THE FENWAY INSTITUTE

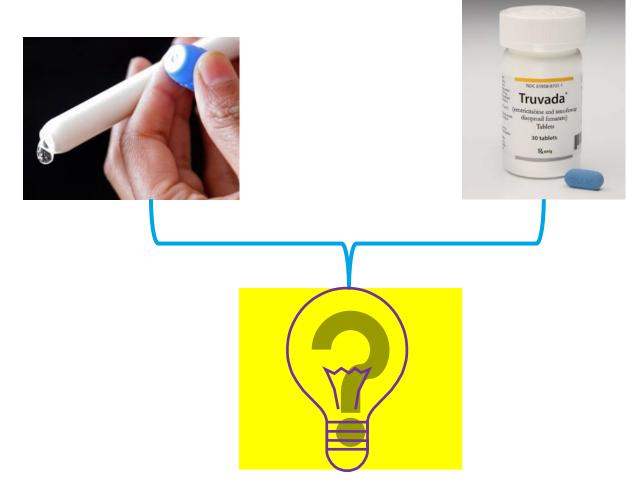


MTN-017 Study Recruitment & Participant Selection

Fenway Site | Boston, MA, USA

Ian R Lemieux, RN, MPH, MLS(ASCP) - Clinical Project Manager Amber Rucker, BS - Senior Research Associate

RECRUITMENT MATERIAL DESIGN CONCEPT





THE FENWAY INSTITUTE



Is there a place for a medicated lube in HIV prevention?



RX

THE FENWAY INSTITUTE

Could a medicated lube help prevent HIV? Help us find out. Fenway Health is looking for males and transgender women to participate in a research study of a medicated gel to prevent HIV. Participants will receive up to \$1,000 for their time.

You may be eligible if you are: O A male or trans woman who has sex with males O 18 or older O HIV-negative O Sexually active



For more information, call 617.927.6450 or email MTN17@fenwayhealth.org

III THE FENWAY INSTITUTE

THE RIGHT PARTICIPANT

Clinic staff will routinely assess participant:

•Punctuality and reliability

•Behaviors – respectful and appropriate

•Honest nature

•Literacy and communication skills

•Understanding of the purpose of this study

•Willingness and ability to follow instructions

•Recognition of potential impact to self and/or study if unable to comply with procedures

I deal characteristics:

•Willing, able, interested; Available, flexible, organized; Motivated to participate; Past research participation; etc.

THE FENWAY INSTITUTE

PRE-SCREENING

Prior to Enrollment prospective participants and clinic staff will interact, at a minimum, via:



*Not inclusive of initial contacts via field recruitment or intra-clinic referral.

III THE FENWAY INSTITUTE

PRE-SCREENING

Telephone Pre-screen

•Led by Recruitment Team; Participant visit Hx reviewed; Provide study background; Assess initial eligibility

Pre-screen Consultation

(Telephone PS Eligible & Interested in Proceeding)

•IRB approved 30 minute sessions; Face-to-face meeting and review of key details of study including *MTN-017 Information Sheet*; Q & A; Provide *MTN-017 Informed Consent Booklet*, if appropriate, for review prior to first part of Screening Visit

•Two-part Screening Visit

•Each part (Visit 1.0a and 1.0b) approximately 2 hours; Requires the participant to visit the clinic an additional time prior to enrollment (staff can assess ability to keep appointments, arrive on time, willingness/readiness to complete study visits)

THE FENWAY INSTITUTE

LESSONS LEARNED

•MTN-007

•Detailed explanation of study during recruitment and screening highlighted its clinical complexities up front

•Leveraged referrals from participants, as well as Fenway staff who were able to connect team with prospective/past participants within study population

•MTN-013

•The need to select appropriate forums for recruitment

•Plan to engage/recruit a large enough cohort to account for missed visits, pre-screen/screen fails, external factors that may preclude participation, etc.

•Institution of required 30 minute, in-clinic, pre-screen consultation to answer/ask questions and meet staff

THE FENWAY INSTITUTE

ENHANCING INVOLVEMENT

Site Leadership

•Daily communications via email or in-person; weekly reports of recruitment and study activities

Clinical Staff

•Weekly Operations Team Meeting for staff to review study status, clinical process, and participant retention

Counseling Staff

•BRWG supervision and assessment of counselors

Community Engagement

•Integration of rectal microbicides in biomedical prevention updates to appropriate community stakeholders

Recruitment

•Weekly meetings with clinical and recruitment staff to review the ongoing success of recruitment strategies, and any enrollment or retention issues







THANK YOU!

Questions for the Fenway site: <u>ilemieux@fenwayhealth.org</u> 617.927.6027

Questions for Fenway MTN-017 Recruitment: jly@fenwayhealth.org 617.927.6227

THE FENWAY INSTITUTE