

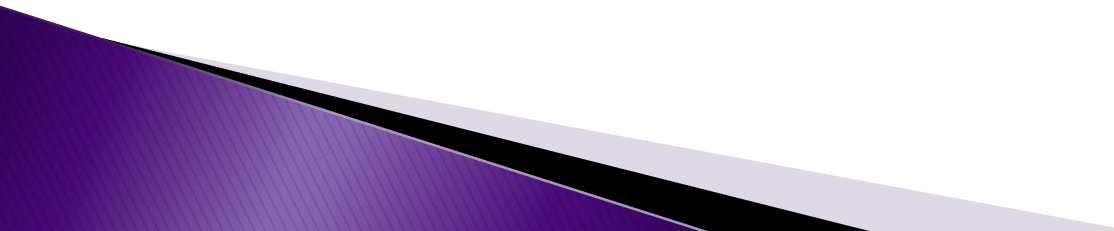
# Pitt CRS

## Our MTN-017 Experience

Stacey Edick– Research Clinician

Sherri Karas– Recruiter and Community Educator

# Presentation Outline

- ▶ Study Summary
  - ▶ Recruitment
  - ▶ Product Use Challenges
  - ▶ Behavioral and Adherence Issues
  - ▶ Lessons Learned
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# Study Summary

- ❑ Date of activation: 9/27/13
- ❑ First enrollment: 10/24/13
- ❑ Last enrollment: 11/10/14



↳ 12 ineligible (5 Rectal GC/CT; 4 Rectal abnormality; 3 Other)

- ❑ 4 (screen): 3 (enrolled) ratio

# Recruitment Methods

## 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:  Middle Initial:  Last Name:

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](#)

For additional information, email [HIVRegis@pitt.edu](mailto: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](mailto: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

## HIV Prevention Research Registry



# Registry (continued)

The screenshot shows a web browser window displaying the McGowan Research Group Data Portal. The page has a header with the logo for Magee-Womens Research Institute & Foundation and the text "McGowan Research Group Data Portal". A user is logged in as "sherrickaras". The main navigation menu includes "Participants", "Studies", and "Reports", with "Reports" currently selected. Below the navigation is a "Reload" button and a date range selector with "From" and "To" labels and calendar icons. The main content area is titled "Participant Reports" and lists several statistics:

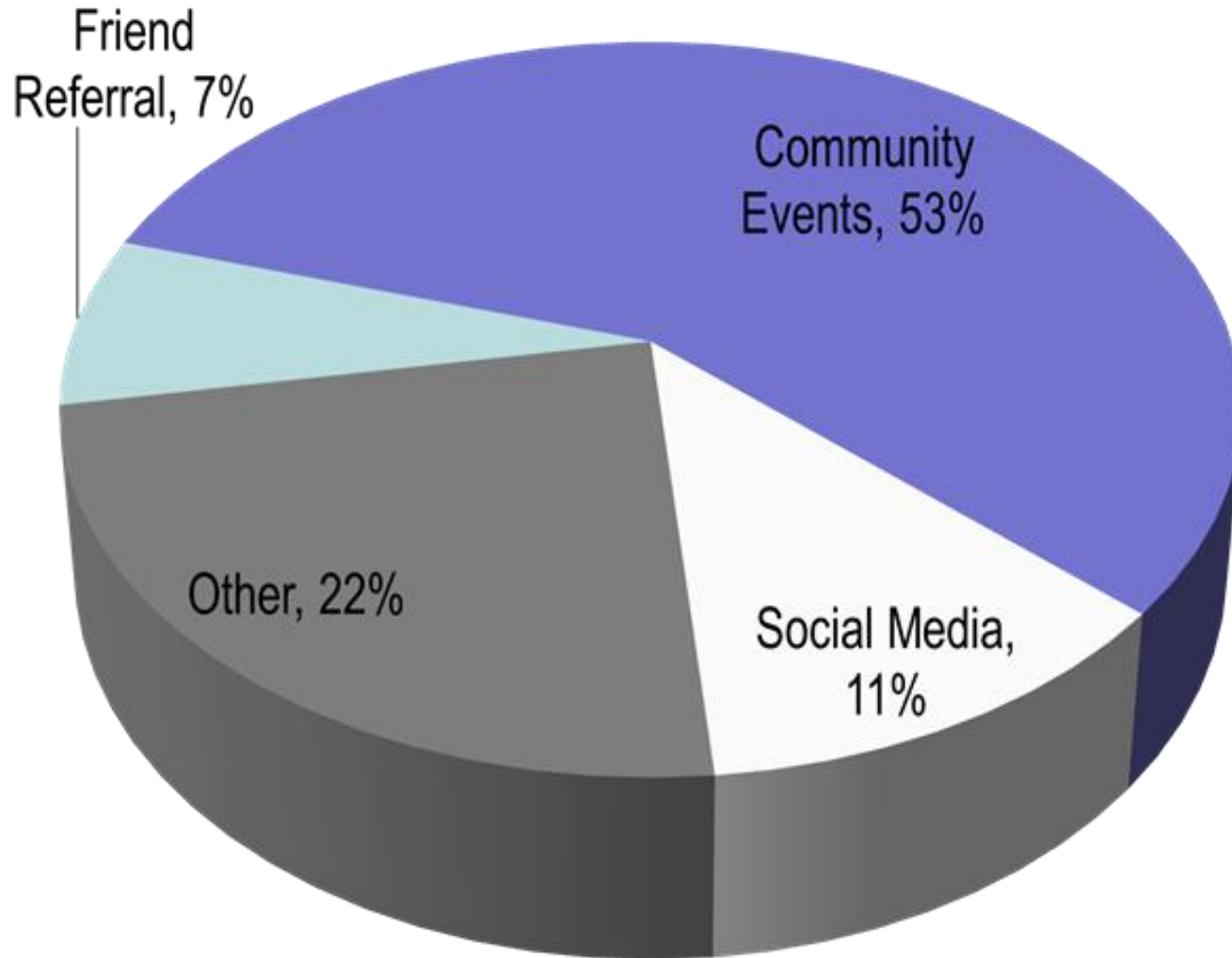
- 1028 currently enrolled in HIVRegis
- 1238 currently enrolled in system
- 960 sent email invitations to complete interview
- 470 who have completed interview
- 0 with pending interviews (sent email, have not completed, have not exceeded 30 day window)
- 490 who have not completed interview in 30 day window

Below the statistics is a section titled "HIVRegis Dates Enrolled" with a table header:

Name	Date Enrolled
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The browser's taskbar at the bottom shows the Windows Start button, several application icons (File Explorer, Internet Explorer, Office applications), and the system tray with the date and time: 11:11 AM, 2/24/2015.

# Registry (continued)



# Other Recruitment Methods

- ▶ Community Outreach



# Other Recruitment Methods

- ▶ Past Participants
- ▶ Word Of Mouth
- ▶ Craigslist/ Social Media

The screenshot shows a Craigslist listing for the 'BE A HERO' HIV prevention research study. The post is titled 'BE A HERO- HIV prevention research for men who have sex with men (Oakland)'. It features a purple banner with the text 'HIV Prevention RESEARCH STUDY' and a photo of two young men. The text of the post reads: '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'. Below the main text, there is a map showing the location of the University of Pittsburgh. At the bottom of the post, it says 'Research Study Seeks Men who have Sex with Men' and '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. COMPENSATION WILL BE PROVIDED. For more information, please call (show contact info) BE A HERO. do NOT contact me with unsolicited services or offers'. The post is dated 'posted: seconds ago' and has a 'post id: 4905476026'.

## BE A HERO. Take part.

By signing up for the HIV PREVENTION RESEARCH REGISTRY, you are taking the first step to becoming a part of local research efforts to prevent HIV worldwide.

If you're straight, gay or bisexual—  
if you're a man, woman, or transgender person—  
if you're HIV-negative, HIV-positive, or don't know your status—  
**YOU ARE WELCOME TO JOIN.**

Text **BeAHero** to **313131** to have information sent directly to your phone.

Sign up for the registry at [www.HIVregis.pitt.edu](http://www.HIVregis.pitt.edu).

Find out more about our program at [www.HIVpreventionstudies.com](http://www.HIVpreventionstudies.com) or call 412-956-9686.

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# Product Use Challenges

- ▶ Tenofovir Gel and Applicator
  - Few issues reported
  - Reports of gel leakage and applicator discomfort usually resolved with counseling, i.e. take your time and ensure you are inserting deeply enough
  - “Easy” discharge of gel was resolved by counseling to leave cap on until just before insertion



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# Product Use Challenges

- ▶ Truvada tablet
  - Widely accepted
  - Few reports of nausea and bloated feeling



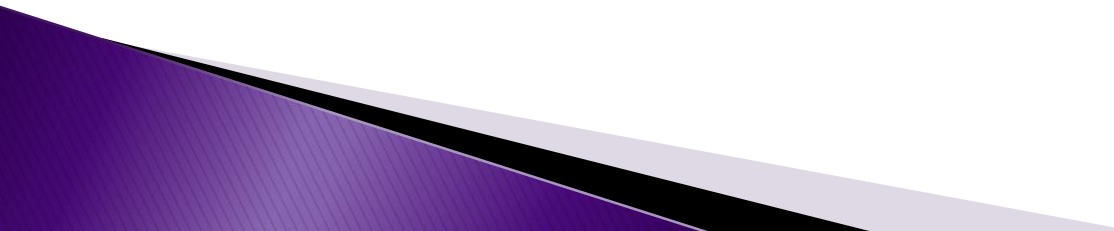
# Behavioral/Adherence Challenges

- ▶ Better adherence with daily regimens
- ▶ In general, very good adherence and positive PKs, making motivational interviewing a challenge
- ▶ Daily texts very often cited as the main reminder to use product, but some participants had frequent issues with the system (certain networks)

# Lessons Learned

- ▶ Product Use vs Procedure Counseling
  - Rectal biopsies while on gel
- ▶ Follow-Up Contact
  - Telephone vs email or text
- ▶ Doin' It for the Cause
  - Participants who had PrEP knowledge and interest in Truvada had a more difficult time accepting the gel

# Thank You

- ▶ Awesome Participants!
  - ▶ MTN Protocol and Behavioral Team, FHI360, SCHARP
  - ▶ Lab and Pharmacy Staff
  - ▶ Site Staff – Coordinators and Data
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Any Questions?