

## The PATH Project: A Randomized Controlled Trial Preparing Patients to Start Antiretroviral Therapy

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### Project Description

The purpose of The PATH Project is to develop and test an intervention to prepare HIV+ men and women who, based on current treatment guidelines, should be but are not currently taking antiretroviral therapy (ART). The immediate goal of the intervention is to address obstacles to ART uptake. The intervention is grounded in the Information, Motivation, and Behavioral Skills (IMB) Model and will consist of:

- One-on-one session
- Small group workshop led by cross-disciplinary experts and peers
- Follow-up one-on-one session
- Booster session provided either at 6 months if a participant has not initiated ART, and/or at the first sign of initiating ART

We will enroll 300 HIV+ men and women in the San Francisco and the East Bay with CD4 counts at or less than 350 who are not on ART. Participants will be assessed at baseline and at three, six and 12 months post randomization. Psychological and behavioral variables will be assessed via computerized (ACASI/CAPI) interviews.

### Significance

Most interventions that focus on treatment outcomes with HIV+ populations seek to change behavior after the individual has started treatment and, in some cases, after a problem with adherence has developed. By this time, maladaptive patterns of medication taking and self-care may be in place and may be more difficult to alter. Our formative work suggests that if we intervene before a patient begins therapy, we may be successful at setting up patterns of treatment behavior that are adaptive to maximizing treatment benefit. Likewise, focusing on those who have not yet initiated ART has the greatest potential payoff of significant health improvements if the intervention is associated with appropriate uptake of ART. We anticipate that if successful, this intervention can be easily exported to HIV care and community service settings for use in preparing patients for whom ART is indicated.

Despite the widespread availability and effectiveness of ART for HIV disease, there is a substantial population with advanced disease who are not on therapy, and an alarming number of HIV+ people die due to failure to access ART. The overarching goal of this line of research is to prevent unnecessary death due to failure to access ART.

**Project Recruitment Date:** We are currently recruiting in the San Francisco Bay Area

**Project End Date:** May 2012