# Voluntary Consent to Research on HIV-infected Children in the CHAPAS-4 and ODYSSEY HIV Clinical Trials

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## Introduction

Voluntary informed consent is a fundamental pre-requisite for ethical conduct of scientific research with human subjects. Few studies have been conducted on the voluntariness of consent among parents consenting for research on their children. This has left researchers and policy makers with little guidance on how to ensure that prospective parents are able to exercise freely voluntary decisions. Available literature has focused on assessment of presence of pressure and influences without ascertaining their effect on the voluntariness of consent[2]. Whether consent was actually experienced as voluntary has hardly been studied. This study assessed the voluntariness of consent in on-going Paediatric HIV clinical trials and the associated factors.

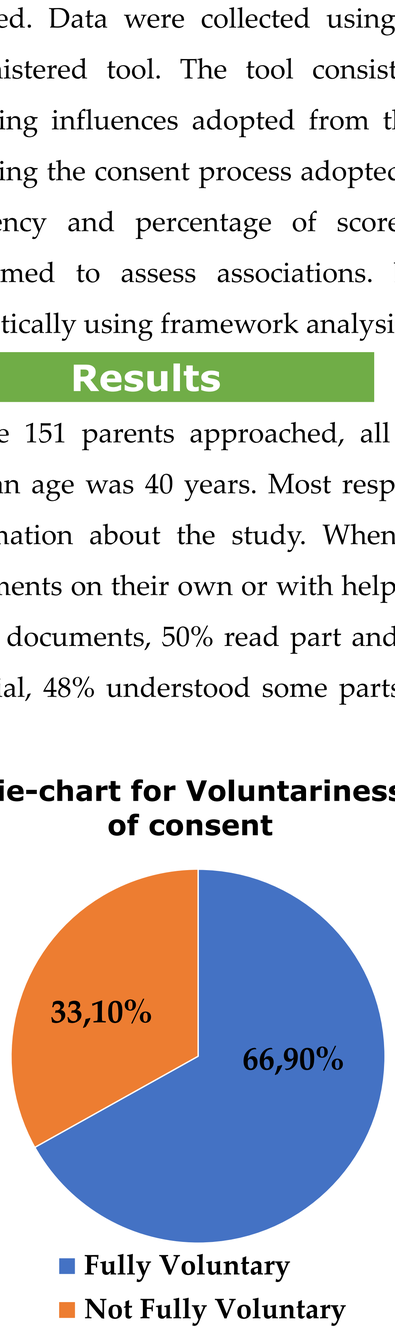
## Methods

We conducted a mixed methods cross-sectional study among parents of children starting first or second line treatment in two paediatric HIV Clinical trials (CHAPAS-4, ISRCTN22964075 and ODYSSEY, ISRCTN91737921) at Joint Clinical Research Centre Mbarara. A total of 151 randomly selected parents were approached and all were enrolled. Data were collected using in -depth interview guide and an interviewer administered tool. The tool consisted of the voluntariness ladder (1-10)[123], items assessing influences adopted from the Survey of influences questionnaire and items assessing the consent process adopted from Tait et al (2003)[4]. Data were analysed using frequency and percentage of scores. Chi-square and logistic analysis were also performed to assess associations. Data from in-depth interviews were analysed thematically using framework analysis. Data were triangulated at interpretation.

## Results

Of the 151 parents approached, all consented and were enrolled. 84% were female. Median age was 40 years. Most respondents (95%) reported that they received enough information about the study. When asked whether they took time to read consent documents on their own or with help from family and friends, 39% reported reading the entire documents, 50% read part and 11% did not read. Whereas 47% fully understood the trial, 48% understood some parts and only 5% did not understand most about the trial.

**Pie-chart for Voluntariness of consent**




**Voluntariness ladder raw scores**

| Raw scores | Frequency(%) |
|---|---|
| 1 | 0 |
| 2 | 0 |
| 3 | 0 |
| 4 | 4(2.7) |
| 5 | 0 |
| 6 | 12(8.0) |
| 7 | 9(6.0) |
| 8 | 13(8.6) |
| 9 | 12(8.0) |
| 10 | 101(66.9) |

- Most respondents (67%) gave a fully voluntary decision with a score of 10/10 on the voluntariness ladder. Only 4 (2.7%) had a score <5/10.

## Contacts

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**Factors influencing the Voluntariness of parent's consent**

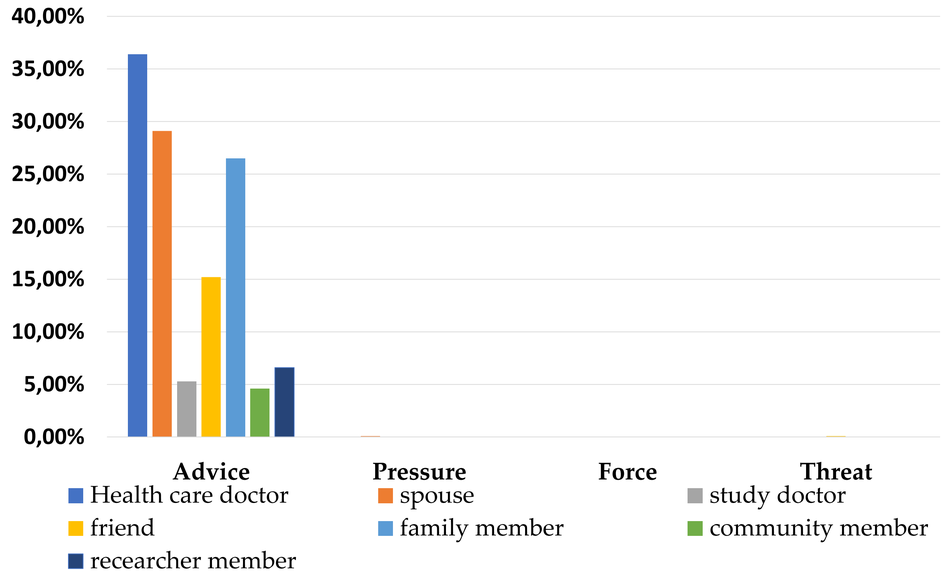
| Variable | Adjusted OR | P-value |
|---|---|---|
| Male parent | 3.66(1.00-13.38) | 0.05 |
| Trust | 9.90(1.01-97.20) | 0.049 |
| Child's experience | 0.31(0.12-0.78) | 0.014 |
| Consulted others | 0.25(0.10-0.60) | 0.002 |

- Trust in medical researchers [aOR=9.90(1.01-97.20), p=0.049] and male parent [aOR=3.66(1.00-13.38), p=0.05] were significantly associated with voluntariness of consent.
- Prior Research experience and consulting others were negatively associated with voluntariness [aOR=0.31(0.12-0.78), p=0.014 and OR=0.25(0.10-0.60), p=0.002 respectively)].

## Source of influence

- The advice was mainly reported to come from Healthcare doctors, spouses and family members. There was almost no reports of pressure (0.7%), force(0.0%) or threats (0.7%) to participate.
- Most (9/14) respondents to the in-depth interviews reported feeling pressure from the child's health.

**Source of Influence**




## Conclusions

- This study demonstrated a relatively high voluntariness of consent, which was enhanced in those with trust in medical researchers and among male parents.
- The study found that advice from healthcare workers, spouses and family members and prior research experience influenced the voluntariness of the parents consent.
- Female parents and parents of children with prior research experience may benefit from additional interventions to support voluntary participation.

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