

# Community Engagement in DAIDS-supported Research

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National Institute of  
Allergy and  
Infectious Diseases

# **History of Community Engagement**

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- **Accomplishments in the field of HIV research have been remarkable**
  - **Development of effective ART has rendered HIV a treatable disease, and PLWH can expect to have a nearly normal lifespan**
- **These achievements have been made possible because of the voices of dedicated and persistent community members demanding focused, accelerated research efforts**
- **Early in the epidemic, researchers and investigators were separated and relationships were contentious**
- **Because of dogged determination to be heard, community members have since become a vital and valued contributor to the research effort**

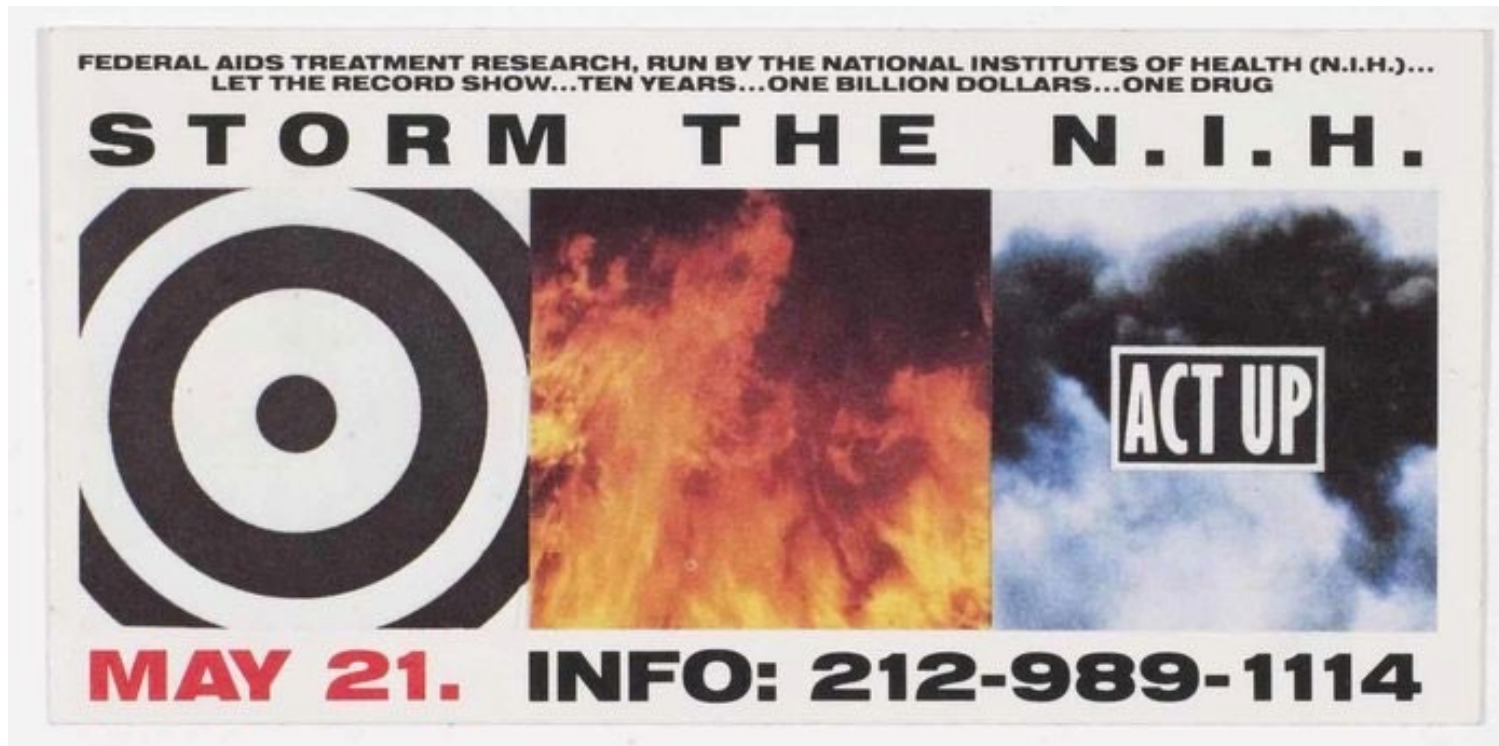
# **History of Community Engagement**

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- **Community engagement has become formalized...mandated and funded**
- **Community advisory boards (CABs) have been mainstay of engagement in HIV clinical trials networks**
- **Good Participatory Practice (GPP) has provided guiding principles for community engagement in HIV research**
- **Types of research and means of engagement have evolved over the years**

# History of Community Engagement

- In 1990, activists were concerned about the slow response of USG and pharmaceutical industry to respond to the AIDS epidemic



# Dr. Fauci Invites Community to Meet

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- **“My decision to open the doors to the activist community was one of the best administrative decisions I ever made. Over the years their input proved to be invaluable to our developing the optimal design of clinical trials that were user-friendly to the participants and still yielded the most valuable scientific and clinical information.”**
- **“I grew to respect and like these brave young people very much even though we sometimes disagreed, and they did not hesitate to publicly criticize me over these disagreements. But we learned from each other...I valued more and more their unique insight into issues that affected them and their community.”**

Quotes from Anthony Fauci in “On Call: A Doctor’s Journey in Public Service”

# Community Engagement – Network Beginnings

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- 1987: ACTG formed, first group meeting
- 1989: ACT-UP attends group meeting uninvited; first community advisory board funded
- 1990:
  - Community members invited to the 8<sup>th</sup> group meeting
  - Community constituency group (CCG) formed
  - CCG members attend Executive committee and scientific core sessions as observers
  - CCG attend the 10<sup>th</sup> group meeting as a formal part of the ACTG (7/90)



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# What is a Community Advisory Board (CAB)?

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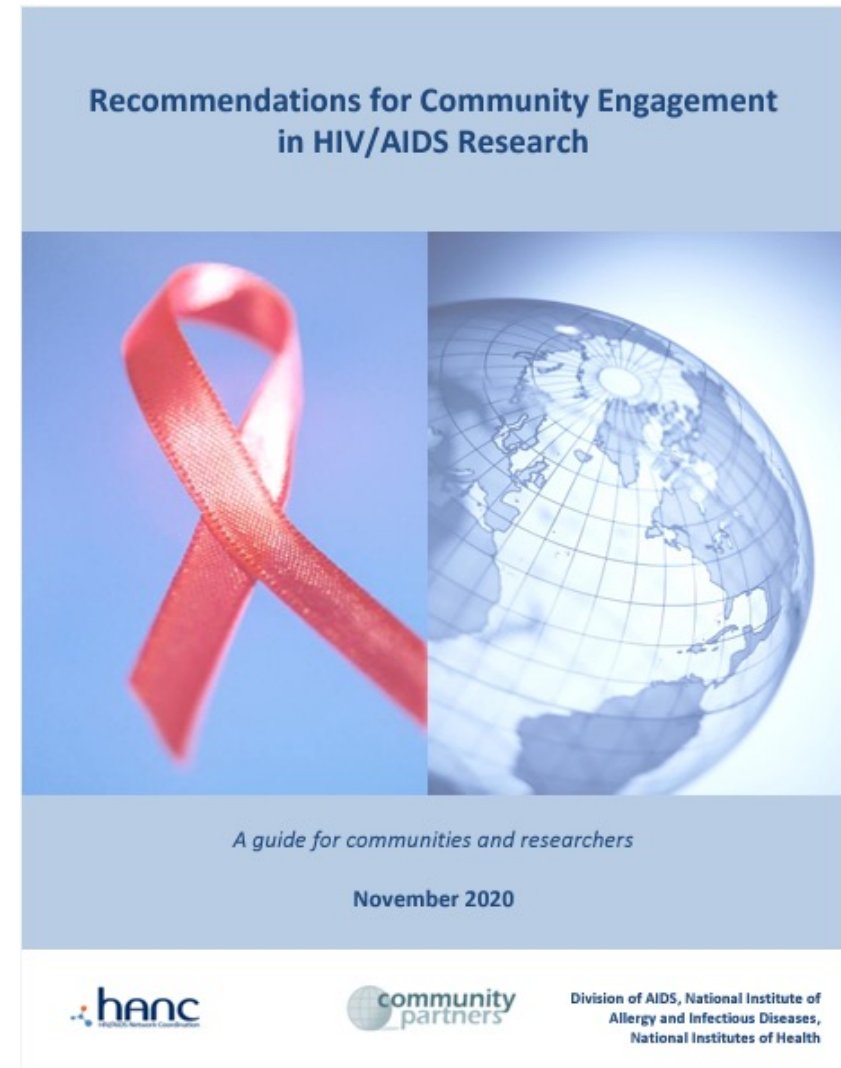
- Formal advisory group that is coordinated by the research study, site or network
- Made up of diverse community members varying in age, race, gender, education, religion, sexual orientation
- Meets regularly to provide feedback to the site on research and its relevance to the local community
- Provides two-way communication channel for information between the research site/network and broader community



# Community Engagement Recommendations

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- Developed in 2009 (updated in 2014, 2020)
- Requested by community representatives as a way to document good community practice
- Focused on CABs but recognizes additional types of engagement
- Aligns with GPP





# Network Community Engagement – Contributions

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- Inform network research priorities
- Participate in scientific committees
- Participate on protocol teams
  - Voice questions/concerns about trials and their development, implementation and outcomes
  - Assure appropriateness of informed consents
- Advocate on behalf of clinical trial participants
- Educate to increase knowledge around areas of HIV research, increase awareness of trials
- Interpret and disseminate research results
- Promote ethical research practices



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HIV VACCINE  
TRIALS NETWORK

# National Center for AIDS Research (CFAR)

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- The CFARs help drive collaborations across multiple HIV research disciplines and provide technical support to HIV researchers across more than 20 universities
- DAIDS strongly encouraged CABs as part of the CFARs in the 2000s
- CFAR CABs are composed of community members, representatives from community-based organizations, and HIV/AIDS Clinical Trials Network CAB members
- The central mission of each of CAB is to increase research capacity of communities and develop relationships and collaborations between HIV researchers and community members



# National CFAR CAB Coalition

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- **The National CFAR CAB Coalition (NC3) was established in 2011 to enhance partnerships between the community and HIV researchers**
- **The mission of the NC3 is to:**
  - Represent the 20 CFAR CABs as a national advocacy group of key stakeholders in HIV research
  - Provide a resource for community engagement and involvement in national CFAR initiatives



# Purpose of the NC3

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- **Provide expertise on community ideas and concerns at National CFAR meetings**
- **Provide recommendations and consultation regarding future cross-CFAR initiatives**
- **Provide community input on RFA development of CFAR grants, e.g., Developmental Awards, New Investigator Awards**
- **Centralize consultation services and resources for individual CFAR CABs:**
  - Community outreach and engagement (inclusive of international settings)
  - Membership recruitment, training, and retention
  - Interaction between community and CFAR researchers
  - Communication platforms
  - Review of research design, protocol, implementation and dissemination
  - Funding sources

# Martin Delaney Collaboratories (MDCs)

- Flagship NIH program on HIV cure research
- The purpose is to foster dynamic, multidisciplinary collaborations between basic, applied, and clinical researchers studying HIV persistence and developing potential curative strategies in partnership with government, private sector, and community.





# Martin Delaney Collaboratories (MDCs) Community Engagement (CE) Activities

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## 2011:

- Each of the 3 MDCs had a community advisory board (CAB) although not required
- A supplement was provided in 2011 for coordination of CAB representatives from all 3 MDCs through the end of the grant

## 2016:

- Went from 3 to 6 MDCs; small pilot clinical trials were allowed but not required
- Recognizing the importance of CE activities in cure research, applicants had to propose a plan for CE, including support of a CAB in response to the RFA. The purpose was to ensure interactions with diverse community stakeholders.

## 2021:

- 10 MDCs; no longer funded to support clinical trials
- Given the importance of engaging community at the earliest stages of HIV cure research, the RFA still included a section on CE
  - Each MDC must have at least one Community Partner (CP), distinct from a CAB, to facilitate community engagement
- Community Engagement Coordinators (CEC) would be supported at each MDC
- Each MDC had to support a CAB as well to help ensure feasibility of future trials

# MDC Community Engagement Requirements

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- **Community Engagement Coordinator (CEC)**

- Define clear roles and responsibilities for the CP and the CAB
- Establish plan for CE activities
- Coordinates CAB meetings, as needed

- **Community Partner(s) (CP)**

- Role is to work with CEC to carry out CE activities, e.g., increase HIV cure research literacy, gauge acceptability of potential interventions, discuss ethical considerations, and set realistic expectations for an HIV cure among communities impacted by HIV cure research
- May be advocates from the community, non-government organizations, non-profit organizations, and/or community-based organizations

- **MDC-specific CAB**

- Distinct and different from CP and CEC
- Role is to advise the Executive Committee and provide community input (especially regarding CE activities and clinical trial protocol development)

# MDC Community Engagement - Contributions

## Recommendations for analytical antiretroviral treatment interruptions in HIV research trials—report of a consensus meeting



*Boris Julg, Lynda Dee, Jintanat Ananworanich, Dan H Barouch, Katharine Bar, Marina Caskey, Donn J Colby, Liza Dawson, Krista L Dong, Karine Dubé, Joseph Eron, John Frater, Rajesh T Gandhi, Romas Geleziunas, Philip Goulder, George J Hanna, Richard Jefferys, Rowena Johnston, Daniel Kuritzkes, Jonathan Z Li, Udom Likhitwonnawut, Jan van Lunzen, Javier Martinez-Picado, Veronica Miller, Luis J Montaner, Douglas F Nixon, David Palm, Giuseppe Pantaleo, Holly Peay, Deborah Persaud, Jessica Salzwedel, Karl Salzwedel, Timothy Schacker, Virginia Sheikh, Ole S. Søgaard, Serena Spudich, Kathryn Stephenson, Jeremy Sugarman, Jeff Taylor, Pablo Tebas, Caroline T Tiemessen, Randall Tressler, Carol D Weiss, Lu Zheng, Merlin L Robb, Nelson L Michael, John W Mellors, Steven G Deeks, Bruce D Walker*

Dubé et al.  
*Research Involvement and Engagement* (2023) 9:39  
<https://doi.org/10.1186/s40900-023-00449-y>

Research Involvement  
and Engagement

COMMENT

Open Access



## Community engagement group model in basic and biomedical research: lessons learned from the BEAT-HIV Delaney Collaboratory towards an HIV-1 cure

Karine Dubé<sup>1,2</sup>, Beth Peterson<sup>3,4</sup>, Nora L. Jones<sup>4</sup>, Amy Onorato<sup>5</sup>, William B. Carter<sup>4</sup>, Christine Dannaway<sup>4</sup>, Steven Johnson<sup>4</sup>, Roy Hayes<sup>4</sup>, Marcus Hill<sup>4</sup>, Rease Maddox<sup>4</sup>, James L. Riley<sup>6</sup>, Jane Shull<sup>7</sup>, David Metzger<sup>5</sup> and Luis J. Montaner<sup>3\*</sup>

RESEARCH

Open Access



## Ethical and practical considerations for cell and gene therapy toward an HIV cure: findings from a qualitative in-depth interview study in the United States

Karine Dubé<sup>1,13\*</sup>, John Kanazawa<sup>1</sup>, Hursch Patel<sup>1</sup>, Michael Louella<sup>2</sup>, Laurie Sylla<sup>2</sup>, Jeff Sheehy<sup>3</sup>, Lynda Dee<sup>4,5</sup>, Jeff Taylor<sup>5,6</sup>, Jen Adair<sup>7,8</sup>, Kim Anthony-Gonda<sup>9</sup>, Boro Dropulic<sup>9</sup>, John A. Saucedo<sup>10</sup>, Michael J. Peluso<sup>11</sup>, Steven G. Deeks<sup>11</sup> and Jane Simoni<sup>12</sup>





**NIH ENGAGE:**  
Engaging the Public  
as Partners in  
Clinical Research



# Overview

- ▶ Patients, communities, and other members of the public are essential partners to the success of research
- ▶ NIH believes that engagement should be tailored to the needs and experiences of people and communities, and that they should guide the direction of research that is impactful to them
- ▶ To accomplish this, NIH has launched an effort to develop a vision and framework for incorporating public voices in all phases and types of clinical research







# NIH ENGAGE

*An Initiative to Increase Public Engagement in Clinical Research*

## Welcome

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NIH is seeking information to assist the agency in developing additional engagement strategies that ensure public voices are meaningfully incorporated in NIH supported clinical research – and we want to hear from **YOU!**

- NIH recently released a **request for information** on strategies to maximize public engagement, see [here](#) for more information on how to submit a response.
- Save the date: NIH will be hosting an [information webinar](#) on July 17<sup>th</sup>, which will also include significant time for public feedback. More details on the webinar will be provided shortly.
- To learn more about the goals of ENGAGE, check out this [Under the Poliscopes blog](#) authored by Lyric Jorgenson and the ENGAGE Co-Chairs, Suzanne Bakken and Christin Veasley.

[PartnersInResearch.nih.gov](https://PartnersInResearch.nih.gov)

# **The Future of Community Engagement**

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- **What needs improvement? What should we change?**
- **How can we extend CE further across research portfolio?**
- **Are there novel methods of engagement that can be employed?**
- **How do we measure effectiveness?**

# Acknowledgements

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