

# Reasons for refusal and or withdrawal of consent to participate in a clinical research study in Zambia

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## Background

Success of a trial lies on the capability to recruit and retain participants in the study. However, participant's refusal to take part or withdrawal of their consent from the study can affect the trial credit and diminish its statistical strength. Understanding the underlying reasons behind refusal and withdrawal to participate in clinical trials can inform researchers and policy.

## Methods

We conducted an observational study to understand reasons for refusal to consent and withdrawal from participating in a randomised controlled trial of two versus three doses of Rotarix™ vaccine for boosting and longevity of vaccine immune responses in Zambia. We extracted data from screening logs, inform consent forms and clients name file.

## Results

Out a total of 109 participants included in this study, 60.5% consented, the age distribution was <20 years 2.8%; 20-24 years 42.2% and >25 55%, with age stratified % consent being 23%, 43.4% and 33.3 % for the respective age groups. With regards to education, 50% of those with primary education and 35% with secondary education refused to consent. Of the 94 participants who were married, 56% consented compared to those not married with 87% (13/15). The main reason for refusal and withdraws of consent was Misconception and cultural/religious beliefs at 60.4 %, followed by fear of needle prick 28%. Relocation and length of study accounted for 7% and 4.6% respectively.

## Discussion

Addressing misconception and cultural/ religious beliefs prior to recruit clinical trial participants in Zambia remains key to achieve high acceptance rate. Further work is needed to determine the extent to which improved understanding of the trial activities and cultural, religious beliefs permeates beyond the immediate group participating in the trial affect consent and retention in the trial.