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### ABOUT ACTION

The AIDS Clinical Trials Information and Orientation Network (ACTION) exists to provide information and resources to those interested in HIV/AIDS clinical trials, and to support an active community voice in local HIV/AIDS research.

### ABOUT DC CARE

DC CARE Consortium works to advocate for and to assure the availability of appropriate HIV/AIDS services in the community, including ensuring the equitable distribution of funding for these services, and promoting quality assurance in their delivery.

### FOR MORE INFORMATION

David Mariner

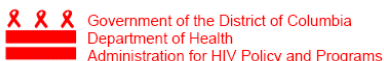
ACTION Coordinator  
DC CARE Consortium  
1156 15<sup>th</sup> Street NW Suite 500  
Washington, DC 20005

dmariner@dccare.org  
202 223-9550 ext 15



www.dccare.org

with support from



## Therapeutic Vaccine Research Luncheon

The DC CARE Consortium and the Vaccine Research Center invite you to a free educational luncheon Thursday July 13<sup>th</sup> at 1:00 PM. The event will be held at DC CARE: 1156 15<sup>th</sup> Street, NW.

A therapeutic vaccine is one that helps the immune system better fight the disease targeted by the vaccine. The goal of therapeutic HIV vaccination is to help control HIV infection without the use of antiretroviral (ARV) drugs.

Join us for a presentation from Dr. Joseph Casazza to hear the latest information about Therapeutic HIV Vaccine Research and to learn about a new trial being conducted by the Vaccine Research Center of the National Institutes of Health.

Please RSVP To David Mariner at 202 223-9550 ext 15 or [dmariner@dccare.org](mailto:dmariner@dccare.org)

## Introducing HYDRA

HYDRA is a coalition of diverse community stakeholders that will work to reduce HIV/AIDS among adolescents and young adults by changing the environments in which our young people live and function.

The HYDRA kick-off and mobilization event will be held on July 12<sup>th</sup> from 5:00 PM until 7:00 PM at 3933 Minnesota Avenue, NE. For more information call 202 884-4102 or visit [gohydra.blogspot.com](http://gohydra.blogspot.com)

HYDRA (Healthy Youth Demand Remarkable Actions) is part of a national project called Connect to Protect that has been launched in 15 sites across the U.S. and in Puerto Rico. Connect to Protect links local researchers with community members, organizations and institutions. Connect to Protect's Washington, DC site is housed at Children's National Medical Center.

## Upcoming Events

- **July 7<sup>th</sup>** – NATAP Free Community Forum on Hepatitis C, HIV co-infection, and HIV Drug Resistance. To find out more and reserve your seat call 888-266-2827
- **July 12<sup>th</sup>** – HYDRA Kick-off Event (see above) For more information call 202 884-4102
- **July 13<sup>th</sup>** – ACTION Luncheon on Therapeutic Vaccine Research (see above). To find out more and reserve your seat contact David Mariner at 202 223-9550 ext 15 or [dmariner@dccare.org](mailto:dmariner@dccare.org)
- **July 14<sup>th</sup>** – ACTION Community Presentation for Transgender Health & Empowerment
- **July 27<sup>th</sup>** – ACTION Community Presentation for the Young Women's Project.

# Seven Principles of Ethical Clinical Research

## An Introduction

Community members play an important role in advocating for clinical research which respects the rights, dignity and welfare of all participants. Community representatives serving on Community Advisory Boards (CABs) and Institutional Review Boards (IRBs) are part of the system of safeguards in place to assure that research that takes place in the United States and internationally is conducted in an ethical manner.

Of course, it is not a perfect process. Our understanding of what constitutes an ethical trial has changed over time and continues to evolve. In the past sixty years, there has been much discussion and debate among researchers, ethicists, elected officials, and community members to develop clear standards for clinical studies. A number of documents have been written on the subject. Each of these documents has played an important role in furthering our understanding of what makes clinical research ethical, and they are all well worth reading and discussing in their own right.

The seven principles for ethical clinical research have been taken from these writings.<sup>1</sup> They provide a framework to use when reviewing clinical studies.

### 1. Value

Each study must have social or scientific significance. The treatment or intervention, being tested should improve health and well being or increase knowledge about the research area.

*Question to Ask:* What are the most important areas of HIV/AIDS research for our community? What will we learn from the study and how will it help?

### 2. Validity

The study should use accepted scientific principles and methods, including statistical techniques to produce reliable and valid data. If you are not familiar with statistics (and even if you are) it might be difficult to understand this aspect of study design. Wherever you are starting, you can ask questions and learn as you go.

*Questions to Ask:* What is the main question being asked by this research? What outcome is being measured to answer that question? Does this make sense? How many trial participants will be needed for this study to get a clear answer to the main question and is this number realistic?

### 3. Fair Selection

Fair subject selection means that stigmatized and vulnerable individuals are not unfairly targeted for risky research and the rich and socially powerful are not favored for potentially beneficial research.

*Question to Ask:* Will this study recruit trial participants from communities and populations most impacted by the HIV/AIDS epidemic? Who will be excluded from the study? Are these exclusions reasonable and fair? Does this study unfairly target certain groups?

### 4. Favorable Risk-Benefit Ratio

Research trials should be designed to minimize risks and enhance potential benefits. Risks to Trial Participants should be proportionate to the benefits to the subject and society. If there are two different arms in the study, both arms should be relatively equal in terms of risks and benefits.

*Questions to Ask:* What are the risks involved in joining this study? What could go wrong and how are researchers prepared to handle these situations? Consider the risks as well as the potential benefits to the individuals involved in the study and to society. Would you participate in this study if you were eligible?

## 5. Independent Review

The major aspects of the study must be reviewed by an independent board which is not affiliated with the research study. This Independent Review Board (IRB) looks at all aspects of the study including the study design, target population, and risk benefit ratios.

*Question to Ask:* Who is serving as the Institutional Review Board (IRB) for this study? Are there community representatives on the IRB? How are IRB members selected?

## 6. Informed Consent

Provision of information to participants about the purpose of the research, its procedures, potential risks, benefits, and alternatives, so that the individual understand this information and can make a voluntary decision to participate.

*Questions to Ask:* Does the informed consent document for the study make sense and will trial participants be able to understand it? Are there other components to the informed consent process such as videos or other educational materials? How does the informed consent process work at your local site?

## 7. Respect for Participants

The same respect that is shown to trial participants during enrollment must be shown during the research trial. This means that:

- Participants can withdraw from the study at any time.
- Confidentiality is honored and confidential information stays secure.
- Participants are informed of newly discovered risks or benefits as the trial progresses.
- Participants are informed of the results of the research.
- The welfare of participants is maintained by maximizing benefits and minimizing harms.

**Questions to Ask:** Does the informed consent make it clear that participants can withdraw from the study at any time? How are participants informed of newly discovered risks or benefits during the trial? How are participants informed of the trial results? How is confidential information handled? What other issues could impact the welfare of research participants in this study?

### For more information

#### Human Participant Protections Education

<http://cme.cancer.gov/clinicaltrials/learning/humanparticipant-protections.asp>

This web-based course presents information about the rights and welfare of human participants in research. The two-hour tutorial is completely free. You will have the option of printing a certificate of completion from you computer upon completing the course.

<sup>i</sup> Emanuel, E., Wendler, D. & Grady, C. J. Am. Med. Assoc. 283, 2701-2711 (2000).