# Survey Monkey questionnaire

## Analysis of parents' responses

November 2013

This paper provides a summary analysis of responses to the Working Party's questionnaire for parents, which was posted to the Survey Monkey website from August to October 2013. 70 questionnaires were started, 53 of which were completed.

Each question is analysed in turn, and key quotes are identified for each.

## 1. What do you understand by the term 'clinical research'?

Respondents addressed this question in four broad ways, namely the aims of clinical research; consideration of 'what' clinical research consists of; who carries out the research; and identifying research participants.

### i. Aims of clinical research

Respondents suggested a wide range of aims, including:

- determining the safety and efficacy of a particular treatment
- obtaining sufficient knowledge to identify the optimal (or indeed alternative) treatment for a particular condition was also identified
- investigating something *new*, whether drugs, procedures or interventions
- considering whether a new drug is ethical by meeting the aim of providing a measureable improvement to a medical condition or situation
- preventing disease
- identifying side effects
- adhering to good clinical practice

### ii. What clinical research consists of

Respondents referred to several types of clinical research in their responses to the questionnaire.

These included studies, reviews, surveys, tests, behavioural studies, statistics, surgical techniques, testing hypotheses, testing medical devices, research into symptom relief, diagnostic tools, medical trials, experimental drugs, treatment protocols, healthcare and healthcare matters.

### iii. Who does the research

The identification of researchers was limited to: professionals and medical teams, and respondents suggested that research should take place within clinics, or “a controlled, medical environment”, and that doctors might use research in their clinical practice.

### iv. Identifying research participants

Respondents also referenced who they thought research participants might be. Suggestions included infants, children, young people, patients, people with a specific condition, and humans and people generally

**Key quotes**

> “Clinical research is a branch of medical science that determines the safety and effectiveness of medications, devices, diagnostic products and treatment regimens intended for human use. These may be used for prevention, treatment, diagnosis or for relieving symptoms of a disease.”
>
> “A study to help prove/ disprove a hypothesis or to form a correlation in certain conditions/ circumstances in relation to a given subject such as management of a health condition.”
>
> “Research aimed at the production of new drugs, vaccines or at identification and characterisation of diseases, among others.”
>
> “The term clinical research can be ambiguous and be interpreted as 'clinical trials'. Health-related research involving infants, children and young people is, however, much broader, encapsulating any research intended to enhance knowledge and understanding of a health-related topic with the overall aim of enhancing the well-being and experiences of health service users.”

## 2. What would be your main concerns about enrolling your child/children into a clinical research study, and why?

A range of concerns were raised by parents, including:

- The safety of the drug or procedure being tested
- Invasiveness of procedures associated with the clinical research
- Unanticipated additional harms
- Risks (generally)
- Whether equipoise achieved
- Getting my child to cooperate
- Data security and privacy
- That my child’s choice is not sufficiently informed
- Side effects
    - Emotional effects
        - Physical effects / discomfort
- Missed school
- Emotional investment in the research, and potential disappointment for my child
- Effects on existing treatments; double burden if the child is already sick

- Danger to child's development
- Burden
    - Time
    - Effort
- Financial costs
- That the child's autonomy would be compromised
- Unexpected results of treatment
- The adequacy of the research centre

**Key quotes**

> "Whether there is true equipoise - are the two (or more arms) truly equivalent according to current evidence? Anticipated regret - what if my child was put in the arm that doesn't do as well. Making decisions when my child is ill - my decision-making capacity will be impaired."

> "The child being subjected to something that may harm them physically or mentally. I would also be concerned about privacy issues. I would not want to subject my child to something that would potentially harm them and I would not want their privacy to be at risk."

> "Concerns would arise from both my child and myself not being fully informed about what would be involved and that consent to participate had been obtained in a participatory manner. That any harm to my daughter would be outweighed any benefits to the aims of the research. That it would be too time consuming."

> "I would have no concern. Research can only be a good thing."

## 3. What could be done to help alleviate any of your concerns about enrolling your child into a clinical research study?

A range of suggestions were made by parents as to what might be done to alleviate their concerns. These included:

- Information:
    - Clear, succinct, easy-to-read information (including lay statements)
    - Option of clarification on available information, if necessary
    - Clear explanation of risks involved
    - About side effects and previous research that has been undertaken in the area.
    - Explained thoroughly prior to participation in a study
- Visual explanation of the protocol
- Face-to-face meetings with researchers
- The option of stepped consent
- Clarification that your child can withdraw (or be withdrawn) from the research at any time.
- Reassurance

    - that the trial will not make an already sick child more sick
    - that the child's education will not be disrupted badly
    - that the child will not have to endure too much discomfort
- Being given the option of accompanying the child where possible.
- More research centres spread across the country.
- Good evidence that the trial will 'work' for the participant
- Good relationship, and communication, between parents and the trial team
    - Thorough introductory meeting with someone who can answer all those questions and concerns
    - A clear process of whom to speak to relating to questions or concerns to a specific information not just a generic telephone be that local or a national number.
- Being sure that it is useful and not just searching for searching's sake.
- Have all research done during our normal days of treatment. Anything that is sent home has proven to be harder to get done and turned in.
- Knowledge that the research has received ethical approval.

The point which was perhaps made most frequently focused on information, and the importance of providing detailed, precise, open and honest information throughout the research process.

**Key quotes**

> "I would be very worried if any new drug is to be administered. Any drug that has been approved and has been used for other conditions would make me feel more relaxed."
>
> "Being reassured that the study would help my child or other children and that participation would not make my child worse."
>
> "Consider stepped consent - where you agree to each part of the research just before it happens rather than everything up front."
>
> "Make the research child-friendly and involve children in the design of the project where possible."
>
> "I would want to know that a parent and/or parent group had been consulted at study design / ethics stage so that the researchers took on board "the man in the street" point of view / opinion when considering children in studies."
>
> "I would need to be convinced that it would be extremely advantageous to my child before enrolling him."
>
> "Being able to discuss the study with someone who had knowledge of it… I was asked to sign a form to say I had had the opportunity to discuss the study with a particular named doctor. I had never met the doctor and was never given the opportunity."

**4. Do you think you would gain anything from enrolling your child in a clinical research study? If so, what?**

Responses were split broadly into three areas: those who felt that something will be gained if their child was enrolled in a research study; those who stated that it would depend on the circumstances; and parents who thought that it would be of little or no benefit. Most responses indicated sympathy with the first of these approaches.

### i. Something will be gained from being enrolled in a research study

- The child will receive better care from their medical team
- Could lead to better understanding of a condition
- May help to develop new treatments and cures
- Potential to get access to an innovative treatment
- Health benefits
- Knowing that other children are being helped by son/daughter's participation
- Helping others/other children
    - Encouraging my child to help others
- Money (to keep in trust for the child's benefit later in life)
- New knowledge
- Possibility of a cure, treatment, or other life-saving measure for a child who takes part
- Children like to take part in new things, and might enjoy the experience
- Hope (for conditions without cure)
- Benefit for everyone, not just children.
- Better access to innovative treatments.
- Satisfaction in contributing – 'feeling good'
- Improved quality of life
- Reduction of medical intervention
- To get a better understanding of research

### ii. Something might be gained, depending on the circumstances

- It would depend on the study
- Depends on the child's health (condition)
- It may be that the effects of the study are not conclusive or may be gains in the future for others
- If there is early treatment, or higher priority to get treatment
- Potential for parent to learn more about child's condition
- Any results are several years away and not readily available
- Determined by the nature of the research.
- We might not gain anything now, but future generations could

### iii. There will be little or no benefit from enrolling a child in clinical research

- Not if there is already a significant health burden on the child

- Likely to be increased monitoring, which might be helpful clinically but might be inconvenient

### Key quotes

> "I believe my child would have more personalised attention and follow up from the consultant in charge."
>
> "My son has recently been diagnosed with an incurable and life-limiting condition and one that will result in profound physical disabilities, so taking part in clinical research into a treatment or cure could be hugely significant for him."
>
> "I have a child with congenital heart defect and I happily enroll him in studies which could be beneficial for him and cast more light on his condition."
>
> "Yes. Many research treatment studies are more effective and beneficial than treatment protocols that have been out there forever."
>
> "If very lucky, he might happen to be an early beneficiary of a wonder drug. But I accept that the main benefit might be for future children, just as my child benefits from children who took part in trials in the past."
>
> "I would gain assurance knowing that all possibilities were considered in either curing the disease and/or alleviating the symptom discomforts."
>
> "No due to the enormous number of procedures my child has already undergone and the additional distress it would cause him. (Unless it involved a very simple blood test or questionnaire only that he would be unaware of)"
>
> "I instil in my daughter a strong sense of altruism."
>
> "There is likely to be increased monitoring, which might be helpful clinically but might be inconvenient. There's also the Hawthorn effect. My child's health might be improved. I would feel that we had contributed to knowledge and to future treatment of children."
>
> "We have participated in studies in the past where we received a gift of some sort, but were not aware this would happen prior to agreeing to participate. It would not have made a difference had we known this would happen or not."

## 5. Would you allow your child to be involved in making decisions about participating in a clinical research study, and why?

No respondents stated outright that they would not allow their child to be involved in making decisions. However, some stated that they would only allow their child to be involved if certain conditions were met. These conditions included:

- Reaching a sufficient age to make decisions
- The capacity of the child
    - If able to digest and understand what it means
    - If the child can engage with his or her parents about the risks and benefits of a particular procedure
    - If they (the child/young person) can explain the procedure
- If there is sufficient support for the child
- As long as it is made clear that the child can leave the study at any time if they can't cope
- Depending on the child's emotional state
- If they're accustomed to medical treatment and research (e.g. have had health problems for a period of time)

Other respondents answered this question in the affirmative, and then provided explanation for their response. Explanations included:

- Children should be involved in decisions about them whenever possible
- Children should be happy with taking part, especially if the research is invasive
- "It is their body"
- "It's their life"
- To protect the child's autonomy
- To protect the rights of the child (potentially) taking part
- Yes – respect the child's ability to decide
- The child has to be onboard with any research that is undertaken
- Especially if the study involves unpleasant procedures

**Key quotes**

> "It would depend on the child. If my child had capacity to make such decisions AND wanted to be involved, then yes. If my child was too young to understand, then no, initially. But if they strongly objected to the procedures being done on them, then I would withdraw them. If they understood but didn't want to make the decision, then I would make it for them."

> "Even at 5 my child knows what he will and won't do."

> "Yes, if old enough to make decisions, but definitely involved in discussions if too young to have final say."

> "I would always ensure my child was involved in decision making processes, recognising her level of maturity and development."

> "Yes, it is important that they understand and can make decision from an early age. You could make good use of play specialists in hospitals to facilitate and advise on these issues."

"I would decide and explain to my child in a way that would encourage them to see the benefits and take part. If they refused after repeated attempts to persuade I would have to respect their decision now my child is getting older (8)."

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

"…where consent is concerned children should be given longer than 24hrs or if this is not possible that there is a cooling off period for them."

"My son was 15 years old at the time that he was going through treatment and I always deferred to him when being asked about a research study. If my son had been a young child, I don't think I would have involved him just because I don't think he could have understood."

"…engagement with ones illness/condition lies at the heart of overcoming it."

"…the child is the most important person in the clinical trial, so he / she must be informed in a comprehensive way and be able to decide and to express his / her opinion."

## 6. If you would NOT allow your child to be involved in making decisions about participating in a clinical research study, would this change if your child was older?

As most respondents stated that the would allow their child to be involved in making decisions about participating in clinical research, there were very few substantive responses to this question.

Several respondents answered with a simple 'yes' to this question, but others provided general comments, including:

"In any case, I would not allow a child younger than 6 to participate."
"With age generally comes competence."
"A parent's job is to look after a child's best interests. This changes when a child is older."
"It would depend on the individual child's preferences to be involved, not just their age."
"Every child if able should be involved in decision making"
"Age doesn't take part in the decision."

## 7. Who should make the final decision regarding your child's involvement in a clinical research study?

The results for this question are as follows (other comments have been included where appropriate/available).

**Parent(s): 12.96% (n=7)**

- “Depending on their age, we are the primary caretaker. Therefore responsible for their decisions.”
- “Clinician can give you options and their motives are biased, and a child is still a child whether they are informed or not, so whether they appear to be a mature child.”

**Child: 3.7% (n=2)**

- “I would… discuss the matter with my son and support him in making the decision, but it would his decision.”

**Parents and child: 33.33% (n=18)**

- “subject to age and understanding, both involved”
- “Based on a good informed consent process, parents should be able to make a decision that does not contradict the best interests of their children, and children would be able to understand the reasons.”
- “I think ultimately the final decision should be the child who is participating however in some situations if part of the research design or activity could cause harm and that could be determined in a number of ways should be in partnership with parents too.”

**Clinician: 0% (n=0)**

**Clinician and parents: 3.7% (n=2)**

**Clinician, parents and child: 37.04% (n=20)**

- Decision should involve researchers/clinicians who have in-depth knowledge and understanding of condition, study, pros and cons, etc. AND parents/child when old enough to understand what's at stake.
- Decision should involve researchers/clinicians who have in-depth knowledge and understanding of condition, study, pros and cons, etc. AND parents/child when old enough to understand what's at stake.
- all three should be jointly happy about it, having discussed it together
- It should be informed choice and all must be involved to achieve this

**Other: 9.26% (n=5)**

- “Parent and child if the child wanted to be involved and was competent to make the decision. Parent only if either of these criteria are not met. But the child would over-ride the parent if the child objected to painful procedures that were not likely to benefit them.”
- “Gillick competent children”
- “It depends on the age of the child and the type of study. Though clinicians should have no say.”
- “Definitely clinicians and parents, involvement of child would depend on age, impact and circumstances.”

**8. How comfortable would you feel about taking your child out of a clinical research study? (For example, if you thought it was being detrimental to their health, or if the arrangements became very inconvenient?)**

Results for this question are as follows:

Very comfortable: 40.74% (n=22)
Comfortable: 33.33% (n=18)
Neutral: 9.26% (n=5)
Uncomfortable: 14.81% (n=8)
Very uncomfortable: 1.85% (n=1)

**9. Would you be willing to involve your child in a clinical research study if you knew that it would not improve your child's condition directly, but might improve treatment options for other children suffering with the same condition?**

The results for this question are as follows, and include other comments where appropriate and available.

**Yes: 61.11% (n=33)**

- "If it can benefit others then surely it is worth trying."
- "If the study was involving negligible risk to my child and potentially benefiting another, I would see no reason to withdraw my child from a study."
- "My son is of an age and fully aware of any implications to taking part in a trial and I know that he would want to do that. I would agree with him as there has to be a starting point and families are taking that decision already."
- "My child has benefited from the results of previous clinical studies. Progress cannot be made if these types of studies are not continued."
- "I would want things to be better for others."
- "We can't change current practice without evidence."
- "My son is taking part in one! Research is vital to move care and understanding forward. It is not detrimental to him and we / he likes the fact that he could be making a historical difference!"
- "Because that is our purpose for being here. Helping others."
- "When our sons were diagnosed [with DMD] there was no hope but now there is something, but we are well aware that it may not be in time for our sons to fully benefit from. We take the positives of participation and the information that we gained on the day to day management of DMD outside to the trial at a local level away from a internationally recognised authority such as GOSH."
- "I feel that it is my responsibility to help those who will come after my child just as those who came before him helped."

- "The blood taken from my child, has since changed her diagnosis and not impacted her directly but has helped other children with the rare syndrome."

**No: 5.56% (n=3)**

- "My son has a short life expectancy and I would not want to put him through anything at his stage in life that would not improve his condition directly, I feel he has enough to cope with as it is."

**Maybe: 33.33% (n=18)**

- "I guess it would depend on the condition and the procedures involved in the study. Most times I would say yes though."
- "If there were painful procedures that weren't going to help them directly and that they objected to, then I wouldn't be willing. But if they wanted to help, despite the pain, then they could continue. If they didn't want to help, and objected, then I wouldn't allow them to be involved."
- "My willingness would need to be set into a context of any risk of harm or inconvenience to the child and other parties - their clinical team and the child's own view."
- "I would like to be able to help others but at the end of the day my child already has significant challenges because of his medical condition so his well being would be my priority."

## 10. What might encourage you/your child to participate in a clinical research study? (Tick any that apply)

Results for this question are as follows:

More information about research opportunities: 68.52%
Appreciation (e.g. thank you letters): 37.04%
Information about the outcome of the research (e.g. articles published in medical journals/changes in medical practice): 81.48%
Participation made easier (e.g. convenient location; easy travel): 81.48%
Small financial reward (e.g. £5 token): 24.07%
Larger financial reward (e.g. £50 token or cash): 20.37%

Further supplementary comments provided by respondents can be sub-divided into the following three categories:

### i. Information and communication

"Information helps with making a determination. Convenience is important because time with family is important."

"Clearer information and the approach to be made by the treating clinician and nurse NOT a registrar or trainee."

“One of my frustrations about being involved in a clinical trial is that you get global results, but very little clinical understanding of how the trial is impacting or helping your child individually through the measurements done. Not an easy ask but sometimes it feels like the individual matters less than the result overall.”

“Good use of media including social media is needed.”

“Understanding what is expected from the participant, what the results are and knowing it would not become a huge chore participating would most definitely encourage me to participate.”

“Communication between both parties and the drug company are paramount and there is no misleading info or false hope given.”

“We also received progress reports and updates on the trial.”

“To get people on board they need to feel special and not a sheep and a big herd. It is the little touches for example good manners, nothing it too much trouble, refreshments on arrival, individual care, someone to have done their homework about your child even if it just checking when their birthday is as I say it is the little touches. Researchers also need a good bedside manner :)”

### ii. Financial considerations

“I think one needs to be careful when offering financial reward especially if people are told in advance this could affect consent and possibly be deemed to be slightly coercive. I think I would feel better not knowing about this as I would be making choice based on what is best for my child and the advancement of treatments and I don't think a small monetary reward feels right somehow, we are talking about children's health and wellbeing? Maybe if children were given something after their involvement? Sorry not sure about this one, I have to also acknowledge that as a social science researcher I have some understanding of research protocol. That said, as a parent of a child with a chronic health problem my decision would be based on clinical information and not whether I would get a token. Further, £5 or £50 seem such small amounts when thinking about whether I would let my child be involved, it kind of does not feel enough? Then again it would be dependent upon the trial and its impact on them. Yes, prefer not to know about any monetary reward about how much or little we might get.”

“Assurance that any profit made as a result of findings would be ploughed back into the health service or future research. Assurance that my child was not just being used as a money-making tool by big pharma.”

“A variety of factors go into enrolling into a research study. What is important is that the participant is made aware of the benefits, risks, and outcomes of research. Compensation is always an added incentive, but must be weighed in proportion of the necessity of the research.”

“They are children at the end of the day so they respond to rewards.”

“The financial payment, would not be the key element in making the decision making - but is always welcome.”

"A small reward would help with the travel/parking costs etc. and inconvenience of taking part. also a small reward like a voucher toward a cost of a meal for the parents or family, maybe a book voucher for the child would be a nice way of saying thank you for your time and cooperation, especially if the test will benefit other people and not themselves directly. I.e. when I give blood, it's nice that the tea and (nice) biscuits or walkers crisps are free, seems like just a little thank you."

### iii. Logistics

"Studies often take place in very large urban centres making it difficult - sometimes impossible - for non-residents to participate (because of time and costs related to travel, and energy required for participants to be well enough to travel a long distance). Would be comforting to know that participation led to an increase in knowledge and understanding of a condition regardless of whether it led to a health improvement (learning what doesn't work can sometimes be as useful as learning what works!)."

"It's a moral decision for us. To help in the cause of managing his disease (Duchenne) seems a 'no-brainer'!"

"When we participated on the boys' trial, travel and accommodation expenses were covered. The boys' food was provided."

"It's always better if the location is convenient."

"Participation must coincide with treatment schedules and not be in addition. The treatment schedule/office visits, hospital stays for a cancer patient is already extensive, so combining visits should be reasonably easy for the researchers."

"Financial rewards are nice bonuses but the main reason I have chosen to participate is the ease of participation. I will do just about any study that does not involve additional travel to and from locations."

## 11. About me/my family (Please add more detail if you wish)

53 respondents answered this question. Responses were split very evenly between parents whose child had taken part (or been invited to take part) in clinical research at least once (49.06% of respondents who addressed this question), and those whose child had never been invited to take part in clinical research (50.94% of respondents who addressed this question).

A number of other details were provided by:

### a) Parents of children who had been invited to take part in clinical research

"Considering enrolling in a trial currently."

"My son was diagnosed with acute myeloid leukemia in 2005 and was a patient at St. Jude Children's Research Hospital."

“MRI scan of muscle in his ankle.”

“I have two sons who have participated in a drug trial.”

“a trial when she was a baby”

“a sample of my daughter’s blood was taken, it took years for the results of the research to come back, and it has help identify a group of people with similar condition be linked with the same chromosome abnormality, but unfortunately it meant that she longer fit into this group.”

“My child was part of a clinical trial 16 years ago. When he went for his 10 year check up, and he was old enough to understand, his doctor told him that she wanted to see him, not because she was afraid that he might be sick again, but to see how his treatment outcome could possibly help other children to be cured. It had a positive impact on how he felt about his situation.”

“My son has spent approximately half his life in hospital and has very severe physical impairment but is educationally very bright. He is therefore often asked to take part in research by health staff that know him, especially if they are eager to ensure children with disabilities take part, as he is able to answer clearly to multiple choice questions.”

### b) Parents of children who had never been invited to take part in clinical research

“One of my children took part in a psychology study at her school, but not clinical research.”

“I have taken part in clinical research and can see the advantages to future generations. My child has a chronic condition and I would happily allow her to participate in a research study that might improve the treatment options for other children (even her own in the future).”

“Too old and does not fit criteria for current research opportunities.”

“[I] am responding to this as parent of a child with learning difficulties; now age 48 but a vulnerable adult perhaps equivalent to a young teenager; also considering our grandchildren.”

“You need to get parents from outside the profession as lay members on panels and I would like to see younger lay representative on these types of panels, they always seem to be retired professionals!”
“My child has had serious health problems since birth including, interstitial lung disease, serve GERD and fundoplication, gastric motility and inflammation issues, severe eczema, immune deficiency and severe JIA all culminating in a bone marrow transplant for an undiagnosed complex immune dis regulation disorder.”

## Question 12
## Age of child/children

The range of ages of the offspring of parents who responded was very wide, ranging from an infant (i.e. under 1 year of age), to 48.