

# Adolescent Medicine Trials Network for HIV/AIDS Interventions (ATN)

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## Abstract:

The purpose of this study is to examine how the consent process affects the acceptability of biomedical HIV prevention trials, from the perspective of high-risk minors and the parents of high-risk minors. Acceptability will be measured by adolescents' willingness to participate (WTP) in and parents' willingness to support (WTS) two hypothetical biomedical HIV prevention trials that are modeled after PrEP studies that included minors. Each participant will be randomized to one of three consent conditions: Condition

1) adolescent self-consent [i.e. no parental consent required], Condition 2) required parental consent, and Condition 3) optional parental consent, to address the following specific aims:

Aim 1. Describe how consent conditions influence high-risk minor adolescents' WTP in a hypothetical biomedical HIV prevention trial.

1a. Test the hypothesis that adolescents assigned to Condition 3 will have the highest WTP scores, followed by those assigned to Condition 1, and then those assigned to Condition 2.

1b. Determine whether concern about HIV, capacity to consent, family context and sociodemographic characteristics moderate the relationship between consent condition and WTP scores.

1c. Describe high-risk minors' perceptions of the risks and benefits of parental consent, how they anticipate the different models of consent would influence their WTP in prevention trials, and whether shared-decision making between minors and parents is feasible.

Aim 2. Describe how consent conditions affect parents' WTS a hypothetical biomedical HIV prevention study in their community.

2a. Test the hypothesis that parents assigned to consent condition 2 will have the highest WTS scores, followed by those assigned to Condition 3, and then those assigned to Condition 1.

2b. Determine whether concern about HIV, capacity to consent, and sociodemographic characteristics moderate the relationship between consent condition and WTS score.

2c. Describe parents' attitudes toward the various consent models, their perceptions of the risks and benefits of each model, and their conceptualization of a shared decision making process for consent.

Aim 3. Describe the effects of the study agent (stage of development and method of delivery) on high-risk minor adolescents' WTP and parents' WTS a hypothetical biomedical HIV prevention trial.

3a. Test the hypothesis that WTP/WTS scores will be higher for the study of an oral medication that is already FDA-approved for adults compared to a topical agent that is still under investigation.

3b. Describe perceived risks and benefits of each study design, and how adolescents and parents anticipate the study design would influence their WTP/WTS the hypothetical trial.