

Appendices

Appendix 1: Interviewer administered tool

Voluntary Consent to Research on Children in the CHAPAS-4 Trial and ODYSSEY Trials at JCRC Mbarara

Recently, you were asked to allow your child to take part in a research study. We are interested in learning about how voluntary your decision was to allow your child to take part in that study and the reasons for your decision.

Part I. General Information and Demographics

1. Have you personally ever been in a research study before? ☐ Yes ☐ No
- 2a). Has your child ever been in any study before? ☐ Yes ☐ No
- 2b) When did your child join the CHAPAS-4 or ODYSSEY study-----
3. What is your sex? ☐ Male ☐ Female
4. What is your date of birth? _____
5. What is your highest level of education?
- ☐ Primary level

☐ Ordinary secondary level

☐ Advanced secondary level

☐ Undergraduate level and above
6. What is the occupation of the main wage-earner in your home? _____
7. Which of the following best describes your total monthly family income?
- ☐ Less than 200,000 Ugx

☐ 200,000-499,999 Ugx

☐ 500,000-799,999 Ugx

☐ 800,000-999,999 Ugx

☐ 1000,000-1999,999 Ugx

☐ 2000,000Ugx or more
8. What is your child’s sex? ☐ Male ☐ Female
9. What was your child’s age at the time of consent? _____
10. What is your relationship to the child?
- ☐ Mother

☐ Grandparent

☐ Father

☐ Guardian

☐ Other(describe)_____
11. Please rate your child’s overall health at the time of consent by circling any number from 1 to 10
- 1

2

3

4

5

6

7

8

9

10

In extremely

Extremely

Poor health

health

PART II. INFLUENCES FROM SITUATIONS

This section asks you about things that may have influenced how voluntary your decision was to allow your child to take part in the study

Using the following scale, circle the number that best describes your answer.

1 strongly disagree	2 disagree	3 neither agree nor disagree	4 agree	5 strongly
12. My decision was influenced by the possibility of better care.	1	2	3	4 5
13. My decision was influenced by the opportunity to have free medications. . .	1	2	3	4 5
14.. My decision was influenced by the need to advance medical knowledge. . . .	1	2	3	4 5
15. My decision was influenced by the trust I have in medical researchers. . . .	1	2	3	4 5
16. My decision was influenced by my desire to help other children.. . . .	1	2	3	4 5

Part III. External control influences

17. Did you talk with anyone else before making your decision about your child taking part in the study?

- ☐ Yes
- ☐ No

18. *If yes above*, with whom (check all that apply)?

- ☐ Spouse
- ☐ your doctor
- ☐ community leader
- ☐ Friend
- ☐ Another research staff
- ☐ Family member
- ☐ Another person (please describe) _____

Person Tick N/A if not applicable.	Qn 19. Did try to influence you to participate?	Qn 20. How did influence you?
a. Spouse . N/A	1. Yes 2. No	1. Threatened me 2. Advised me 3. Pressured me 4. Offered me something. 5. Forced me Specify
b. Study doctor N/A	1. Yes 2. No	1. Threatened me 2. Advised me 3. Pressured me 4. Offered me something. 5. Forced me Specify

c. Friend N/A	1. Yes 2. No	1. Threatened me 2. Advised me 3. Pressured me 4. Offered me something. 5. Forced me Specify
d. Another research staff N/A	1. Yes 2. No	1. Threatened me 2. Advised me 3. Pressured me 4. Offered me something. 5. Forced me Specify
e. Your doctor N/A	1. Yes 2. No	1. Threatened me 2. Advised me 3. Pressured me 4. Offered me something. 5. Forced me Other, Specify
f. Family member N/A	1. Yes 2. No	1. Threatened me 2. Advised me 3. Pressured me 4. Offered me something. 5. Forced me Other Specify
g. A community leader N/A	1. Yes 2. No	1. Threatened me 2. Advised me 3. Pressured me 4. Offered me something. 5. force Other, Specify
h. Another person (please describe) _____	1. Yes 2. No	1. Threatened me 2. Advised me 3. Pressured me 4. Offered me something. 5. Force. Other, Specify

Part IV. Informed Consent process.

21. When you were given the consent form for the study, did you:

- a) Read the form? ☐ Completely ☐ Partly ☐ Not at all
b) Understand the study? ☐ Completely ☐ Partly ☐ Not at all

II. In what language was informed consent offered?.....

22. Was the information given to you by the researcher the same as that described on the consent form?

- ☐ the same ☐ mostly the same ☐ different ☐ don't know

23. Was the amount of information you received about the study...?

- ☐ too little ☐ just right ☐ too much

24. Overall, how clearly was the information you received about the study presented?

- ☐ not at all clear ☐ fairly clear ☐ very clear

25. Did the researcher ask your child if they wanted to be in the study?

- ☐ Yes ☐ No

a. If **yes**, did your child want to be in the study?

- ☐ Yes ☐ No ☐ Too young

26. Did your child's decision influence your own decision?

- ☐ yes ☐ no ☐ Not applicable

27. In addition to asking parents about having their child in a study, do you think researchers should also ask the child's permission?

- ☐ Yes ☐ No

28. At what age do you think it is appropriate to ask a child to be in a study? _____ years

- ☐ Not appropriate for children under 18 yrs of age

29. When making decisions regarding your child's medical care do you prefer to:

- a) ☐ make most of the decisions yourself (or with family)
b) ☐ make decisions equally with the doctor
c) ☐ let the doctor make most of the decisions

Comments: If you have any comments regarding the process of recruiting your child into the study, please include here

Section 6: Voluntariness Ladder

Now I'd like you to think again about your decision to enter your child in the clinical trial she/he is enrolled. Use the ladder of numbers below to show me how voluntary (willing to participate) your decision was. Circle the number that best matches your decision, from completely voluntary (10) to not at all voluntary (1).

Completely voluntary choice

10
9
8
7
6
5
4
3
2
1

Not at all voluntary choice

Appendix 2: In-depth Interview Guide

In this session I would to get more detailed information regarding how voluntary your decision was to allow your child to participate, the things that influenced your decision and how they did so. I will be tape recording our conversation so that I can get all the details and to stay attentive to our conversation.

1. Tell me about yourself.
2. How many children do you have?
3. How old was your child when you joined this study?
4. How are you related to the child?
5. Tell me about your family
6. How did you get to know about this study?
7. What did you do when you learnt about the study?
8. Describe your first journey to study Clinic

Influence from people

9. Did you talk to anyone about participating in this study? If yes who? How did they respond.
10. Did that affect your decision? How?
11. Would you not have participated had this influence not been there
12. To what extent did you feel that this influence affected your decision.

Influence from situations

13. Are there any other situations that influenced you to participate in the clinical trial? If yes which ones
14. How did they influence your decision?
15. Would you not have participated had this influence not been there. Why?

What changes should be made to improve how voluntary consent is in future?

Appendix 3: List of themes

Themes	Subthemes	Description	Example
Health condition of the child	Expectation of improvement in the health condition of the child	They perceived that only participation would improve the health of the child including cure of the child's disease and this led them to put emphasis on participating in the trial.	<i>VC053 "...I wanted the health of my child and I was seeing that my child's condition was only getting worse.... I even repeat it about my child, the condition I brought him in hit me hard, yet he was in good condition at first. But his condition reached a time and failed. I got scared so much to my heart and then I had to put emphasis on that trial so that I could save my child."</i>
	Fear of negative consequences to the health of the child	The fear of what would happen to the child if they did not participate left them no option but to participate	<i>VC079 "...we both didn't understand it at first when they told us that in the study there are drugs that will be tested on children with HIV to see if the drugs work...it was hard for me and for us to comprehend. But later I decided to participate, and when the drugs were given, I realized that the child was getting better from one stage to anotherI also have relief that I thought I was going to suffer with her but now I see she is a normal child and the frequency of falling sick reduced since she was enrolled on the study"</i>
Influence from others	Advice of others increased the parent's confidence and	Advise from others, increased their confidence and happiness with the decision to participate.	<i>VC149 "Yes, when I saw that her father has liked it (parent study) and again has advised me... I lost the fear in me and I started coming to this side (referral site) without any doubt. I am in it willingly nothing has bothered me".</i>

	satisfaction in his/her decision.		
	Influence of the referring Health care workers advice.	Told by the referring health worker that this was only option for their child to have better health and so they had to participate.	<i>VC53 “I accepted because they (referring Health workers) told me that my child has to get the medicine that will make him better from the other side (research Centre) and so I had to accept and ok I also accepted willingly”</i>
	Change in perception of the decision after the advice of others.	They had concerns and fears about making the decision to participate but their perception changed when the advice drew their attention to reasons why they should participate.	<i>VC079 “.... when I told him (husband), he said “my dear you have to do what health workers(researchers) want...those people have more experience than us the local people(ordinary)...” then I said I want this child alive and healthy, so I have to agree to whatever the healthy workers have told us. From that instance on, we joined the study and haven’t regretted it a bit and we have never had second thoughts about it.... ”</i>
Opportunity of better care	More advanced tests than standard of care	More tests than standard of care	<i>VC149 “When we reached here...I saw that my child was going to be tested on everything which was not the case on the other side (Health Centre IV) On the other side she was only getting drugs but not tests like liver tests, bone and all other things and tests that were done this side all along the other side they had never been done and it was good on my side and I wanted to be part of it.... ”</i>

	Access to better medication	That they would be able to access better medications than soc	<i>VC063 “because the other side he was getting medicine, it was not working well, and they told us that they brought an organization that has new medicine that was more powerful (better) than the other one....”</i>
	Access to specialised services	To access more specialised services.	<i>VC132 “..... at least where we were (Health Centre IV), the services were there, and we were receiving them. But I saw that when you come from Health Centre IV and you come to the regional referral, services might be better compared.... (to the Health Centre IV services) ...because even the services that they give from Health Centre IV come from here (from Regional Referral hospital) be it drugs and the rest.”</i>