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Assessment of the Voluntariness of Consent for an HIV Vaccine Trial in Haiti

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Voluntary and informed consent are necessary for the ethical conduct of clinical research, but ensuring that consent is both voluntary and informed is challenging in resource-poor settings. Prior efforts to improve consent have focused on participant comprehension. (1) We report the results of an assessment of the voluntariness of consent for an HIV vaccine trial conducted at the GHESKIO Center in Haiti.

The Step Study was a randomized HIV-1 vaccine trial in participants aged ≥ 18 years at high risk of HIV-1 acquisition. (2) The study was approved by Institutional Review Boards (IRBs) at Cornell University and GHESKIO. Potential participants reviewed the informed consent form during three educational sessions. A counselor, not involved in the trial, tested participants' comprehension of the consent form. If participants passed, they underwent an individual assessment of voluntariness.

The assessment of voluntariness was designed with community members, former research volunteers, and Haitian IRB members and consisted of five open-ended questions about 1) the purpose of the study, 2) reasons for volunteering, 3) hopes for study participation, 4) “bad things” that could happen, and 5) reaction if something in the study made them unhappy. Responses were content coded and analyzed for emergent themes.

A total of 596 potential vaccine trial participants attended three education sessions and completed the assessment of comprehension, and 529 (89%) passed. Of the 529 who passed, 492 completed the assessment of voluntariness. The median age was 27 years; 392 (80%) were female, and the median income was less than one dollar/day. Of the 492, 22 (5%) were separated from their sexual partner, and 219 (45%) were in *plasaj*, an unstable sexual relationship, commonly not monogamous, and not formalized by ceremony.

Of the 492 potential vaccine trial participants, 54 (11%) gave at least one “red flag” response suggesting involuntary consent, (Table). The “red flags” were: 1) perceived financial benefit; 2) expectation of an effective HIV vaccine, 3) belief that doctors would

never expose participants to risk, and 4) belief that a “volunteer” is a person who has the willpower to remain in a study. Of note, the word “volunteer” translates to “volonté” in Haitian Kreyol, and similar to many romance languages, also means “willpower” or “fortitude”.

Multivariable analysis found that these “red flag” or ethically problematic responses were associated with participants being separated from their sexual partner ($p < .001$) or being in a “plasaj” unstable sexual relationship ($p = .025$). Of note, prior studies in Haiti have shown that women in “plasaj” are more likely to suffer domestic violence and acquire sexually transmitted infections. (3) Neither education level nor performance on the assessment of comprehension (4) was significantly correlated with providing “red flag” responses.

Our assessment identified 11% of study participants enrolling in an HIV vaccine trial whose voluntary consent was in doubt, even after they had attended three educational sessions and demonstrated good comprehension of the consent form. These participants expressed hope of financial benefit, expected to receive an effective HIV vaccine, deferred to medical authority, or viewed a “volunteer” as one who makes an irreversible commitment to remain in the study. The association between being separated from one's sexual partner or being in an unstable sexual relationship and providing an ethically problematic response on the assessment of voluntariness suggests that social vulnerability may impair voluntary consent for clinical research.

An assessment of comprehension during the informed consent process has become the standard for clinical trials conducted in resource poor settings. We recommend the addition of a few open-ended questions to assess voluntary participation and to identify volunteers with unreasonable expectations of financial or therapeutic benefit or other misperceptions that may compromise voluntary consent. (5)

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Table

Questions and Responses Suggesting Involuntary Participation

Questions and Themes of Responses	Number (N=492)	Percent	Representative Quote Suggesting Involuntary Participation
Can you provide the main reason why you are volunteering to participate in this vaccine study?			
Obtain perceived effective vaccine	11	2%	*"They give you a vaccine that protects against the AIDS virus. You have to participate, but once you take the vaccine, it'll prevent HIV infection."*
Gain employment or financial benefits	10	2%	*"If you volunteer, they'll give you a card that says you're a participant. You can ask for work with the card."*
What do you hope will come out of this study?			
Gain employment or financial benefits	10	2%	*"I want them to give us something after the study; a job, loan us money."*
What bad things do you think could happen in this study?			
Doctors would never cause harm	12	2%	*"If they felt bad things could happen, they would never do it."; "After the Good Lord is the doctor."*
What would you do if something in the study made you unhappy?			
A volunteer is obliged to stay in the study	13	2%	*"I'm obligated to accept whatever because I'm a volunteer"*

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