

Addressing Regulatory Issues in Creating Culturally Appropriate Recruitment Tools Targeting High Risk MSM

Kim Louis
Recruitment Supervisor
Seattle HIV Vaccine Trials Unit
Fred Hutch Cancer Research Center
Seattle, Washington

HIV VACCINE
TRIALS UNIT © SEATTLE

FRED HUTCHINSON
CANCER RESEARCH CENTER
A LIFE OF SCIENCE

Poster Objective

Discuss regulatory issues in creating culturally appropriate tools for recruiting MSM volunteers into HIV vaccine efficacy trials.

Background

- January 2005-2007 Seattle HVTU recruited high-risk MSM for a phase IIb HIV vaccine efficacy study
- Study criteria for MSM (last 6 months)
 - unprotected anal intercourse with another man *and/or*
 - anal intercourse with 2 or more male sexual partners.
 - Excluded: men who had been in a monogamous relationship with an HIV-1 seronegative partner for >1 year.

Methods

- Specific advertising campaign created based on input from MSM community members
 - Tops and Bottoms ad created
- Community Advisory Board felt ad appropriate for recruitment in Seattle MSM community
- IRB submission



tops &
bottoms
WANTED

Help us fight HIV. We need HIV-negative volunteers who are 18-45 to take part in a paid HIV vaccine research study. You can't get HIV from the vaccines, but you can help us beat an epidemic.

If you are a man who has sex with other men and have had more than one sex partner in the past 6 months, please call us at **206.667.2300** to see if you qualify for our study.

HIV VACCINE
TRIALS UNIT © SEATTLE
206.667.2300



tops &
bottoms
WANTED

Help us fight HIV. We need HIV-negative volunteers who are 18-45 to take part in a paid HIV vaccine research study. You can't get HIV from the vaccines, but you can help us beat an epidemic.

If you are a man who has sex with other men and have had more than one sex partner in the past 6 months, please call us at **206.667.2300** to see if you qualify for our study.

HIV VACCINE
TRIALS UNIT © SEATTLE
206.667.2300

Meeting between IRB and HVTU

- HVTU staff invited to meeting
 - HVTU Regulatory Coordinator
 - Recruiter
 - Community Educator
 - Director of Community Education,
HIV Vaccine Trials Network
- Other ads targeting MSM used as examples

The Link between HIV & Herpes

80% of gay men with genital herpes don't know they have it.

1 out of 4 gay men have genital herpes which makes them two times more likely to get HIV, if exposed.

HSV-2 is the virus that causes genital herpes...
If you have HSV-2, or want a free test to find out, call

The Link Study

206-520-3800



©Steven Miller 2004, www.smiller555.com

Knowing your herpes status may keep you HIV negative.

We'll test you for free as part of a University of Washington research study.

206-520-3800

Participants receive:

- Free herpes treatment
- Free STD counseling and treatment
- Free HIV/STD testing
- Free condoms and lube plus, compensation for your time

Results

- Discussion between HVTU and IRB led to ad approval with suggested changes to text
- New expedited process established to approve online advertising
 - e-mail submissions to the IRB Assistant Director
 - returned approx. five days or less
 - precedent for other departments to have an expedited approval process for online advertising



tops & bottoms

WANTED

Help us fight HIV. We need HIV-negative volunteers who are 18-45 to take part in a paid HIV vaccine research study. You can't get HIV from the vaccine and it is unknown whether it will protect you from HIV.

If you are a man who has sex with other men and have had more than one sex partner in the past 6 months, please call us to see if you qualify for our study.

206.667.2300

HIV VACCINE
TRIALS UNIT • SEATTLE

Results

- Similar ads submitted and approved
 - Approx. 30 ads submitted and approved
- 117 MSM enrolled for phase IIb study in Seattle, WA



GIVE US YOUR BEST SHOT. PREVENT HIV

206.667.2300 WWW.SEATTLEVACCINES.ORG



**HIV VACCINE
TRIALS UNIT • SEATTLE**

Help fight HIV! Take part in a paid study to help find an HIV vaccine. Call today.

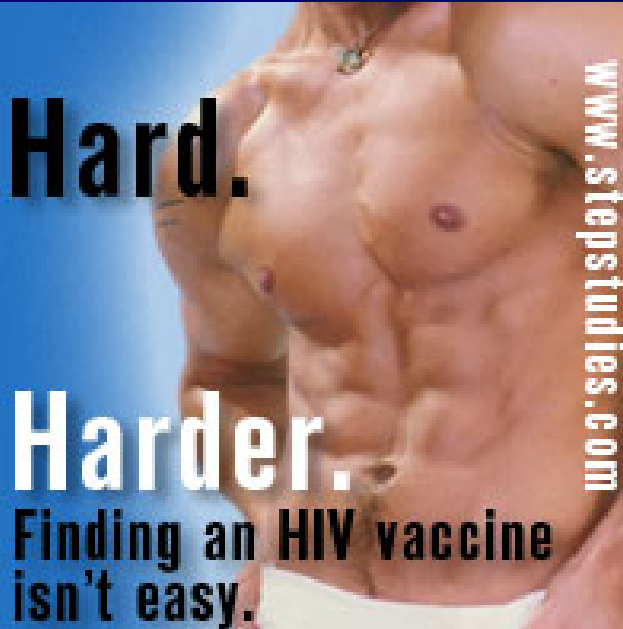
206.667.2300
www.seattlevaccines.org



**Don't be shy,
Join an HIV vaccine study today!**

Visit
www.seattlevaccines.org

Call Today!
**HIV VACCINE
TRIALS UNIT • SEATTLE
206.667.2300**

A close-up photograph of a very muscular man's torso. He is wearing a white tank top. The lighting highlights his abdominal muscles.

Hard.

Harder.

Finding an HIV vaccine isn't easy.

www.stepstudies.com

Conclusion

- Research conducting studies targeting MSM need to be proactive with their local IRBs
- In Seattle, culturally appropriate advertising assisted with high enrollment and helped reach a population that will benefit greatly from an HIV vaccine.

Acknowledgements

Co Authors: David Garcia, MPH, Community Educator, HVTU; Karen Mark, MD MPH, Director, HVTU

M. Juliana McElrath, MD, PhD; Principal Investigator, Seattle HVTU

Seattle Community Advisory Board for the HVTU & HPTU

Gina Query Regulatory Coordinator, Seattle HVTU

**Steven Wakefield Former Director, Community Education, HVTN
Director, Legacy Project, HVTN**

Connie Celum, MD, MPH; Principal Investigator, HIV Prevention Trials Unit

George Froehle, BA; Community Educator, HIV Prevention Trials Unit

Seattle HIV Vaccine Trials Unit study volunteers!