



MTN-017

Recruitment & Retention

Renee Weinman | Research Recruiter/Outreach Coordinator

Jonathan Baker | Rita Labbett | Mythili Ramakrishna

University of Pittsburgh



The 'Right' MTN-017 Participant

- The “right” participant does not have a certain look; they vary by race, age, socioeconomic status, education, background, etc.
 - However, the “right” participants have common characteristics:
 - They ask thought-out questions
 - They understand the purpose of the study, and can explain it back to you (and their friends)
 - They understand what is required of them and why
 - They are genuinely interested and motivated by altruism (even if they are motivated by compensation as well)
- *Flyers/ads state “compensation will be provided” but no actual amount is listed

Pre-Screening Participants

- Participants are pre-screened by study staff (recruiter) who is culturally competent and familiar with study protocol
- Phone screens include an explanation of the study focusing on time commitments and participant expectations
- Eligibility criteria are reviewed
- Increased detail in phone screen helps identify most appropriate participants

Informed Consent

MTN-017: A Study of Truvada Pills and Tenofovir Gel

Contact the Study staff with any concerns:

Stacey xxx-xxx-xxxx

Carol xxx-xxx-xxxx

Carly xxx-xxx-xxxx

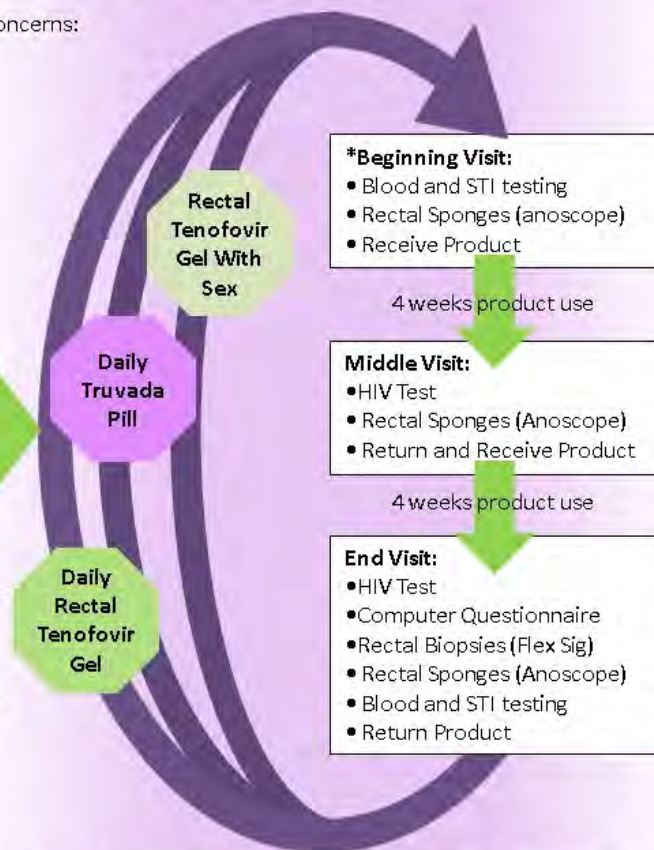
Purpose: To look at the safety of tenofovir gel and Truvada pills, and find out how men feel about using them

Screening Visit: (about xxx hour)

- Review a consent form
- Complete paperwork
- Physical exam
- Rectal exam
- STI and HIV tests

Tenofovir is a medication which is experimental for HIV prevention. This means we do not know if it works to protect against HIV. It may cause burning or soreness in the genital area and pain in the pelvic area.

Truvada is a pill taken for HIV prevention. The most common side effect is nausea/upset stomach



After a screening visit you will try three sets of pills and gels for 8 week each. During each of these eight week periods you will have 3 visits (beginning, middle, and end)

*Beginning Visit:

- Blood and STI testing
- Rectal Sponges (anoscope)
- Receive Product

4 weeks product use

Middle Visit:

- HIV Test
- Rectal Sponges (Anoscope)
- Return and Receive Product

4 weeks product use

End Visit:

- HIV Test
- Computer Questionnaire
- Rectal Biopsies (Flex Sig)
- Rectal Sponges (Anoscope)
- Blood and STI testing
- Return Product



Risks: You may experience discomfort or embarrassment with anal swabs, exams, and questions; Fear or worry about test results. Blood draw may cause pain, bruising, or dizziness.

Biopsies: Biopsies are pieces of tissue approximately the size of a pin head. These should not be painful. There is a small risk of damaging the rectum or causing irritation or infection. They may cause slight bleeding with bowel movements for 1-2 days.

Enema: The tip of an enema bottle will be inserted into your anus, and about 4 ounces of fluid will be squeezed into your rectum. Holding and releasing this fluid may be uncomfortable

*The first beginning visit

- Rectal Biopsies
- Blood draw; HIV Test
- Computer Questionnaire

Participant Retention

- Text or call to remind him of appointments. Texting has yielded high retention results.
- Greet participants in the lobby. Introduce them to staff. Offer them a drink/snack. Make them feel welcomed and relaxed.
- The study staff serves as “hand holder” during the process.
 - Especially for first time participants
- Retention Rates:
 - 100% - MTN-006/RMP-02 - 100% (8 flex. Sig w/ biopsies)
 - 100% - MTN-007 (3 flex. Sig w/ biopsies)
 - 100% - Project GEL Stage 2 (3 set of anoscopic biopsies)

We've Learned This Population:

- Uses of current social media and technology (Craigslist, MSM chat/date sites, Facebook, Twitter, Smartphones)
 - Craigslist has been highly effective, whereas facebook has not. Grindr?
 - Popularity of MSM dating sites vary by geographical location
 - Text messaging is preferred method of communication
- Is very active (school + jobs + activities) and needs clinical flexibility
- Have varied definitions of relationship and condom usage
 - Confident/empowered MSM with friends/family support engage in ↓risk behavior
 - Condom use in “monogamous relationships” is low
 - MSM may be non-monogamous but *think* their partners are monogamous



We've Learned This Population:

- May view exams/testing as benefits, but men may
 - Fear of invasive procedures (rectal exams, needles, biopsies)
 - Fear of knowing HIV/STI status (stigma, privacy)
 - Fear being treated at and reporting findings to local health department
 - Most have never had a rectal exam
- May be wary of trusting researchers, especially black and ethnic minority MSM
 - Recruiters must **repeatedly involve themselves** in the population's culture such as ball scene, bars/clubs, events, and activities
- Maintain function (social/school/work) even with high levels of substance abuse



Our Study Staff

- Site Leadership is available to speak to participants before entry and during participation. Leadership updated on bimonthly at staff meetings
- Clinical staff have experience with MSM and are involved in community outreach events such as Pride
- Counseling staff conduct culturally appropriate counseling specific for MSM. Patient-centered risk-reduction counseling provided, rather than one-size-fits-all approach



Recruitment Efforts

- #1- Tap into our well-established participant pool
- Our HIV Prevention Registry has 311 participants
- Participant word of mouth

Have You Thought about Participating in HIV Prevention Research?

You can be part of local research efforts to prevent HIV worldwide. Anyone 18 or older may join our Research Registry to be contacted to participate in HIV prevention research studies.

If you're a man, a woman, or transgender person—if you're straight, gay, or bisexual—if you're HIV-negative, HIV-positive, or don't know your status—you're welcome to join. For basic information about the clinical research process, [click here](#).

Completing this consent form enrolls you into this Research Registry and gives your permission for us to match you with research studies you may be interested in and to use information provided by you. You will be emailed a password-protected link so you can answer some medical and social questions. Our studies mostly look at developing new ways to prevent HIV such as using [microbicides](#), [vaccines](#) and [PrEP \(pre-exposure prophylaxis\)](#).

There is no compensation for joining this Registry. But, if you are enrolled in a study you will be compensated for your time and travel. Every study compensates differently based on what is involved in participation.

Only members of the HIV Prevention Research Registry staff will have access to your identifiable, self-reported medical information and use this information in a confidential, HIPAA-directed manner. However, just as with the use of your medical information for health care purposes, we cannot guarantee its privacy. Thank you.

1. Please use your full legal name:

First Name:	<input type="text"/>	Middle Initial:	<input type="text"/>	Last Name:	<input type="text"/>
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2. Email address I don't have email, please call instead

3. Phone (XXX-XXX-XXXX)

4. I was born Male Female

5. Date of Birth? (MM/DD/YYYY)

[Press to Confirm your Permission to Enroll in this Research Registry](#)

www.hivregis.pitt.edu

For additional information, email HIVRegis@pitt.edu, call 412-956-9686, or write to HIV Prevention Research Registry, 3520 Fifth Ave., Ste. 510, Pittsburgh, PA 15213.

The Registry is supported by funding from the [National Institutes of Health \(NIH\)](#) and the Registry's Director is [Ian McGowan, MD, PhD](#).

You may withdraw from the Registry by email at HIVRegis@pitt.edu or writing to the address above. Questions you have about research participant rights are answered by the Human Subject Protection Advocate at the [University of Pittsburgh IRB Office](#) at 866-212-2668.



University of Pittsburgh

IRB Number: PRO11110371

Approval Date: 1/2/2013

Renewal Date: 1/1/2014

Recruitment Efforts

- New designed ads that will be:
 - In local publications focused on GLBT- Equal Magazine and broader audiences - City Paper
 - Updated weekly on Craigslist
 - Sent to and posted at local LGBT organizations, bars, bath house, etc. and universities/colleges, non-profits, clinics

HIV Prevention RESEARCH STUDY

The University of Pittsburgh is looking for HIV-negative men 18 years of age and older who have sex with men for a research study that is looking at anti-HIV pills and lubricants for future use to prevent HIV transmission.

BE A HERO. TAKE PART.

COMPENSATION WILL BE PROVIDED.

For more information, please call **412-956-9686**

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Recruitment Efforts

- Pittsburgh Gay Pride (June) and the Black Gay Pride (July)



Be A Hero!
by taking part in an
HIV Prevention Research Study
www.hivregis.pitt.edu
University of Pittsburgh



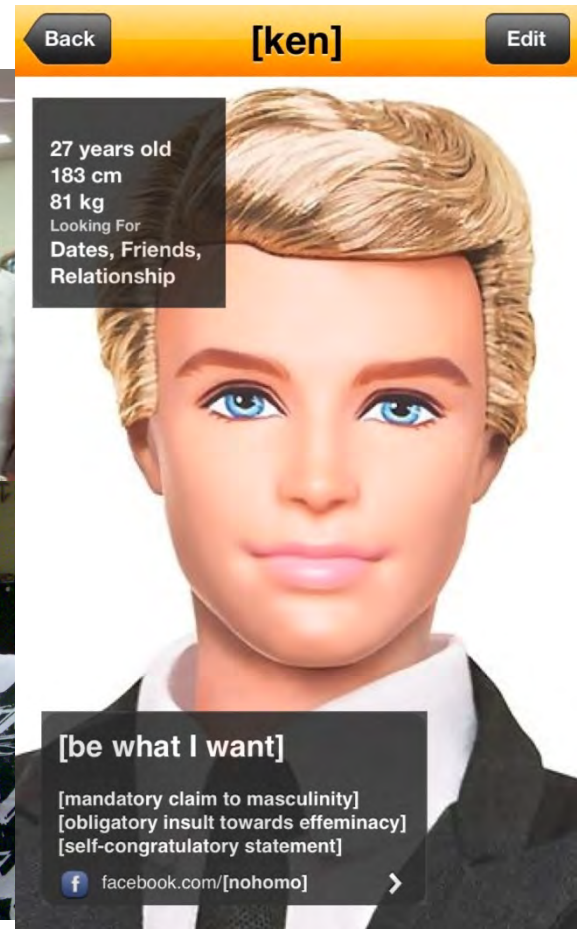
Recruitment Efforts

- Utilize the Pitt Mens Study (Pittsburgh site of the Multi Center AIDS Cohort Study) for HIV-negative controls and serodiscordant couples
- Attend health fairs and community events such as Black HIV Awareness Day events at University of Pittsburgh



Recruitment Efforts

- Backup Plan: may include hosting events, using Grindr, accessing the ball community





Get a Heart-On for HIV Prevention Research

Thursday, February 9th from 6-9 p.m.
at The Warhol Museum

Good Food Music Prizes Free Parking

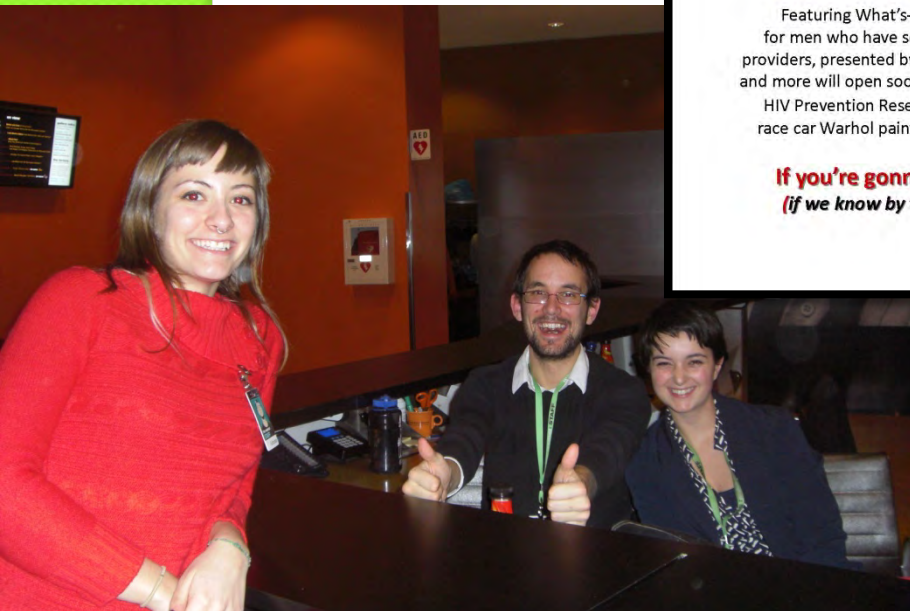
Featuring What's-Going-On in HIV Prevention Research for men who have sex with men, and their LGBT healthcare providers, presented by local researchers. Many studies are open and more will open soon! Your host is the University of Pittsburgh HIV Prevention Research team. **Bonus:** The wild BMW M1 race car Warhol painted in 1977 will be on display that night!

If you're gonna come... call 412-383-1313
(if we know by the 6th it helps us plan the food)

EDUCATION SESSIONS

6:30
7:10
7:50
8:30

PICK UP A PRIZE
AFTER IT'S OVER
(YOU'LL LIKE IT!)





Questions?