: I think it is really important that the study is as personal as it can be – a personal connection between the researcher and the participants, especially not calling them subjects or anything like that – you have to have this personal touch and I think that it is really important for the participant to feel safe and kind of well and understand what they are getting themselves into.

*Sixth form college student*

GIRL: I think that they really shouldn't think of all the participants as a whole group of people but more as individuals because

everyone has different lives and it could affect them in different ways.

*Sixth form college student*

GIRL: I think those people are really right about how wrong it is cos they are keeping the people and the children as subjects. They are not subjects they are actually living people.

*Secondary school student*

### **What's it all about? The importance of being fully informed**

- 3.11 When talking of the possible harms linked to the study (see paragraph 3.18 below) workshop participants emphasised how children and young people (and their parents) needed to be well informed of possible risks, but also more generally about what taking part in the study might involve.

BOY: They should be told what could go wrong and like if they are still willing to do it they should be able to do it like. If they know that it might be painful and they still want to go through with it, I don't really see anything wrong with that. But like if they are just told we are going to do some research on you, this is what we are going to do but don't say anything but it could go wrong then that's bad.

*Secondary school student*

GIRL: You would also want to know how you are doing the research if it is going to involve you meeting other people or are you just going to do it all on computers.

BOY: If you don't know how you are going to do it you might have to do something and do it wrong or you might have to do something this way or the other way. So you want to know how you are doing it so you can get probably the best result at the end.

*Junior school students*

GIRL: I don't think they really explain well enough. In the consent form I don't think they really explain well enough properly how they are going to test the outcomes of it and sometimes like consent now or young people don't know exactly what all these tests are called and they've used the proper health care names for them. It needs to be something that is properly explained and how often they are going to have to do that.

*Sixth form college student*

BOY: And also they should actually be told exactly what's going to happen and what might happen afterwards in that way they would be more prepared.

*Secondary school student*

- 3.12 Some participants highlighted how important it was that children and young people fully understood *why* the trial was being conducted.

BOY: It wouldn't be good if they were doing it for no reason at all. Like it is good if you know what is actually happening to the results and why they are doing it.

*Junior school student*

- 3.13 A further key area of information was what might happen *after* the trial finished. Participants' concerns included questions of privacy (see paragraph 3.18 below), but also ideas linked to justice and the possible unfairness of leaving children without the appropriate support and treatment following their participation in the trial.

GIRL: They would kind of want to know when the study ends and are they going to just take the drug away from you? Or are you allowed to carry on with that if you think that is positive. Or if you want will they go back to prescribing your original drug. I think that something that you would wanna consider during the study is whether after it had finished are they going to withdraw the drug from you if you don't like it and maybe it's not the right form or something like that you could go back to the original prescribed drug or how it is going to work after.

*Sixth form college student*

GIRL: For me they have to consider and make sure what happens once they have finished their study and make sure the drugs they are giving and all the treatments they are giving are sustainable in the way that they would still be in particular the NHS to support that child with that drug maybe for the rest of their life. Cos you don't want to give them a drug that makes them feel loads better and just suddenly pull it from beneath them.

*Sixth form college student*

### ***Communicating information and creating a dialogue***

- 3.14 Whilst emphasising the importance of being fully informed, as noted above, young people were also often critical about the volume and content of written information (in terms of study information sheets) that would be given to children. This written information was described as 'boring' and perhaps 'too technical' for children. As a consequence, some young people were concerned about the

possibility that children may not read all the information presented to them and thus, would be under-informed about the proposed study.

GIRL: I don't think that it would hurt for it to be shorter. And the language in it a bit more kid friendly so they can answer a bit easier then it will be an honest opinion instead of being a bit confused and ticking it because it is there.

*Sixth form college student*

- 3.15 This concern was reiterated by the adult REC discussions, but with specific reference to the use of 'age-appropriate' information. However, in contrast to simply re-writing information sheets to make them age-appropriate, workshop participants also made some alternative suggestions to help ensure that children are well informed about the study. Suggestions included the use of visual methods such as a film outlining the study, and participants also noted that young people could offer (alternative) suggestions when study materials were being developed.

GIRL: They could also do a video as well. Obviously if there is a lot of children that could be taking part – not waste a lot of time but it would be quicker for them to get the information. GPs could just literally give them a DVD or a website to go and look at it.

*Sixth form college student*

BOY: Maybe shown something that explains it, like people show a video or a clip so that will explain it.

*Junior school student*

BOY: I think one of the things they could do [is] ask either the participants or people in that age range to look through the different information sheets and the way it is being carried out and say improvements on what they don't understand.

*Sixth form college student*

- 3.16 When discussing the importance of being well informed, the oldest group of workshop participants emphasised the value of discussions where a researcher, or another trusted adult, talks about the study with children and their parents. This could help make communication more genuine and effective and, again, more 'personal'. Dialogue could also involve a study participant's doctor.

GIRL: I think something a bit more personal is needed to talk to children about it rather than just an information sheet. Maybe the person in charge of the experiment could come in and talk to the children and explain what it really is about.

*Sixth form college student*

GIRL: I think that they should talk to their clinicians and their doctors who actually know their children, know their symptoms, instead of just reading it off a sheet that is general to all children with asthma.

*Sixth form college student*

GIRL: I think there needs to be a combination so talks with the doctor and an information sheet for the parents to go back and look at to go back and double check something.

*Sixth form college student*

GIRL: I was going to say if they gave an information sheet that was relatively simple and made sure there was a chance for people to ask questions about anything that they didn't understand or they wanted more information on.

*Sixth form college student*

### ***Having a say: decision-making with parents***

- 3.17 Workshop participants talked about children and young people's consent for participation in the trial, both in terms of the initial decision to take part, and for continuing to take part. They frequently saw scope for children and young people's decision-making, but sometimes presented a preference, even in the sixth form workshop group, for making decisions about participation along *with* their parents.

BOY: It's a bit like this really – you gave us a letter but you didn't force us to do it. We didn't have to do it.

*Junior school student*

GIRL: If you are going to have side effects you are probably not going to want to do it. Cos you are going to have to go through them and you don't really have much choice to say 'oh actually I don't really want to do it'.

*Junior school student*

GIRL A: At some stage you have to think about yourself and say enough is enough – this is my life I am risking. It is a bit selfish but then at the end of the day it is you that is doing it.

GS: So it is a bit of a balance.

GIRL B: I like what [GIRL A] just said but however I think if it's from the bottom of your heart and just go for it then if you don't like it then you can stop.

*Junior school student*

GIRL: I think it should be a joint decision but it also depends on how old you are, say you are 10, like me. I would want to have a say but my parents decide with me because they might know what's better and what the test is all about cos they might be looking into it more than I am and I might not be as bothered as they are.

*Junior school student*

BOY: I would like to have my say but I would like my parents to help me out with it... My brother and he is 8 and I know that he would like to have a say.

*Junior school student*

BOY: I think that personally I would listen to my parents. 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.

*Sixth form college student*

GIRL: With regards to consent unless it is a really, really young child that parents should ever be allowed to completely force their child into it. I think it should as well involve the clinicians speaking with the children and independent clinicians speaking with the children and the parents all speaking together as a family with the professionals as well. But even at the age of seven, kids should still have the power to say no.

*Sixth form college student*

GIRL: I think it would be important to make sure that they are actually realising that it is the children that are taking part in it and not the parents. So to make all the consent forms and information sheets relevant to the children and then maybe give out different ones to the parents and then they can decide which one fits their child the best.

*Sixth form college student*

### **Putting children at risk: health and social harms**

- 3.18 Workshop participants identified and discussed what they thought were a number of health-related and social harms associated with participation in the clinical trial. Physical or health-related harms stemmed from the proposed changes to treatment and possible range of side-effects experienced, as well as concerns about the proposed two-week 'wash-out period' during which time children would stop taking their regular asthma medication. Social harms identified by workshop

participants usually centred around the possible impacts on the family, as well as disruption to the child's everyday routines and involvement in activities.

### ***Health-related harms***

- 3.19 Across all three workshops, young people involved in the project were particularly concerned about the possible side-effects and associated health-risks arising from the proposed changes to treatment of a child's asthma as part of the clinical trial.

BOY: In the video [Film 1] they said it could be life threatening and so if they change the medication and it's not working it could threaten their lives.

*Secondary school student*

GIRL: If it is a really bad asthma that they have had all of their life they might have an asthma attack cos they are so used to one medicine and cos you know the other one is not actually working they could have an asthma attack...

BOY: And also if it turns out that it doesn't work on them and it worked on their other things that were helping – they're pretty much in a bad situation cos they will be putting them that much more at risk.

*Secondary school students*

BOY: The drugs they are taking they could be allergic to them. It could have a really bad effect on them.

*Secondary school student*

- 3.20 Specifically, these proposed changes in a child's asthma treatment were thought to hold a number of (significant) health risks for the children participating in the trial and some participants described these as being potentially 'life-threatening'.

GS: Can you say a little about how it might affect children?

BOY: The drugs could make them worse or they could be allergic – if they have got asthma there is usually other allergies and things like that.

*Sixth form college student*

GIRL A: But that could be dangerous cos they could in that time say have an asthma attack or something else because of not being on their medication and it would have been the person whose doing the survey's fault for them pretty much.

GIRL B: They have to be safe enough to go without it... They have to agree that they will be safe before they go through with it...

*Secondary school students*

- 3.21 Of particular concern to young people, especially after seeing discussions amongst the adult REC, was the proposed 'wash-out' period.

GIRL: What they were saying about the wash out period – I think that was important to know kind of the actual, if there was any research behind the safety of a wash out period and how like that would physically affect children cos it might be safe but it might actually affect how they feel in themselves – you know so I think that was really important.

*Sixth form college student*

BOY: Yes he said you would have to leave a child without medication for two weeks, and if your asthma is extremely serious then two weeks could be too long and you could get have serious asthma attacks in two weeks... I would understand that two weeks is a long time and people with really serious medication and asthma yes can make them ill and have an asthma attack quite bad. But I would only agree with the point about two weeks if they were having something else but if you just leave them without it they are not going to have it – they are going to be having asthma attacks and are going to be ill and going to be getting infections in their lungs and stuff.

*Junior school student*

BOY: But doing that is like putting them at risk. So if they can find another way to like make sure their body is free of that medication and stuff then good, but if you are going to leave them that is a bit of a risk cos you would worry.

GIRL: In his letter he was like going to leave them for two weeks and then he continued with another point and it didn't really explain how it could affect the children – he was like this will help with the results if we wash out their body of all medication but it didn't say what no medication could do to the children. So it was kind of like being putting some kids in danger.

*Junior school students*

- 3.22 Workshop participants identified possible consequences of communicating the risk of physical harms.

BOY: You need to look at something like if it went wrong – I understand if you want to be straightforward. You don't want to have any like things about it going wrong, cos if it does goes wrong then you don't know what to do so you want to be prepared for what might happen... They could warn the people that just saying you're taking this test but it not might work out very well...

There's side effects to it and they will tell you what those side effects are so if they see that you've got the side effects then they know that they can do something about that.

*Junior school student*

- 3.23 Young people's concerns about the potential for young participants to be harmed physically were echoed in the discussions held by the adult REC. However, young people in the workshops also extended these discussions to the possible impact of these risks on families, highlighting the possibility of increased anxiety for parents of children involved in the study. Here, workshop participants underscored the importance of children and their families feeling and being 'prepared for what might happen' during the course of the trial and how they might manage any associated adverse events or reactions at home.

GIRL: Parents might be worried that their kids might not be getting the correct medication...If their asthma's bad enough for them to have to take the extra drugs as well as the inhalers then it might be a bit of a worry if they have to come off it because what if they can't just cope with the inhalers – it might be a bit of a worry for some parents.

*Sixth form college student*

GIRL: If they stopped taking it, it could possibly make them more ill and also it could lead to dangerous outcomes that the parents don't know how to handle – like if they were just ill in the night and they didn't know how to handle it they would have to go to the hospital.

*Secondary school student*

GIRL: They have thought a bit about what could happen. It could be life threatening but I don't think they have thought about the children in this situation, or how it can affect the adults as well.

*Secondary school student*

GIRL: The doctor should tell the children what it's all about and what could be the possible effects to it and definitely tell the adults – the parents might be going through, would happen. Like the possible effects and dangers... And also if there is any dangers or if anything could go wrong, how they could deal with it as well. It could be quite dangerous.

*Secondary school student*

### ***Social harms and the impact on everyday life***

- 3.24 Participants also identified some of the wider social harms they thought may arise as part of children's involvement in the study. Of concern to young people

were the limits the trial may set on children's time and freedom to go about their everyday lives. Disruption to daily routines and involvement in activities such as sports and attendance at school featured in their discussions.

BOY: I think it is important to consider not only the health effect but actually the effect on the child's day to day life and how that will psychically affect them so that kind of comes into what for the medicine and how much it takes them out of school and how many times they would have to go up to hospital – so it is about how it affects their day to day life.

*Sixth form college student*

BOY: Is it important to do it if like going into this thing about disrupting your time and stuff. If it's not that important then you might not do it...

*Junior school student*

GIRL: Well it's quite like it's taking away your freedom, if you have to always do tests like every week or something then you won't have much time to do what you actually want to do in your normal life or as in just being tested all the time and stuff.

*Junior school student*

GIRL: You probably would want to do it but for a year that's quite a long time...The tests can make you really exhausted and all these things that you do on you so you get back home and you're really exhausted so you won't be able to do as much things, just sleep all the time.

*Junior school student*

GIRL: To test the effectiveness of the study they might do things like peak flows on the children and stuff like that – maybe that is an ethical consideration if they were gonna do things like blood tests and a lot of rigorous testing that the kids wouldn't want to do. They wouldn't want to be put through that.

*Sixth form college student*

GIRL: We said that doctors don't understand the affect that it has on routines and the children. Because one second they could be taking two tablets and the next they could be having five – or they could forget and go back to the other routine.

*Secondary school student*

3.25 During these discussions of social risks, workshop participants once again framed their responses in terms of the importance of the individual child taking

part. They noted that researchers should not rely solely on parents' perspectives on the costs of participation and argued that children's experience of risk had wider implications for decision-making and a child's experience of the study as a whole.

GIRL: I think that they shouldn't really just base it on what the parents think about whether their children should take part but also what their children want to do as well. But obviously taking into account advice from their parents if they think it would be best to or not to, but more on children and what they want to do. After all it is them that is getting the study and they should - I think they should be able to go back to their original medication or just drop out of the study altogether at any point through it if they feel that uncomfortable about it or they felt it wasn't working or having a negative effect.

*Sixth form college student*

### **Valuing children's contributions: incentives and rewards**

3.26 As the accounts above illustrate, workshop participants suggested that children and young people's decisions to take part in any clinical research should be done in partnership with parents and the research team. One particular area of concern for workshop participants and participation in the trial was the idea of receiving an incentive. Specifically, some young people expressed strong concerns that offering a (monetary) reward could be construed as a form of bribery – with potentially (negative) effects on children's participation.

GIRL: I think that it is kind of a bit of a bribe, that maybe the children they could be swayed into thinking one certain thing if they were getting a treat out of it. So they might be kind of forced into thinking a specific thing about the drug or you know feeling a certain way that they wouldn't necessarily if they were doing it honestly without anything involved in it.

BOY: Well that's a bit like bribing. Because if they don't really want to do it and you get loads of stuff afterwards it's kind of bribing them to do it... If you don't feel confident about the project and you don't want to do it and he says you get a £20 [gift] voucher at the end it kind of changes your opinion and you might, but if he gives it you at the end you would feel a bit like – kind of doesn't affect...

*Junior school students*

GIRL: Yes it's not good if you tell them you will get £20 as it's a bit like blackmail and we were just talking about whether the seven and nine year olds should choose themselves and see if it is good for them and it is a bit like forcing them to do it... It could make you choose the wrong thing. Cos if your parents thought 'oh this is not very good for their health', and then the doctor whispers in

your ear “but I’ll give you a £20 [gift] voucher” and you’re like ‘yeah Mum I actually really want to do it. And I really think it would be good for me.’ And then it might not turn out to be as good as you planned and it might not help your asthma it might get worse.

*Junior School Student*

- 3.27 These same young people talked about the importance of doing something good for others and thus did not feel there would be a need for any form of (financial) reward – a point echoed by some members of the adult REC. However, the workshop discussions also tied compensation and rewards to the overall importance and benefits of the proposed study. Here, the participants’ desire to help others sometimes came to the fore as they talked about the value they attached to doing something good for others. However, for others, the possible range of health risks linked to the clinical trial seemed to warrant an appropriate form of compensation as the following exchanges reveal.

GIRL: I don’t think they should get money at all because it’s helping other children for finding different cures and if you would like to do that means you would like to help – you don’t have to get paid to be a nice person, do you?

BOY: But you are risking your life.

GIRL C: You get to choose if you want to do that and you don’t get paid for being a good person. A good person is about the choices that you make.

GIRL B: They should get a reward. I think you should get a reward because like not everyone could do it and if you do it you should get a reward for it. Cos you are risking your life, like we are saying and at least you get something out of it.

*Secondary school students*

BOY: I think that people should do it out of the goodness of their hearts rather than the money. Cos if they are risking their lives to help everyone in the future rather than just helping themselves so it would be much more selfless! If you don’t want to do it then that is fine too – cos you don’t want to die. If you do it – it’s doing it out of the goodness of your heart. And if they decide to reward you afterwards then that is good.

*Secondary school student*

GIRL B: I also think that erm although they could be helping people in the future instead of just helping themselves but you can’t go your whole life – helping everyone else and not thinking about yourself...

BOY D: You would be doing this good thing to help tons of people in the future – like you don’t have to do tons of good things – if the

only good thing in your life is helping tons of people. So if you want to do it fine and if you don't want to do it's also fine.

GIRL G: In my opinion I actually think I would do it if I had asthma – I wouldn't do it for any money any vouchers – any holiday trips – nothing. I would just do it cos it is helping myself I might find a cure but it is actually helping other people with bad asthma.

*Secondary school students*

GIRL: I like what [student] just said but however I think if it's from the bottom of your heart and just go for it then if you don't like it then you can stop. But if you are doing it for money that's greed – you should just do it cos you are a nice person and if you risk your life you will do that. But at first you would want to know what it is all about and ask about all the risks before you get into that.

*Secondary school student*

GIRL: It's not about the amount of money – it's about the good deed that you have done. If you really wanted to go through with it then the prize shouldn't really matter. If it is something that you really want to do then there doesn't need to be a prize or whatever – a reward.

*Secondary school student*

GIRL: I think depending on how the study works – maybe the fact that the drug would work better would maybe be enough of a reward.

*Sixth form college student*

- 3.28 Whilst some participants felt that beneficence was paramount, other workshop participants (and members of the adult REC) viewed the voucher as important in acknowledging their contributions to the study. In this way, many participants discussed the importance of having their contributions recognised and appropriately rewarded. Importantly, and to avoid any concerns about bribery, young people highlighted a preference for any (monetary) reward to be given at the end of a study by way as a thank you for participation, rather than as an incentive for participation. Also of interest was the idea that any tokens of appreciation for participation should go directly to the child participant (and not the parent). Participants suggested that any such rewards should be 'child-appropriate' or something valued by, and of use to, children themselves.

BOY: Well you pay doctors to actually do the research so you need to pay people to do the research.

*Secondary school student*

GIRL: If you were going to give a child a £20 [gift] voucher then it is clearly going to their parents and maybe it would be like,

obviously not worth putting your child through a whole year of medical treatment for £20. But I think that might be something that would sway them and doesn't really seem like it's there to thank the kids, it's more to thank the parents who are putting their kids in it cos having £20 on [gift] might not necessarily benefit the child themselves.

*Sixth form college student*

GIRL: I think it would go towards the parents more...if they were going to give a reward it should be like a day out with the family or something that they know that the children would enjoy as well.

*Sixth form college student*

- 3.29 However, after watching the second part of the film in which adult REC members discussed different age groups and the value of the proposed reward, some disagreements about the amount of the reward emerged amongst workshop participants. Some workshop participants aligned themselves with the perspectives of the adult REC in suggesting that an 18 year old might want more than a £20 voucher. Others referred to equity, suggesting that an equal contribution to the study in terms of participation should be matched by equal rewards for all participants, irrespective of participants' ages.

GIRL: Everyone should probably get the same kind of reward from the study because then it is kind of saying that the contribution from certain people is more valuable than the others.

*Sixth form college student*

GIRL: It should be relative like [student was] saying earlier. £20 to an 18 year old doesn't mean the same thing to a seven year old and if they were going to get any compensation from it then it would be something that would directly go to them, something that they actually want and something that would like help them for a person of their age.

GIRL D: I agree with [student] I think everyone is contributing the same amount that they should definitely be given the same reward even if they are different ages they still are committing the same amount of time and effort, I think it should be equal.

GIRL: Everyone should get the same because it shouldn't be about older people should get more money because they older and they need it. They are not doing it for money they are doing it to benefit other people.

*Sixth form college students*

- 3.30 Despite these differences, overwhelmingly young people agreed that children and young people participating in research should be valued and their contributions respected and acted upon.

## Privacy, confidentiality and data management

- 3.31 One final key concern for participants was linked to ideas around privacy, confidentiality and anonymity of the study. Specifically, workshop participants discussed concerns about the potentially sensitive questions that researchers might ask about their health, but also how the researchers would use the data and whether they could be (individually) identified. Issues linked to sensitive information, anonymity, and data storage and sharing were highlighted across all three workshops.

### ***'It's too personal': sensitivity and privacy***

- 3.32 Research with a specific focus on children's health was seen by some workshop participants to be potentially sensitive and could involve personal questions about their health and lives. Of concern to these young people was the idea that such information could be shared with others, including people they know such as their family, friends, and fellow school students.

BOY: It could be quite invasive if they have to continually answer questions about their life.

*Sixth form college student*

BOY: They're too personal though... When they're asking you your postcode, it's so obvious it's not anonymous...

GIRL: Me and my sister both go to the school and if we both did the questionnaire we both live in the same house so they can't actually tell who is who.

BOY: Yes but they know that these two people live in the same house – so they are siblings. They would know how many siblings there are, how many and if they are asking if you are straight or gay, they'd know what percentage of people are gay, straight, bi whatever... why would they need to know – really why would they need to know? It's too personal.

*Secondary school students*

GIRL: And also you might want to find out if it is going to get shown to other people or told to other people, you might feel a bit unsecure about your health or anything... Cos it's about health maybe you're not as healthy as others were and you might feel a bit upset, it might get out to your friends or something and then you might be a bit like worried that they might, they know about your health. Cos usually you don't really know every single detail about them if it got out to them you might feel a bit upset.

*Junior school student*

### ***Being identified: anonymity and confidentiality***

- 3.33 As above the illustrations at paragraph 3.32 suggest, workshop participants were not concerned solely with personal or sensitive information being gathered about children, but with the associated risks of being identified. Concerns about anonymity and the possible ways in which children's responses to sensitive questions could be 'found out' were debated amongst the groups. These participants often drew upon other related examples of how they thought they could be identified – particularly if data were collected through the use of online surveys, or when using public or school computers. These concerns about confidentiality and the security of online information led some young people to suggest that they would conceal or even falsify their responses in online surveys.

GIRL: Yes, what [student] said – when people say this person won't say anything around people, like they are saying if you have ever done drugs, have you ever smoked, have you ever had alcohol? So they know and they are asking for your postcode – it's pretty obvious they are going to be sending this information off if you say the wrong thing like you *do do* drugs or you smoke or you've ever had alcohol before.

BOY: Even if some people went to me what I did try it once but I put down I never tried smoking or drugs because I don't want to get in trouble.

*Secondary school students*

BOY: Usually they would have a licensed agreement, if you read through it to make sure what they say – that they won't spread your information that it will be confidential...

BOY H: Well the government never keeps their promises.

*Secondary school students*

- 3.34 Discussions linked to issues of confidentiality and anonymity of data highlight that data storage and sharing may be a key concern for some children. In line with the discussions held by the adult REC, workshop participants similarly highlighted the importance of knowing what happens to the information collected and how and by whom the data could be used.

GIRL A: I was quite shocked that they didn't put the DNA thing in the consent form and also what would happen to the DNA after the study-taking place... I would be quite a bit worried for the parents not so much the children, but the parents to know what is going to happen to their child's DNA. I think the DNA consideration would be quite a big worry for parents to know how that would be stored, who it would be stored with and kind of how any information from the trial would be shared within different organisations.

*Sixth form college student*

BOY: This information could go anywhere. It could go to people who are going to make something out of it, it could go to people who are going to do something bad with it. It could go to good causes and stuff. You want to know where it is going cos if you don't then you kinda don't know... you know what it's about but you don't know how it is going to be used...

GIRL: You might also want to know who is going to be looking at all of this cos it might be universities or it might be just people you know and that might affect whether you want to do it or not.

*Junior school students*

GIRL: I think taking into consideration what they will do with the information afterwards – in this case [the] obvious example would be what they do with the DNA. The information would be very important and just make sure that all the researchers outline clearly what they will do with the research at the end of the experiment, study.

*Sixth form college student*

- 3.35 These examples further underscore the importance that workshop participants attached to having full information, appropriately given, about *all* aspects of the study – not simply what they may be asked to do as part of the study. These young people signalled the need to ensure that children have the opportunity to engage in a meaningful dialogue with the research team in order to support their participation and crucially, to ensure that the study centres on the feelings and perspectives of the children involved, about all aspects of their involvement.

## Chapter 4: Discussion

4.1 The literature review detailed at the beginning of this report emphasised the relevance – and value for researchers – of including children and young people in discussions about research and research ethics. The work reported here comprised a small exploratory study – addressing just one exemplar clinical trial, and working with young people of different ages in only three schools. Nevertheless, the themes to emerge from students’ discussions were striking in their consistency, picking up many of the same issues as adult REC discussions, but they also brought a distinctive concern, with the individual child’s lived experience of participating in a research study. These findings highlight the value of meaningful engagement of children and young people in discussions about research ethics, in bringing adults’ new insights into the ethics of clinical research with children. In this final part of this report, we consider how these findings can help to inform our understanding of ethics in research on children and young people’s health. Following Lundy’s criteria for participation,<sup>29</sup> we focus specifically on the possible ways in which children’s perspectives may help to shape research ethics guidance and training for researchers.

### A child-centred approach

4.2 Discussions with workshop participants consistently underscored the importance of a child-centred approach to research ethics. This ‘personal’ element was not described in terms of identifying age-appropriate techniques to establish a child’s competency, but rather signalled young people’s preference for researchers to develop an advanced appreciation of their own perspectives and understandings on how research may ‘play out’ in their everyday lives.

4.3 To be fully informed, in this light, is not about the researcher designing a sufficiently detailed information sheet. Rather it is about *communication*, as a dialogue in relationship with young people in all their diversity.<sup>30</sup> The students advocated a more contextualised approach to research, in which researchers engage with the everyday concerns of children and their own understandings of health and social issues (irrespective of their ages). This understanding highlights the importance of building relationships with children and young people during the course of the research process – a point widely advocated in the literature from the sociology of childhood.<sup>31</sup>

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<sup>29</sup> Lundy L (2007) ‘Voice’ is not enough: conceptualising Article 12 of the United Nations Convention on the Rights of the Child *British Educational Research Journal* **33(6)**: 927-42.

<sup>30</sup> Spencer G (2013) *Empowerment, health promotion and young people: a critical approach* (Abingdon: Routledge).

<sup>31</sup> See, for example, Mayall B (2002) *Towards a sociology for childhood: thinking from children's lives* (Buckingham: Open University Press); Morrow V (2008) Ethical dilemmas in research with children and young people about their social environments *Children's Geographies* **6(1)**: 49-61.

## **Building meaningful relationships**

- 4.4 Research ethics decision-making can risk creating a binary between adult and child perspectives in two ways. First, in some cases, the binary arises because the adult is seen as competent to consent while the child is not; second (as was the case in the Gillick ruling), adult and child views are seen in opposition; adult ‘gatekeepers’ function as barriers to children’s own decision-making. Such views were expressed by adult professionals who took part in Boddy and Oliver’s study of research governance in local authority children’s services. For example, a senior academic researcher observed: “It’s the dog that doesn’t bark – we don’t know if children are being excluded. Parents have different views of what is right for children.”<sup>32</sup> By contrast, a senior manager in a local authority cautioned: “I believe in children’s rights but they are not independent individuals because they are children.”<sup>33</sup>
- 4.5 In the context of our earlier discussion of the UNCRC (see paragraphs 1.6 and 1.12 above), the adult in these framings either serves a protective function for the vulnerable, dependent child, or acts to ‘exclude’, limiting the child’s rights to participation. A more complex perspective emerges from the discussions with young people who took part in our study. Here, workshop participants underscored the value they attached to building meaningful relationships with the research team and the importance of creating a three-way exchange of information (i.e. between children and young people, their parents/guardians, and the research team<sup>34</sup>). Contrary to the idea that as children get older they may want to make decisions by and for themselves, workshop participants of all ages (including those attending the sixth form college) highlighted the importance of discussing their participation in research *with* their parents. They were equally clear that the decision of whether or not to take part has to involve the child – as one said, “at the end of the day it is you that is doing it”. But crucially, young people involved in this project suggested that they were likely to follow the advice and guidance of their parents and make decisions about participation *with* them.

## **Information**

- 4.6 Curtis *et al.* found that information presented to young people is often partial in order to ‘protect’ them from having to make ‘adult’ decisions.<sup>35</sup> Yet findings here signal the careful and thoughtful ways in which children and young people make skilful assessments of research. Their insights raise questions about the widely accepted view that children’s engagement in complex discussions should be

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<sup>32</sup> Boddy J and Oliver C (2010) *Research governance in children’s services: the scope for new advice*, available at: <https://www.gov.uk/government/publications/research-governance-in-childrens-services-the-scope-for-new-advice>, at page 48.

<sup>33</sup> *Ibid.*, at page 47

<sup>34</sup> Spencer G (2013) *Empowerment, health promotion and young people: a critical approach* (Abingdon: Routledge).

<sup>35</sup> Curtis K, Liabo K, Roberts H, and Barker M (2004) Consulted but not heard: a qualitative study of young people’s views of their local health service *Health Expectations* **7(2)**: 149-56.

based on an assessment of age-appropriate and based on competencies. This area has been strongly contested by Alderson, who demonstrated that even very young children are able to understand, synthesise and question information about their own health and lives.<sup>36</sup>

- 4.7 A key message from participants in the present study concerned the *nature* of information provision. In discussing the information provided for the hypothetical trial, they warned that over-technical or over-detailed written information would be boring and inaccessible, limiting rather than enhancing understanding. They generated creative suggestions about how a more detailed level of understanding might be achieved – for example, through a combination of video information and discussion with trusted adults (clinicians and family members). Their observations are entirely consistent with an academic literature in medical and social sciences, which highlights the centrality of trust in understanding whether (and why) people consent to take part in research.<sup>37</sup> Children and young people in the present study reiterated their preference for a dialogue and meaningful relationship with the research team across the research process. Identifying ways in which researchers can build trust and respect with young people in research would appear key to adequate information provision, and points to a pertinent area for future research.<sup>38</sup>
- 4.8 The importance of trust also firmly featured in participants' discussions about privacy, confidentiality and anonymity of data. Some participants in this study expressed strong concerns about data sharing and storing; for example, by highlighting their concerns about being identified through postcodes, but also how schools could access information about them (for example, through schools having access to online survey results if these are completed during school time).<sup>39</sup> These insights provide some possible counter-evidence to recent broader discussions in the media that appear to suggest that young people are increasingly 'relaxed' about sharing personal information, or that young people lack a sufficient understanding of issues about privacy and confidentiality.<sup>40</sup>

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<sup>36</sup> Alderson P (2007) Competent children? Minors' consent to health care treatment and research *Social Science & Medicine* **65(11)**: 2272-83

<sup>37</sup> See, for example, Corrigan O (2003) Empty ethics: the problem with informed consent *Sociology of Health & Illness* **25(7)**: 768-92; Crow G, Wiles R, Heath S, and Charles V (2006) Research ethics and data quality: the implications of informed consent *International Journal of Social Research Methodology* **9(2)**: 83-95; Doucet A and Mauthner N (2012) Knowing responsibly: ethics, feminist epistemologies and methodologies, in *Ethics in qualitative research (second edition)*, Mauthner M, Birch M, Jessop J, and Miller T (Editors) (London: Sage); Morrow V, Boddy J, and Lamb R (2014 - forthcoming) *The ethics of secondary data analysis: learning from the experience of sharing qualitative data from young people and their families in an international study of childhood poverty: ESRC National Centre for Research Methods working paper* (Swindon: National Centre for Research Methods).

<sup>38</sup> See also: Spencer G (2013) *Empowerment, health promotion and young people: a critical approach* (Abingdon: Routledge).

<sup>39</sup> See paragraphs 3.31 to 3.35 above.

<sup>40</sup> Byron P, Albury K, and Evers C (2013) "It would be weird to have that on Facebook": young people's use of social media and the risk of sharing sexual health information *Reproductive Health Matters*

Whilst these recent concerns about young people's use of social media may hold for some young people, findings from this study highlighted participants' comprehensive and insightful grasp of the issues – indeed, such issues were paramount in some young people's decisions whether to participate in research (or not).

- 4.9 Whilst we cannot generalise from the findings of this study, the discussions reported here do support findings from other recent research that likewise indicates that young people are not oblivious to privacy, confidentiality and anonymity issues.<sup>41</sup> These findings further underscore the importance of ensuring young people are well informed of all aspects of a study – including how and why information from research may or could be stored and used in the future. Without such information, research may well compromise the possibilities for building the forms of trust and personal relationships that are so highly valued by young people.<sup>42</sup>

### Putting children at risk: protection versus participation

- 4.10 A particular concern expressed by workshop participants was the idea that research may put children at (unnecessary) risk. Discussions held during the workshops signalled participants' awareness and concern for a range of health-related and social risks and closely followed the discussions and concerns raised during the mock adult REC (with the latter discussions particularly focusing on proposed changes to a child's treatment of asthma and the 'wash-out' period). However, whilst young people involved in the study often talked at length about physical or health risks associated with participation in a clinical trial, they also pointed to some of the social risks, including a potential loss of freedom and constraints on their time and activities of everyday life. Of note are the benevolent and often altruistic motivations for children's participation; these motivations must be carefully considered by researchers so as to ensure due consideration is given to the activities or freedoms children may (willingly) give up as a consequence of their participation in research. As Kellett describes, by drawing on young people's expertise in their own lives, researchers can uncover an 'insider' perspective on the potential impact any research may have on

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**21(41)**: 35-44; Van Der Velden M, and El Emam K (2013) "Not all my friends need to know": a qualitative study of teenage patients, privacy, and social media *Journal of the American Medical Informatics Association* **20(1)**: 16-24.

<sup>41</sup> Ibid.

<sup>42</sup> Morrow V, Boddy J, and Lamb R (2014 - forthcoming) *The ethics of secondary data analysis: learning from the experience of sharing qualitative data from young people and their families in an international study of childhood poverty: ESRC National Centre for Research Methods working paper* (Swindon: National Centre for Research Methods); Spencer G (2014 – forthcoming) 'Exploring the 'everyday': situated ethics and ethnography in health research with young people *Qualitative Health Research*.

children's everyday lives – making visible to the outsider adult, the concerns most important and relevant to children themselves.<sup>43</sup>

### Valuing children's contributions

- 4.11 Closely linked to the development of a child-centred approach is the importance of *valuing* children's contributions. Of interest is the idea that children may not value monetary rewards unless they hold meaningful value and can be directly used by the individual child, rather than their parent.
- 4.12 However, in this study, participants' discussions about rewards and incentives did seem to shift after they watched part two of Film 1 and when the adult REC members discussed ideas around 'payment' and compensation for participants' time. After viewing the film, workshop participants articulated more firmly the idea of fair recompense for children's participation – although this was often a contested discussion area amongst participants, suggesting that children may not have the same expectations about 'payment' as adults may hold.
- 4.13 The discussions held by participants on the issues of rewards and incentives closely link to concerns about the Nuremberg principle of *undue influence*; yet they also offer a more nuanced argument. For example, workshop participants discussed undue influence on the child in terms of bribery, but they also talked about undue influence on their parents – if any incentive for participant is targeted at (or appealing to) parents, and not (necessarily) the child. Such discussions once again raise critical questions about children's power in (and over) research,<sup>44</sup> including the possible ways in which parents may (unwittingly) exert influence on, or over, children.
- 4.14 Participants in this study made a clear distinction between what they saw as an inducement and a 'thank you' for their time and contribution to the study – the latter appearing to be most important to young people in this study. An expression of gratitude and valuing children and young people's contributions was seen by participants as a mark of respect for who they are and what they do. As findings suggest, this expression of gratitude could include providing information about what happens with the results of research and how young people's contributions to a study may have been taken up (in policy or practice) to inform broader issues.

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<sup>43</sup> Kellett M (2010) Small shoes, big steps! Empowering children as active researchers *American Journal of Community Psychology* **46**(1): 195-203.

<sup>44</sup> Best AL (2007) *Representing youth: methodological issues in critical youth studies* (New York: New York University Press); Allen L (2008) Young people's 'agency' in sexuality research using visual methods *Journal of Youth Studies* **11**(6): 565-77; Spencer G, and Doull M (2014 – forthcoming) Examining the concepts of power and agency in research with young people *Journal of Youth Studies*.

## **Conclusion: implications for research ethics committees and research involving children and young people**

- 4.15 This small exploratory study on children and young people's perspectives on the ethics of clinical research has revealed the value some young people attach to being included in all aspects of research. Findings from this study point to some possible ways in which researchers and research ethics committees could meaningfully engage children and young people in research. However, before offering some suggestions, we highlight some limits to the present work and the extent to which the findings can be used to inform future discussions in this field.
- 4.16 Inevitably, conducting the study in just three schools in one locality does not capture the potential diversity of children and young people's perspectives in differing contexts and from different backgrounds. Similarly, workshop participants were identified (and selected) by school staff and thus the sample of young people involved in workshop discussions may well have included some (more articulate, confident) whilst excluding others. That said, the research team did discuss with school staff the importance of including and eliciting a diversity of perspectives from children and young people from a range of backgrounds. The extent to which this goal was achieved is difficult to ascertain, however, as socio-demographic data on participants was not collected in this small exploratory enquiry.
- 4.17 The use of different techniques to prompt discussion helped to accommodate different preferences and ways of encouraging children and young people's participation in the workshops. However, differences in technique may well set limits to the comparability of workshops and resultant data – indeed, the workshop facilitator (GS) found herself directing the workshops according to the contributions offered by (and the prior knowledge of clinical research and research ethics of) participants. Whilst accommodating different perspectives and group preferences, this style may have steered discussions along a particular line of thought.
- 4.18 Despite these constraints, the themes to emerge from students' discussions were striking in their consistency and often echoed many of the same issues as adult REC discussions. Crucially, findings reported here highlight the value of meaningful engagement of children and young people in discussions about research ethics, and may be used to inform the discussions and actions of researchers and research ethics committees in a number of ways. Here, we draw together some of the key messages through identifying some questions for researchers and RECs to consider in research with children and young people and around the following three important issues from the workshops: keeping it personal; being fully informed; and valuing contributions.

### ***Keeping it personal***

- How do researchers and RECs meaningfully engage children and young people in the development, design and review of research?
- How do researchers respond to the diversity of children and young people and their perspectives?
- How can respect and trust be built with children and young people?

### ***Being fully informed***

- How do researchers inform children and young people about research and its implications? For example, the use of visual methods such as a project film, creating a dialogue with children and their families, ongoing communication.
- How far do researchers involve and inform children and their parents/guardians at different stages of the research?
- How can researchers ensure ongoing communication with children and young people throughout the research and beyond?

### ***Valuing contributions***

- How do researchers value the time and contributions made by children and young people?
- At what point do researchers express gratitude for children and young people's contributions? (i.e. at the beginning, during or end of the project?).
- What are the expressions of gratitude most valued by young people and how can they be introduced into research? For example, monetary rewards, vouchers, certificates of participation, information on study conclusions, participating in dissemination and impact events.

4.19 Addressing questions of this kind require further exploration, but posing such considerations in the context of clinical research ethics review may help to ensure the perspectives of children and young people remain at the centre of any research on their own lives. Of importance is the extent to which researchers and RECs attend to the ways in which power relations between an adult researcher and younger participant can shape the research landscape and the emergent ethical issues. The conclusions drawn from this study highlight the significance of ensuring children and young people remain at the centre of research on their own lives; without such insights researchers arguably run the risk of overlooking or missing the issues that children and young people see as being most significant to them. This requires researchers and RECs to engage in meaningful dialogue with children and young people at all stages of research – signalling respect for their contributions, but also rightfully acknowledging children and young people's expertise on their own lives.

## Appendix 1: Film 1, Part 1 – storyboard: asthma trial and family scenes

Participant	Description/transcript
Narrator	<b>A street scene</b> Over a million children in Britain have asthma. It's the most common chronic disease amongst young people.
Trudi, Ruby's mother	<b>Ruby at home using her inhaler</b> Life with Ruby's been difficult... We've been in and out of hospital, chest infections, It's not been great every since she's been tiny. It is frightening... for the whole family as well as Ruby
Somnath, Ruby's Consultant/ Professor	<b>Scenes of Ruby using her inhaler and taking medication</b> Ruby has had a lot of hospital admissions ...has had severe asthma over a number of years, have been times, where the asthma has been life threatening for Ruby
Trudi	<b>Shot of blackboard in kitchen</b> This board shows Ruby's morning and night time medicines, so we know what to give her
Ruby	I can do my inhalers by myself, but mummy helps me do my tablets.
Narrator	Most children with asthma take a blue and brown inhaler, but as Ruby's asthma is more severe she's on a long list of additional daily medication
Trudi	<b>Shot of Ruby taking several more medicines</b> She takes a lot of medicine. You'd look at her normally and think she's a normal little girl. But a lot of medicines make her be that person.
Narrator	What do you think about taking all this medicines every morning?
Ruby	It's Ok but I don't like it
Narrator	<b>Scene of Hospital Outpatients department, showing Somnath</b> The Professor is Ruby's doctor and a pioneer in the treatment of children with asthma. Today she is having a routine check up to see how her current medication is working
Somnath	<b>Shots of Ruby and other children arriving/ in the Clinic</b> We have had to see Ruby quite frequently in the clinics. We've had to very carefully fine-tune her treatment, add different medicines
Narrator	Traditional treatment for children with severe asthma involves trying several different drugs over time to see what works best. But the Professor believes the genes of children like Ruby may make one drug more effective than another. It's not about the quantity of drugs, but taking the right one that matters.
Somnath	You sometimes find that the child is on three or four different medicines... they're expected to take them continuously, regularly... year in year out. <b>Scenes of Ruby being going through the clinic with a nurse, being measured</b> We have started to question whether this is the right way of treating asthma, particularly in children, because we found 15 per cent of children carry a particular genetic change which makes them resistant to certain medicines that we commonly use in asthma therapy. We have started to ask whether in these children it would be appropriate to withdraw medicines and substitute the medicine with something else. But this model needs to be tested through scientific studies.

Narrator	<p><b>Somnath greets Ruby and her family in the hospital clinic. Scenes of Ruby taking lung tests.</b></p> <p>The professor is keen to test his theory. He wants to undertake a clinical drug trial where 100 children will have their DNA taken. If they fall into the 15% of children whose genes are resistant to the standard asthma medication they will be given a drug called Verabreath. The one hundred-strong control group, who won't have their DNA tested, will stay with the standard medication, Exhalin.</p>
Somnath	I'm trying to get the application to the committee as soon as possible... almost finished...
Narrator	The Professor may believe his medical research is imperative to help children like Ruby, but first his work has to be independently assessed
Somnath	An ethics committee is made up of people from all walks of life. Their job is to look at the research plan from their own perspective and to decide whether they think this is the right way to go about it.
Narrator	Whether this piece of proposed research will ever see the light of day and become a medical trial is now in the hands of these six people.

## Appendix 2: Film 1, Part 2 – storyboard: mock adult REC

Participant	Description/transcript
Setting the scene	<b>The start of an adult Research Ethics Committee meeting</b> Men and women arrive at the Nuffield Council for Bioethics Offices, greet each other and sit down, shots of papers that describe an application for approval by the committee.
Bobbie, Ethics Committee Chair	<b>[Talking off camera]</b> Ethics committees have a bit of a bad reputation. Sometimes people think we like to get in the way of what they want to do, but we're absolutely committed to helping good research go forward. But at the same time it's our responsibility to ensure that the risks and the benefits weigh out in a good way and that people really do care about the interests of the very good individuals who volunteer to be part of their study.
Ruby's Consultant / Professor (Somnath)	<b>[Talking off camera]</b> I think it is difficult to get drug trials approved in general. It is always much harder when it involves children. Children are a vulnerable population.
Narrator	The professor's design for this proposed clinical trial is about to be put under the microscope, along with the information sheet he intends to give to parents and the accompanying consent forms. Only if it gets approval will it get the go-ahead.
Bobbie	My reading... is that we are looking at children/young people with quite severe asthma... whose condition isn't well controlled with the standard two inhalers.
Elin, Child Advocate	<b>The study design - includes a wash-out period where children receive no asthma medication</b> My understanding is the first group will be tested for this MAS gene and if they're positive they will be given Verabreath, and if they're negative they'll be given Exhalin. We would be taking them all off the medication for two weeks beforehand... brings a scientific and an ethical question. Is it right to take them off their medication and have them on this to wash out. It would be more appropriate ... to recruit children as they start to come to the point where they need that third line of defence drugs
Bobbie	There's a lot of nodding... Do people share those concerns? [others agree]
Simon, Anaesthetist	Is it ethical to recruit children when we know some of them will be harmed by getting one of the study drugs, which is the Exhalin, we need to think about the ethical issues about that control group
Becky, Medical student	<b>Safety of study participants – also some might lose out on participation</b> This is... underplayed in the information given to parents... It is an issue, particularly with children that might suffer more severely from their asthma... [they] might end up... excluded from the study because it's not safe for them to have a wash-out period.
Simon	<b>Insufficient information on risks and dealing with adverse events</b> There's very little information in here about what the risks are of participating in this study... [no] information about what happens if their child gets worse during the wash out period, [nothing on] who to contact, where to get advice...
Dez Holmes, Director,	<b>Retention and use of biological samples</b> [Another gap] in information...it's proposed, we'll take saliva [others voice

Research in Action	agreement] and we can't tell you how we'll use it in the future. Given current furore about DNA databases/ spying, I don't feel comfortable about that at all...
Isla-Kate, Research Governance Officer, Sussex University	<b>Consent needs to be sought for retention of biological samples</b> That's also entirely omitted from assent/consent forms for children/young people and parents. That's something that they certainly have to give explicit consent for. Remarkable it has been missed from those forms.
Dez	<b>Insufficient recognition of agency in young people. Inappropriate language</b> Inappropriate [to propose] they will seek permission from children to take part but they will only require parental consent. We're talking about... young people are 15/16/17/19, old enough to vote some of them... to have children, but we're treating them like very young children themselves. Mirrored by some of the language of the documentation for families - too complex for seven year olds and too patronizing for 18 year olds, not enough nuance in it... It didn't feel that research team really understood children and young people... they were treating them as subjects of research
Bobbie	that horrible word did slip in... we're going to have to warn against that
Isla-Kate	the word subject [has] been used rather than participant, both in the information for young people and for their parents/carers, which just isn't best practice
Bobbie	<b>Insufficient engagement with children and young people</b> Is one of the problems that nobody has spoken up front to young people about what's important to them – so what might count as a good important outcome measure in this project.
Isla-Kate	<b>Engagement to identify priority end points and concerns</b> ...could be some reported outcome measures around, e.g. being able to participate in sports and how it affected that, in social activities, or how they felt in general, whether they felt better/worse. That kind of information would be really important, particularly for the children and young people who have this condition.
Simon	<b>Clinicians might have different priorities than study participants</b> School stuff is important, but isn't necessarily going to make me say I'm happy to start using this medication... I want some good quality end points, e.g. how much use reliever medication, what their peak flow is; lung function test... that kind of information is relevant to me as a clinician.
Bobbie	<b>Incentives / rewards / altruism amongst participants</b> There is a small - I have to say very small - award. If we are going to incentivise or reward... we have to think, is it at an appropriate level? How would you feel, as an 18 yr old if you'd come for four additional appointments, kept a diary, logged in on a more or less daily basis, and you get a £20 voucher at the end?
Dez	I'd feel wholly insulted & patronised. It's not like when we were 18, £20 is not a lot of money these days. [Group members laugh] Doesn't get you very far.
Elin	I don't think we can underestimate children's altruistic motives for taking part in these sorts of studies. I have no problem with £20 - it is just a nice little gesture. If you give too much, it would be a little bit over the top and I would worry. Is just a cherry on top of the cake?
Bobbie	<b>Summing up</b> Everything brings us back to the science. We've got to go back to these researchers and say this is a job worth doing, but it has to be done to a very high scientific standard. We're not comfortable with the current study design. In

	the re-design it's going to be crucially important to involve children and young people from the outset [to] dismiss fears that it's about subjects rather than participants, and [to ensure] the risks and potential benefits are set out clearly from the outset
Elin	<b>Engagement can improve participation rates too</b> If the children and young people and parents themselves were allowed to be a part of the development of the study and understand the important questions being asked, they are more likely to understand the whole process, and to initially consent to take part to it, but also to stay with the study too
Bobbie	Thank you everyone. I've got a long and rather diplomatic letter to write... but we've given it our best and I hope we'll get a new protocol in due course that we can look at again.
	<b>Change of scene</b> Back at the hospital, the Professor is at his desk, waiting for the committee's decision
Narrator	For passionate professionals like the Professor, who are keen to pioneer new medical treatments for debilitating conditions like Ruby's, waiting for a decision from the ethics committee can be an anxious time.
Somnath	...I'm pretty sure they're going to ask us to make some changes, but it's very important... to hear whether they are in principle backing the proposal or not... [opens email] The committee is keen to work with you to enable this valuable project to go ahead. However, they have a number of concerns about the apparent lack of children and young people in developing the trial design. They are not very pleased with us referring to the children as subjects rather than participants and I think that is a very valid point. They want to see us involving children and young people right through the period of the study and I think we can achieve this
Narrator	One of the ethics committee's most serious concerns was a two week wash out period. They felt it put children like Ruby at too great a risk.
Somnath reads the Committee's response to the ethics application	There is quite a lot of evidence to indicate that it's safe to stop medicines for two weeks. I need to make the committee aware of these studies. And ...just as importantly, if we said that we are going to recruit patients right at the time when then third line defence medicines were being started, this trial will take ten years to complete. It would need a much larger amount of money, we would have to recruit in many different clinics and it may not be feasible.
Narrator	Having enough information to take part in a clinical trial is what's most important. At the end of the day, the success or failure of ground-breaking research like this relies on the participation of children like Ruby.

## Appendix 3: Film 2 – storyboard: workshops

Participant	Description/transcript
GS and participants	GS: So who knows what we are doing this afternoon? Has anybody got any idea? JUNIOR GIRL You're asking us questions about what we think about what the adults think. GS: That is exactly right I think – it sounds a bit complicated. LAUGHTER.
Text/aston	In the Autumn of 2014 a group of researchers from the University of Sussex, Brighton and Sussex Medical School, University of Nottingham and the Institute of Education in London began working on a project with the Nuffield Council on Bioethics.
GS	Children don't get asked a lot of the times what they think – so you are absolutely right – we are asking you to think about the way that adults do research and the way they think about it.
Text/aston	Their aim was to learn what young people think about the research studies adults devise and the decisions they make about children's involvement in clinical research.
GS	First of all have any of you been involved in research before. Do you know what clinical research is?
Narrator	Dr Grace Spencer from the University of Nottingham is leading workshops with students in three schools.
GS	<i>Today we are going to look at a piece of health research that we have made up for the purposes of this project.</i>
Narrator	Grace is to show them two films – one introduces a research study about treatment for asthma in childhood. The other is an adult research ethics committee discussing the planned research. The study and the research ethics committee were devised in order to stimulate debate. Both are fictional.
GS/ participants	So if I said to you 'what are ethics'? What do you think ethics are about? GIRL: what's right or wrong in a situation? GS: yeah, absolutely. BOY: isn't it a place? GS: The Only Way is Ethics, eh?
Narrator	<b>Visuals from Film 1</b> Children and young people rarely get to express their views about the medical research they take part in
GS	So you are absolutely right ethics is about...
Narrator	<b>Classroom actuality</b> By talking to young people the aim is to learn from them and to find out what they think about ethics in clinical research.
Text	<b>TITLE: Be A Part of It. What Young People think of Research Ethics</b>
Somnath	Ruby has had a lot of hospital admissions and she has had what I would say is severe asthma.
Narrator	<b>Ruby has a lung function test</b> These young people aged between 10 to 18 are watching the first film which follows chronic asthma sufferer, 7 year old Ruby, and the efforts of her consultant, Somnath to find the correct medication to control her condition.  Blow! Well done...

Narrator	<b>Somnath writes his proposal</b> Somnath has written a proposal for a clinical trial to test a new approach to treating severe asthma. First though he has to get his study approved by an adult research ethics committee.
GS	<b>Classroom – GS talks to participants</b> There's usually a big group of people – a bit like this – they get given all this paperwork about a study.
Narrator	Our students have been given the information that Somnath has written for his application.
GS	<b>Participants look at information sheets</b> You're going to be like a research ethics committee.
Narrator	They've been asked to review his study design and the information and consent forms that he intends to give to young people and their parents. <b>(ASTON: keep it personal)</b> What appears to be crucially important is the relationship between the researchers and young people.
Girl	<b>Participants write their thoughts on posters</b> The researchers need to think about the children in this situation because it could really affect these children's benefits and their future.
Narrator	<b>Classroom actuality</b> Just like the adult ethics committee the young people say a personal touch is needed.
Participants	Girl: They just need to make sure that they consider all the young people's feelings – what they might be thinking and also take a lot of things into account. Girl: They should work really closely with the doctors so that they know the children more and they have a closer relationship... Girl: I think it is really important that the study is as personal as it can be – a personal connection between the researcher and the participants.
Narrator	<b>Participants examine information sheets</b> The information sheets are scrutinised, not just to see if they clearly explain the health risks and day to day commitments, but that they give a bigger picture. <b>(ASTON: what's it all about?)</b>
Participants	Boy: They should be told first of all what could go wrong and like if they are still willing to do it they should be able to do it like. If they know that it might be painful and they still want to go through with it, then I don't really see anything wrong with that. But like if they are just told we are going to do some research on you, this is what we are going to do but don't say anything but it could go wrong - then that's bad! Girl: In the consent form they don't really explain properly how they are going to test the outcomes of it and sometimes young people don't know exactly what all these tests are called and they've used the proper health care names for them. It needs to be something that is properly explained and kind of how often they are going to have to do that.
Narrator	<b>GS displays information sheets</b> Most of the young people agree – the information provided needs to be accessible and appealing for young people.
GS and participants	GS: How would you like to be told then, what it's about – how would you like to know? GIRL: Maybe shown something that explains it, like people show a video or a

	<p>clip. That could explain it.</p> <p>GIRL: Obviously if there is a lot of children that could be taking part it could be quicker for them to get the information. The GP could just literally give them a DVD or a website to go and look at it.</p> <p>BOY: I think there should be both an information sheet and a video – some of the language in particular on this sheet – for lots of children that would go straight over their heads. They would need a conversation with the doctor of what's it about.</p>
Narrator/ participants	<p><b>GS with students</b></p> <p>Narrator: But making it personal also means talking to people about what's involved.</p> <p>GIRL: Maybe the person in charge of the experiment, kind of coming in, talking to the children, explaining what it really is about.</p> <p>GIRL: I think there needs to be a combination, so talks with the doctor but also an information sheet for the parents to go back and look at if they want to just double check something.</p>
Narrator/ participants	<p><b>Classroom actuality</b></p> <p>Having a say is at the heart of the discussions. But young people also want to make sure that the researchers include their parents in any discussions before or during the trial.</p> <p>GIRL: Personally if my parents told me I wasn't allowed to take part in the trial I think that I would listen to them... I would kind of trust their judgment on whether they think it is safe or not.</p> <p>GIRL: I think it should be a joint decision but it also depends on how old you are, like say you are 10, like me. I would want to like have a say but my parents decide like with me because they might know what's better and what the test is all about and I might not be as bothered as they are.</p> <p>GIRL: I would like to have my say but I would like my parents to help me out with it...</p> <p>BOY: My brother and he is 8 and I know that he would like to have a say with probably my mum and dad.</p> <p>GIRL: I think it would be important to make sure that they are actually realising that it is the children that are taking part in it and not the parents. So to make all the consent forms and information sheets relevant to the children and then maybe give out different ones to the parents and then they can decide which one fits their child the best.</p>
Narrator	Key to any research ethics review is the question of whether the potential risks are worth the benefits – now and in the future.
Aston	<b>ASTON: Balancing risks and benefits</b>
Participants	<p>GIRL: Maybe in the future we able to cure asthma and to stop asthma attacks.</p> <p>GIRL: If you only had to take one or two tablets instead of a lot then it would make morning routines quicker and easier.</p>
Aston/ narrator	<p><b>ASTON: Balancing risks and benefits</b></p> <p>But the possible benefits are countered by worries about the potential health risks that this study poses.</p>
Participants	<p>GIRL: I don't actually think they have thought about the children in this situation, or how it can affect the adults as well.</p> <p>BOY: And also if it turns out that the medicine doesn't work on them and they weren't on the other things which were helping then they're pretty much in a bad situation cos they will be putting them that much more at risk.</p>

	GIRL: They should know how reliant they are on that – they should know if they stop taking it they are going likely to have an asthma attack.
GS/ narrator	<b>GS explaining protocol to participants</b> GS: So before they started the study they would have to come off their medications that they normally take... Narrator: Just like the adult research ethics committee the young people pick up on the potential harms of a two-week 'wash out period'.
Participants/ GS	GIRL: That was important to know kind of the actual, if there was any research behind the safety of a wash out period and how that would like physically affect children. GIRL: If they tell you – you are going to have loads of side effects and stuff like that you are probably not going to really want to do it. GS: Do you have the choice do you think? GIRL: You should. BOY: He said he would have to leave a child without medication for two weeks and if he is testing people with serious asthma and if you had serious asthma – 2 weeks - you could get have an asthma attack in two weeks if you didn't have any medication at all. GS: so that's really serious isn't it? BOY: If you just leave them without it they're going to be having asthma attacks and they are going to be ill and get infections in the lungs and stuff.
Narrator	<b>Various scenes: classroom, adult REC, Ruby at hospital</b> Concerns about side effects were raised by the young people and the adult research ethics committee, but these young people are also worried about a possible negative effect on the parents and families too.
Participants	<b>Classroom actuality</b> GIRL: They should think about the impact on the family as well as what they are doing. GIRL: It could lead to dangerous outcomes that the parents may not know how to handle – so like if they were just ill in the night and they didn't know how to handle it they would have to go to the hospital. GIRL: The doctors should tell the children what it's all about and what could be the possible effects to it and definitely tell the adults – the parents might be going through will happen. GIRL: And also if could go wrong how they would deal with it as well.
Narrator	<b>Ruby playing</b> From physical dangers, the students move onto looking at how the drug trial could interfere with the day-to-day quality of family life. <b>ASTON: quality of life</b>
Participants	GIRL: I think it is important to consider not only the health effect but actually the effect on the child's day to day life and how that will physically affect them and how many times they would have to go up to hospital. GIRL: Well it's quite like it's taking away your freedom, if you have to always do tests like every like week or something then you won't have much time to do what you actually want to in your normal life. GIRL: The tests can make you really exhausted and all the stuff that you do on you so you get back home and you're really exhausted so you won't be able to do as much things, just kind of sleep all the time.
GS and participant	GS: Now what this doctor is planning to do in this study is to get you all to complete a questionnaire. OK? Online.

	GIRL: It could be quite invasive if they have to continually answer questions about their life.
Narrator	It would seem that children and young people are no different to adults when it comes to safeguarding their personal information. <b>ASTON: Privacy, Confidentiality and Data Management.</b> Of paramount concern is how the researchers intend to use the personal data they gather during the trial.
GS/ participants	GS: have you all done online questionnaires before? CHORUS Yes... GS: So you kind of know what that would be like if you were to do that. BOY: They're too personal though... When they're asking you your postcode, it's so obvious it's not anonymous. GIRL: Me and my sister both go to the school and if we both did the questionnaire we both live in the same house so they can't actually tell who is who. GIRL: You might want to find out who's going to be looking at all of this cos it might be like, say, universities or it could be like just people you know and that might affect if you want to do it or not.
Narrator/ participants	<b>ASTON: Personal information</b> The students are worried about the sort of information they would be expected to divulge. Who would have access to it, and how would it be used? GIRL: When people say this person won't say anything around people, like they are saying if you have ever done drugs, have you ever smoked, have you ever had alcohol. So they know and they are asking for your postcode – it's pretty obvious that they are going to be sending this information off if you say the wrong thing like you do drugs or you smoke or you've ever had alcohol before. BOY: Well the government never keeps their promises.
Narrator/ participants	<b>Classroom actuality</b> Just like the adult research ethics committee these young people want the researchers to clearly explain what they intend to do with all their personal information. GIRL: I was quite shocked that they didn't put the DNA thing in the consent form cos that's quite important – and also what would happen to the DNA after the study taking place... GS OFF CAMERA: Do you think that would be concern for children and young people? GIRL: Maybe not now – especially to seven year olds who might not understand – but later in life it could be used against them somehow. BOY: This information could go anywhere. It could go to people who are going to make something out of it, it could go people who are going to do something bad with it. It could go to good causes and stuff. You know what it's about but you don't know how it is going to be used.
Aston/ narrator/ participants	<b>ASTON: What happens when the study is over?</b> Narrator: what happens when a drug trial is over? After committing to a year of being tested and closely monitored, these young people want to know what happens next. GIRL: It wouldn't be good if they were doing it for no reason at all. Like it is good if you know what's actually happening to the results and like why are doing it. GIRL: I think for me they have to consider and make sure what happens once they have finished their study and make sure the drugs they are giving and all

	<p>the treatments they are giving are sustainable in the way that they would still be in particular the NHS to support that child with that drug maybe for the rest of their life. Cos you don't want to give them a drug that makes them feel loads better and just suddenly pull it from beneath them.</p>
Narrator/ participants/ GS	<p><b>ASTON: Incentives and rewards</b>  Narrator: Should young people be rewarded for taking part in clinical research? Or if others may benefit in the future, is that enough of a reason? This study proposed to give young people a £20 gift voucher.  GIRL: I think that it is kind of a bit of a bribe, that maybe the children might be— I don't know - they could be swayed into thinking one certain thing if they were getting a treat out of it.  GIRL: If they don't really want to do it and you get loads of stuff afterwards – well it's kind of bribing them to do it.  GIRL: If I was 7 or 8 I would probably want to do it for an Amazon voucher but like now that I am older I'd probably be like it is it worth it?  GS: is £20 not enough? LAUGHS</p>
Narrator	<p>Narrator: But rewards aren't everything for all of these young people  GIRL: If they were going to give a reward it should be like a day out with the family or something that they know that the children would enjoy as well.  GIRL: I don't think you should get money at all because it's helping other children for finding different cures and you don't have to get paid to be a nice person, do you?  BOY OFF CAMERA: But you are risking your life.  GIRL: Yeah, but you get to choose if you want to do that and you don't get paid for being a good person.  BOY: I think that people should do it out of the goodness of their hearts rather than for the money. Cos if they are risking their lives to help everyone in the future rather than just helping themselves, so it would be much more selfless! And, like, if you don't want to do it then that is fine too – cos you don't want to die. But if you do it – it's doing it out of the goodness of your heart.  GIRL: In my opinion I actually think I would do it if I had asthma – I wouldn't do it for any money any vouchers - nothing. I would just do it cos it is helping myself, I might find a cure, but it is actually helping other people with bad asthma. It could change the world.</p>
Narrator/ Bobbie Farsides (film 1); GS; participant	<p><b>Participants watch Film 1/finish workshop</b>  Narrator: the young people and adults agree on many points.  BF: It's interesting, isn't it, on this project that there is a small reward – and I have to say it's very small.  Narrator: All see the importance of involving young people from the start.  GS: I just want to say an absolute massive thank you. You've been absolutely brilliant. LAUGHTER.  Narrator: Young people addressed risks and benefits in the study. They emphasise the importance of researchers considering the risks in relation to children's everyday lives, as well as the potential for long-term harm. Above all, this means that ethical research needs a personal touch.  GIRL: They really shouldn't think of all the participants as a whole group of people but more like individuals because everyone has different lives and it could affect them in different ways.</p>
Aston	<p><b>ASTON: Thanks to all the children and young people who took part and the schools: Brighton Aldridge Community Academy (BACA), Varndean</b></p>

	<b>College and Downs Junior School for allowing us to film.</b>
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