

# Community Assistance in Preparation of MTN001

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# **History of Community Involvement with CWRU/UH AIDS Clinical Trials Unit**

**CWRU/UH AIDS Clinical Trials Unit was established in  
1987 as a founding unit of the AIDS Clinical Trials Group**

As required of all ACTG, a Community Advisory Board (CAB) was established and has continued to meet since its founding through today

- Monthly Meetings
- Annual Retreat
- Community Education Sessions
- Patient Appreciation Events

# History of Community Involvement with CWRU/UH AIDS Clinical Trials Unit

- Reviews all ACTG protocols prior to implementation; evaluates draft outreach/education materials; discusses medical developments and challenges with physicians and staff; also serves as Community Advisory Board for CWRU/UH Center for AIDS Research & other AIDS related projects
- The CAB has not had a traditionally strong role in recruitment rather trying to strike a balance between CAB members educating community of importance of clinical trials and the dangers of possibly misrepresenting specific trial benefits
- Membership open to all interested parties, but has as a goal to be as inclusive as possible and to reflect that demographics of HIV infection in the Greater Cleveland area

# History of Community Involvement with CWRU/UH AIDS Clinical Trials Unit

- Community Staff Liaison: Full-time Outreach Coordinator, serving both the ACTU and the CFAR. Duties include: staff liaison to CAB; creation, dissemination of ACTU/CFAR documents, including professional and community outreach/recruitment materials; coordination of professional and community educational events; website development and maintenance; press/media relations; fundraising for outreach activities.
- The CFAR Ethics in AIDS Program also provides salary support for a Research Associate to actively participate in the CAB and to provide an ongoing ethics dialogue with the CAB and the greater community

# Pre-MTN Education and Outreach

## Cleveland Steps Up to the Challenge: May 2005 – July 2005

“Cleveland Steps Up to the Challenge”: an education and outreach campaign to inform community of need for HIV vaccines/microbicides and to create pool of people potentially interested in clinical trials.

Establish database to record name, basic demographic characteristics, contact information, and contact preferences (email, postal mail, telephone)

Provide means for interested persons to sign up to be on database: paper form; telephone calls; on-line registration

Conduct education/outreach campaign: speaking engagements; flyers; post-cards; email lists

1. To determine level of community interest in participating in HIV microbicide and vaccine trials
2. To determine effective methods of reaching potentially interested populations
3. To create database of potentially interested HIV-negative people who could serve as outreach/recruitment pool and/or community volunteers/educators

Phase I of Campaign:  
Started: May 10, 2005  
Ended: July 1, 2005

CLEVELAND STEPS UP TO THE CHALLENGE

# AIDS-

Over 40 million people are currently living with HIV worldwide. More than 40,000 people are newly infected each year in the United States. Vaccines and microbicides, a substance such as a gel that would prevent HIV infection, are our best hope to stop this epidemic.

The Case Western Reserve University/University Hospitals of Cleveland AIDS Clinical Trials Unit is asking Cleveland to step up to this challenge. In preparation for offering vaccine and microbicide clinical trials in Cleveland, we are inviting HIV-negative (not infected), healthy adults, ages 18-60, to sign up to receive information about these clinical trials. Signing up does not imply that you agree to enroll in a clinical trial, just that we can send you information about the trials when they open in Cleveland.



It's easy to sign up on our website at

[www.clevelandactu.org/html/negative.html](http://www.clevelandactu.org/html/negative.html)

or you can do so and receive additional information by calling (216)844-2247.



[www.clevelandactu.org](http://www.clevelandactu.org)

# Results of Education/Outreach Campaign

HIV-negative Database							Total
Gender	Females 374	Males 216				Not Selected 11	601
Race	African-Amer/ Black 79	Caucasian/ White 449	Asian/ Pacific Island. 38	Native Americans 6	Other  16	Not Selected 13	601
Ethnicity	Hispanic 20	Non-Hispanic 443				Not Selected 138	601
Ages	18-29 312	30-39 133	40-49 93	50-60 50	60+ 3	Not Selected 10	601

Selected Contact Methods		
Category	Preferred	Alternate
Cellular Phone	28	81
Email	341	45
Fax	1	0
Home Phone	29	75
Pager	0	4
Postal Mail	103	63
Work Phone	16	43
No Response	83	290

# Ongoing Educational Campaign: July 2005 – September 2007



Scaled Down Version of Education Campaign.

1. Recognizing importance of biomedical prevention tools
2. Introducing word/definition of 'microbicide'
3. Linking AIDS Clinical Trials Unit and microbicide trials

How message delivered:

1. Speaking Engagements
2. Festivals/Events
  - Pride Festival
  - AIDS Walk

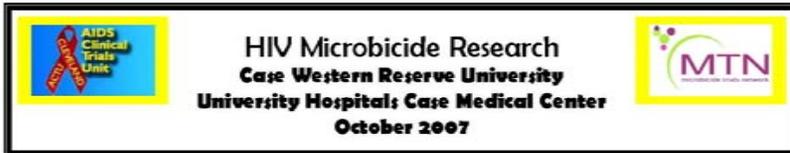
September 2005

University Hospitals, in conjunction with yearly AIDS Walk, hosted a display of the Global Campaign for Microbicides' *Giving Women Power Over AIDS* exhibit in the hospital atrium. Was able to successfully obtain press coverage of the exhibit and the issue of the need for microbicide development.

14 presentations during this time frame, focusing on groups already involved in HIV/AIDS, including the Ryan White Titles I/II planning council/committee, HIV prevention regional advisory group, HIV case managers (social workers) and HIV prevention specialists.

# Preparation for MTN001 Enrollment: October 2007 - Present

October 2007: All individuals in HIV-negative database contacted for first time since enrollment in 2005.



## HIV Microbicide Clinical Trials to Start in Cleveland

Earlier this year, the National Institutes of Health informed the Case Western Reserve University/University Hospitals AIDS Clinical Trials Unit that its application to become one of a handful of units in the country to participate in the newly formed Microbicide Trials Network (MTN) had been successful. Establishment of the MTN is the result of increasing recognition of the critical need for an effective HIV microbicide. Only 12 centers in the world are now funded to conduct this critically important work, and only 5 of them are located in the United States. Participation in the MTN will expand Case's long-term leadership in HIV clinical trials research, and will allow Case investigators to contribute to global efforts to develop an effective HIV microbicide, a goal that has been the focus of much international attention as a promising method of slowing the spread of HIV around the world. Statistics from the Center for Disease Control and Prevention show that approximately 40,000 people become infected with HIV each year in the United States, while over 4 million people become infected each year with HIV around the world.

"By joining the new Microbicide Trials Network," Michael Lederman, MD, Principal Investigator of the Case/UH AIDS Clinical Trials Unit, said, "we will be able to bring our local researchers into collaboration with an international network focused on topical strategies to prevent HIV transmission. We will also be able to provide Greater Clevelanders with the opportunity to participate in research that could directly save millions of lives".

## A Micro What?

**Microbicide** literally means any substance that will kill a microbe (such as a virus). An HIV microbicide refers to a topical treatment in the form of a gel, foam, cream, or depot device that could decrease or prevent sexual transmission of HIV. As HIV continues to spread throughout the world, the search for an effective, safe, affordable HIV microbicide continues to increase in importance.

## Microbicides

(my · crow · besides)



## In 2006

Over 4 million people were newly infected with HIV  
 Over 39.5 million people were living with HIV  
 17.7 million were women  
 3.8 million were children  
 Over 2.9 million people died of AIDS

## Empowering Women to Protect Themselves

*"The availability of microbicides would greatly empower women to protect themselves and their partners. Unlike male or female condoms, microbicides are a potential preventive option that women can easily control and do not require the cooperation, consent or even knowledge of the partner".*

- World Health Organization

All people enrolled in the HIV-negative database were contacted with a personalized letter and a newsletter providing education on microbicides and detailing the development of CWRU/UH joining the MTN

51 of the 601 enrollees' primary contact methods failed, e.g. bad email, returned letters, phone out of order. Additionally, 13 people reported leaving the Cleveland area

51 primary contact failures	
Secondary contact not listed	7
Secondary contact failure	32
Secondary contact successful	12

# Integration of Microbicide Trials Network into existing Community Advisory Board Structure

July 2007. Created CAB ad hoc committee of interested individuals to provide additional input into development of MTN001 and to provide CAB additional community input into microbicide trial preparations. Membership suggested by CAB – included representatives from AIDS service organizations, women’s health organizations, and interested community members. Communication with ad hoc committee done on an as needed basis, as opposed to the monthly CAB meetings.

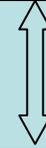


CAB discussed how best to integrate ongoing, formal community input and oversight into MTN activities at CWRU/UH

Issues considered:

- Additional time requirements for existing CAB members
- Membership goals for CAB – reflective of HIV demographics
- Different education/outreach/recruitment populations
- Don’t want to over-bureaucratize/segregate information from different networks
- Important contributions HIV-positive people can make to microbicide trial efforts

Community Advisory Board



Biomedical HIV Prevention Subcommittee

1. Needed to change bylaws of CAB to reflect official role with MTN, and to establish subcommittee.
2. Representatives of the CAB and of Subcommittee will attend both meetings.
3. Hold meetings on different days of the month; not sufficient time to hold both meetings on one day.

# Community Assistance in Preparation of MTN001

The Community Advisory Board and the ad hoc committee have provided direct assistance in the preparation for MTN001.

1. Reviewed drafts of MTN001 to provide questions, feedback.
2. Reviewed draft consent forms
3. Provided feedback on issues as requested from the MTN, e.g. availability of female condoms in the Cleveland area
4. Established focus groups to provide ideas for outreach/recruitment campaign
5. Review draft outreach/educational/recruitment materials
6. Provide connections with individuals/agencies that can assist in outreach/education/recruitment efforts

# Community Assistance in Preparation of MTN001

Planned direct assistance:

1. Role playing with staff re: when someone calls the Unit re: microbicide trials; behavioral questionnaires.
2. Continued review of educational/recruitment materials
3. Assistance in distributing outreach/educational materials.
4. Assistance in booking speaking engagements.

# Community Assistance in Preparation of MTN001

Issues to be/being addressed:

1. What will the role of the Subcommittee be in addition to the specific protocol questions requested by the MTN?
2. Are there significant differences between the ACTG studies and the MTN studies to encourage more direct recruitment activities by CAB members?
3. How to best tap into existing community activism around HIV/AIDS?
4. How to best provide education and outreach to specific subgroups, e.g. African-American community
5. How and who to recruit for new Subcommittee members.
6. Educating Subcommittee members on basic clinical trial definitions/procedures