



Case Western Reserve University/
University Hospitals Case Medical Center
AIDS Clinical Trials Unit

MTN001 Recruitment/Enrollment
Lessons from a Newly Pluripotent Site

April 22, 2009

Bob Bucklew, Outreach Coordinator

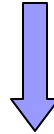
Case Western Reserve/University Hospitals Clinical Trials Unit





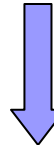
MTN001 Recruitment Process

Community Engagement



Initial Contact (begin tracking form)

Initial Discussion



Education Session



Screening

Case Western Reserve University Clinical Trials Unit
HIV Microbicide Trial Recruitment Form: MTN001

Potential Participant: _____

Contact Information: _____

Initial Contact: Date: _____ Staff Member: _____

Method of Contact: _____

How did PP learn about microbicides/MTN001 recruitment? _____

Initial Potential Participant Discussion: Date: _____ Staff Member: _____

_____ Following Discussion, potential participant identifies as ineligible for MTN001

Reason: _____

Include in HIV-negative database? _____

_____ Following Discussion, potential participant identifies as being eligible, but not interested

Reason: _____

Include in HIV-negative database? _____

_____ Following Discussion, potential participant identifies as eligible and interested in participating in MINT001.

Pre-screening Education Session Scheduled: _____

Follow up to schedule Pre-Screening Education Session (timeframe/contact information) _____

Comments: _____

Pre-Screening Educations Session: Date: _____ Staff Member: _____

_____ Following Session, potential participant identifies as ineligible for MTN001

Reason: _____

Include in HIV-negative database? _____

_____ Following Session, potential participant identifies as being eligible, but not interested

Reason: _____

Include in HIV-negative database? _____

_____ Following Session, potential participant identifies as eligible and interested in participating in MINT001.

Screening Visit Scheduled: _____

Follow up to schedule Screening Visit (timeframe/contact information) _____

Comments: _____

Screening Visit:

Date: _____ Staff Member: _____

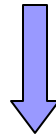
_____ Potential Participant Enters Protocol Screening Process

Include in HIV-negative database? _____

Comments: _____

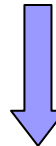
MTN001 Recruitment Process

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Education Session



Screening

Initial Discussion

Brief pre-screening conversation, generally held on the telephone with a Research Nurse.

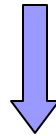
Provides overview of MTN001: standardized sheet of info

- trial purpose
- description of trial procedures, including meds, visits
- inclusion/exclusion requirements
- compensation

If potential participant states she is eligible and interested,
Educational Session scheduled

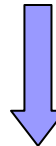
MTN001 Recruitment Process

Community Engagement



Initial Contact (begin tracking form)

Initial Discussion



Education Session



Screening



Education Session

Visit to the clinic

20-30 minute session with Research Nurse

More extensive explanation of all aspects of MTN001
(educational flip chart provided to Nurses)

If potential participant states she is eligible and interested, a Screening Visit can be scheduled, or she can take Informed Consent Form for further consideration and to talk with male partner(s).



Original Outreach/Recruitment Work Plan July – November 2008

Shotgun Approach:

Flyers/post cards

Email lists

HIV-negative database

Speaking engagements

Media



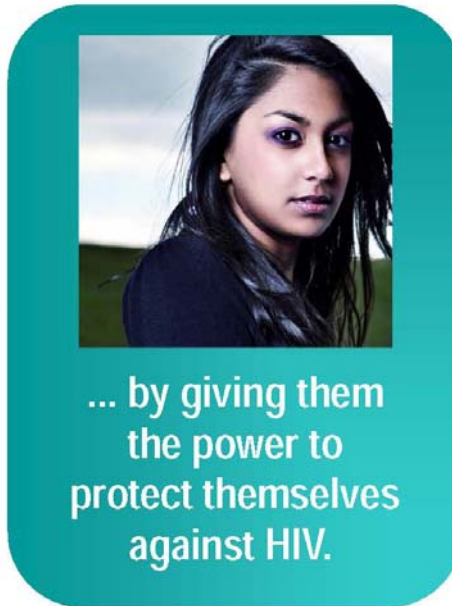
You can
 be involved in a
 research study
 that may help
 generations of
 women. . .

The Case Western Reserve/University Hospitals Clinical Trials Unit is now enrolling women in clinical studies of microbicides and other women-controlled strategies to protect against HIV infection.

If you are an HIV-negative, healthy woman, age 18 to 45, you may be eligible to join the study. Compensation provided.

An HIV microbicide is a gel, cream or foam that can be used by a woman to protect herself from the sexual transmission of HIV. Women-controlled HIV prevention strategies are those that can be used without the male partner's active participation.

For more information call (216) 844-AIDS
 or go to www.clevelandactu.org



... by giving them
 the power to
 protect themselves
 against HIV.



Initial Contacts

July 9

August 9

September 4

October 20

November 7



Outreach/Recruitment Work Plan

December-March 2009

Shotgun Approach:

Flyers/post cards

Email lists

HIV-negative database

Speaking engagements

* Purchase advertisements in media



Initial Contacts

December 9

January 30

February 22

March 23



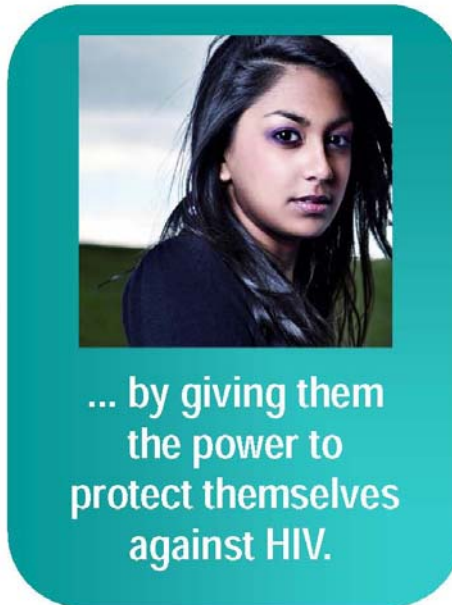
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Outreach/Recruitment Work Plan

April 2009

IRB submission: February 2, 2009

IRB approval: March 23, 2009

Women Needed to Participate in a Clinical Research Study



If you are a sexually active, healthy woman, age 18 to 45, you may be eligible to participate in a research study looking at a new medicine or gel to prevent infections. Compensation provided.

For more information, contact the Clinical Trials Unit at 216-844-2437 or rob2@case.edu.

CWRU/UHC IRB Appr Ad
Eff Date: 3/19/2009
UHC IRB Prot: 02-08-20



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February 22

March 23

April 15th 22

Total: 155

Initial Contact - results

Total (155)

Positive = Schedule Ed Sess (74)	48%
Negative = Did Not Schedule Ed Sess (68)	44%
Ongoing = Attempting further contact (13)	8%

April 1 – April 15 (22)

Positive = Schedule Ed Session (14)	64%
Negative = Did Not Schedule Ed Sess (9)	9%
Ongoing = Attempting further contact (6)	27%



Thanks

to CWRU/UH Community Advisory Board

to Rhonda White, Jonathan Lucas and Cheryl Cokley,

to Kaila Gomez and Sherri Johnson

to the MTN001 Protocol Team

to Angelina Gangestad, MD

to our Unit Research Nurses: Dawn Antosh, Trisha Walton & Barb Philpotts

to our UnitData Manager: Dan Gebhardt

Special thanks to all the Greater Cleveland women who have screened and enrolled in MTN001