

Example topic guide for interviewing parents- CONNECT CATCH Sample

Key bioethical areas to cover

Area A: Motives for participation:

- a) Autonomy and individual rights
- b) Justice and research for the common good

Area B: Decision making – information and competency to give informed consent

Area C- Voluntariness, relationships and autonomy (including paternalism)

Area D- Beneficence and non maleficence- clinical benefit and risk

Area E- Health literacy (affective and cognitive components)

Intro: My name is Kerry and I am a researcher from the University of Liverpool. I am carrying out a study that is looking at consent methods used in children's research. I don't know if you remember, but you completed a questionnaire when your child was in hospital and was approached to take part in the CATCH trial? On that form you stated that you would like to take part in an interview, which is why I am ringing. (Obtain consent for interview and arrange time).

Interview: introduction

I have a few questions about the CATCH consent process, as well as some about your views about research that involves children in general. It will take about 40 minutes. I will record the interview so that I can listen to it again later, it won't be used for anything else, is that ok? (Obtain consent). You can stop the interview at anytime. All interviews for this study will be used to write a final report and I will include some quotes to illustrate what people have said. Your name will not be used; everything you say will remain confidential. Is that ok? Do you have any questions?

Before I start, how is [child name] now? Has he/she recovered from his/her hospital visit?

Area	Number	
Section 1- Demographics		
Do you mind if I start by asking a few questions about you and your child (who was approached about the CATCH trial)?		
	1.1	Where do you live?
		Would you describe yourself as being: employed or unemployed? - (If employed, what is your profession?)
	1.2	How old is your child?
E	1.3	What would you describe as being your first language? (Prompt: e.g. mine is English)
	1.3	In terms of your experience of the CATCH trial, did your child enter hospital as an emergency, or was this a pre-scheduled visit that you knew about in advance?
	1.4	In which hospital did your child receive treatment?
Section 2- The CATCH consent process		
	2.1	Would you mind if I start by getting an overall picture of what happened when you first heard about the CATCH trial... could you tell me a bit about that?
B	2.2	Could you tell me what went through your mind when the issue of your child taking part in CATCH was first raised?

B/E	2.3	Was there anything that you found: a) unclear b) surprising?
B/E	2.4	Could you tell me what the CATCH trial was looking at? <i>(Prompt: what was CATCH looking at?)</i>
B/E	2.5	Could you tell me about any information you were given about the trial? <i>(Prompt: explore written and verbal)</i>
B	2.6	When did you receive this information <i>(Prompt: explore written and verbal)?</i>
	2.7	Was any brief written information given to you about the trial when you first arrived at the hospital, before it was explained to you in detail?
B/E	2.8	Did you read the information leaflet?
B/E	2.9	What did you think about the information leaflet?
B/E	2.10	Was there anything that you found: a) unclear? b) surprising?
B/E	2.11	Could the information leaflet be improved in any way? [If face to face interview show leaflet] <i>(Prompt: If so, how?)</i>
B/C/E	2.12	How did you feel when you were with the nurse or doctor talking about the trial?
B/C	2.13	Is there anything else that sticks out in your mind about the discussion?
C/E	2.14	How was the doctor or nurse in dealing with you that day?
B/E	2.15	What did they explain about CATCH?
B/E	2.16	So on the whole, how would you say that discussion went?
B/E	2.17	Children taking part in CATCH were split into three groups by a process called randomisation. Could you tell me how this process was explained to you?
B/E	2.18	Was there anything about this process that you were unclear about?
B/E	2.19	Did you ask any questions about randomisation? <i>(If yes, did this help you make a decision about your child taking part in the trial?)</i>
B/E	2.20	Was there anything else that was unclear?
B	2.21	How long did you get to think about whether you wanted your child to take part in CATCH?
B/C	2.22	Do you think this was long enough?
B	2.23	Did you have the opportunity to ask questions about the study?
B/E	2.24	Did you ask any? <i>(Prompt, what questions did you ask?, if not, why not)</i>
B/C	2.25	How long do you think people should be given to think about taking part in a trial?
E	2.26	Is there anything about how CATCH was explained to you that could have been handled a bit differently?
	2.27	Did you provide consent for your child to take part in the CATCH trial?
Section 3 - Reasons for participation and decision-making		
B	3.1	In making the decision about your child's participation in CATCH, what sort of things went through your mind?
B/E	3.2	Some parents have said that it's difficult to take in all the information about a trial when their child is ill or about to have an operation. Is that something you experienced at all?
B/E	3.3	Could you tell me if you found anything about the trial unclear or confusing?
B	3.4	Was there anything you found particularly helpful in making up your

		mind?
B	3.5	Was there anything you found unhelpful?
B	3.6	How hard was this decision?
B/C	3.7	Was there anything specific that influenced your decision?
A/C/D	3.8	Would you mind telling me what were your reasons for (providing consent/not providing consent)?
B/C	DECLINERS	Was it difficult to say no?
A/B/C/E		When making that decision, did you know what care your child would receive if they did not participate in CATCH? (Prompt: the type of catheter that would be used)
B/C		Did you worry about how the doctor or nurse would respond?
C		How did they respond?
A/D	3.9	Did you feel that your child may benefit from taking part in the trial?
A/D	3.10	Could you describe the possible benefits you expected your child to gain from taking part in CATCH?
A/D	3.11	Did this influence your decision in any way?
A/D	3.12	Did you have any concerns about your child taking part?
A/D	3.13	What were the possible risks to your child in participating?
A (b)	3.14	In making your decision, did you think about how the research may benefit other children in the future?
B	3.15	Apart from the doctor or nurse, did you discuss it with anyone else? [Can you tell me a bit about that?]
B/C	3.16	Did you ever feel under pressure in making your mind up? [If yes: where did that pressure come from?]
B/C	3.17	In your opinion, did your relationship with the doctor or nurse who asked you to take part in CATCH influence your decision? [If so, could you tell me a bit more about that?]
B/C	3.18	In making your decision how important was their manor, such as what they said and how they said it?
B	3.19	Now that a little time has passed, how do you feel about the decision you made?
	3.20	Have you thought of any questions you would have liked to have asked that you didn't ask at the time?
Section 4: Child Assent (If 5 and under (youngest CATCH assent version) and up to 16 years)		
A	4.1	Did the nurse or doctor explain the CATCH trial to your child and give them a leaflet to seek their permission to take part? [Could you tell me a bit more about that?]
B/E	4.1a	<i>Do you think they understood the information they were given?</i>
	4.1b	<i>Did they give their permission to take part?</i>
B	4.1c	<i>Did they ask any questions?</i>
	4.1d	<i>Did they agree to take part?</i>
A/B	4.2	Did you discuss the CATCH trial with your child separately? [Could you tell me about that?]
A/B	4.2a	<i>Could you tell me your reasons for involving them/not involving them in the decision making process?</i>
A/E/B	4.2b	<i>Did your child ask any questions about the trial?</i>
A/E/B	4.2c	<i>Did they raise any concerns?</i>
A/B/C	4.2d	<i>Did they want to take part?</i>
A/B/C	4.2e	<i>If your child had not wanted to take part in CATCH would their</i>

		<i>opinion have influenced your decision about the trial? [Could you tell me a bit more about that?]</i>
A/B/C	4.3	Do you think that children should be involved in making the decision about their participation in a trial?
A/B/C	4.4	In emergency situations do you think that children should be asked whether they would like to take part in trial when they have recovered?
A/B/C	4.5	What do you think about older children being involved in the trial discussion between doctors and parents as part of a family approach to consent? Or do you think it should discussion should be kept separate?
	5a.1	Some of the families involved in CATCH provided consent after the catheter was fitted. We call this deferred consent. Could you tell me if you provided consent before or after the catheter had been fitted? (If knew continue, if not ask 5b question)
Section 5a: EMERGENCY- Deferred consent patients		
	5a.2	Could you tell me if you provided consent before or after blood had been taken from your child?
B	5a.3	What did you think when you found out that your child had already been entered into the trial before you were approached by the doctor or nurse about your consent?
	5a.4	Could you tell me a bit about that?
	5a.5	What do you think about the use of deferred consent in an emergency situation (for example, when a child has entered hospital via A&E or born very early)?
B	5a.6	Would you have provided consent for your child to take part in the trial if deferred consent had not been used? For example, if the nurse approached you about the trial and it involved taking blood and fitting a catheter?? <i>[Could you tell me a bit more about your reasons for this?]</i> EXPLORE
Section 5b: ELECTIVE TREATMENT: Prospective consent patients		
If your child had entered hospital as an emergency, consent for the CATCH trial would have been taken after the catheter was fitted.		
B	5b.1	Could you tell me if you provided consent before or after blood had been taken from your child?
	5b.2	Would you have provided consent for your child to take part in the trial if deferred consent had used. For example, if the nurse approached you about the trial and they had already taken blood and fitted a catheter?? <i>[Could you tell me a bit more about your reasons for this?]</i> EXPLORE
	5b.3	What do you think about the use of deferred consent in an emergency situation (e.g. when a child has entered hospital via A&E or born very early)?
Section 6: Approaches to consent		
B	6.1	When is the best time to approach parents to obtain consent in an emergency situation? (Prompt, CATCH is within 24 hours of admission)
B	6.2	If a child is brought to hospital in an ambulance, what do you think about parents being provided with some brief information about a trial in the ambulance? A) Should it be written or verbal information? b) Do you think parents would be able to understand such information in this situation?

	6.3	Do you think that it is necessary for parents to be consulted about their child's involvement in a trial that is comparing medical device rather than drugs (like the CATCH trial)?
	6.4	Many of the drugs that are used to treat children have not been previously tested in children; they are unlicensed or they have been tested in adults and then doctors have adapted doses for children. Did you know this?
	6.5	Which of the two options would you prefer? a) your child to receive an unlicensed drug as part of routine care or b) your child receive an unlicensed drug as part of routine care but as part of a trial where they are being monitored? Could you explain your reasons for this?
	6.6	Do you think that it is necessary for parents to be consulted about their child's involvement in a trial that is comparing medicines that are already used to treat children in the UK? <i>[Could you tell me a bit more about your reasons for this?]</i>
	6.7	Do you think that parents should be consulted about their child's involvement in a trial when the trial is comparing a new medicine with one that is already used to treat children in the UK? <i>[Could you tell me a bit more about your reasons for this?]</i>
Section 7 - Previous experience of RCT and views towards medical research.		
	7.1	Before the CATCH trial, have you ever been approached to consent for your child to participate in medical research? (If yes) <i>[If more than one go through the trial prior to CATCH]</i>
	7.1a	<i>Could you tell me a bit more about it?</i>
	7.1b	<i>Did you provide consent for your child to take part in the research?</i>
B	7.1c	<i>Could you tell me a bit about what informed your decision (not) to take part?</i>
B/C	7.1d	<i>Was anyone else involved in making this decision?</i>
	7.1e	<i>Could you tell me anything about being approached about this research that has stuck in your mind?</i>
A (b)	7.2	Do you think that research to improve treatments for critically ill children should be done?
C	7.3	What advice would you give to researchers who approach families about a clinical trial in an emergency situation?
A (b)	7.4	Finally, do you feel that taking part in medical research is important? If so, could you tell me why?

Is there anything else that you think is important to mention that I have not covered?

Thank you very much for your time, which has been really helpful.

Would you like to be sent a copy of the study findings when they are published?

Would you like to be contacted in the future about any further research connected to this study?