

The Office of HIV/AIDS Network Coordination (HANC)

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February 18, 2023

Why we are here today

- **Invited**
- **Listen and learn**
- **Share**
- **HIV & other health disparities**
- **Support Cure agenda**

Dedication



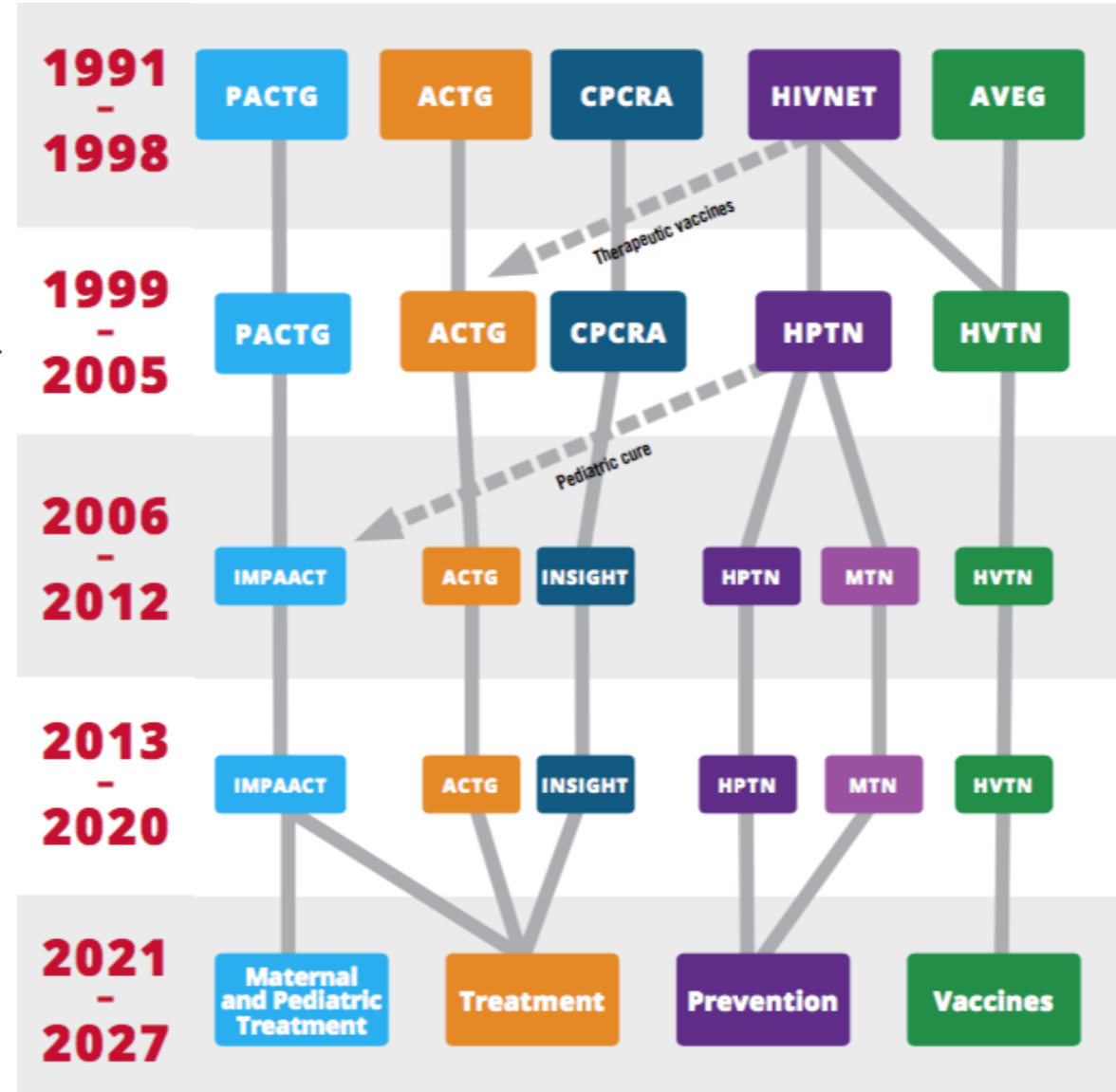
HANC Team



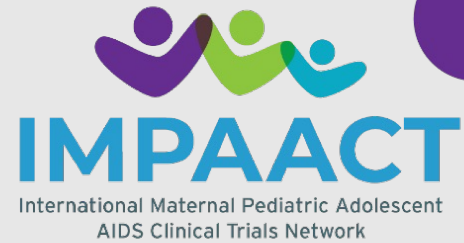
HANC Introduction

Founded in 2004, the mission of the Office of HIV/AIDS Network Coordination is to support the science and operations of the NIAID HIV/AIDS Clinical Trials Networks by increasing efficiency and resource-sharing through coordination of critical activities across networks and with other research and advocacy partners.

HANC & the NIH-funded HIV Research Networks

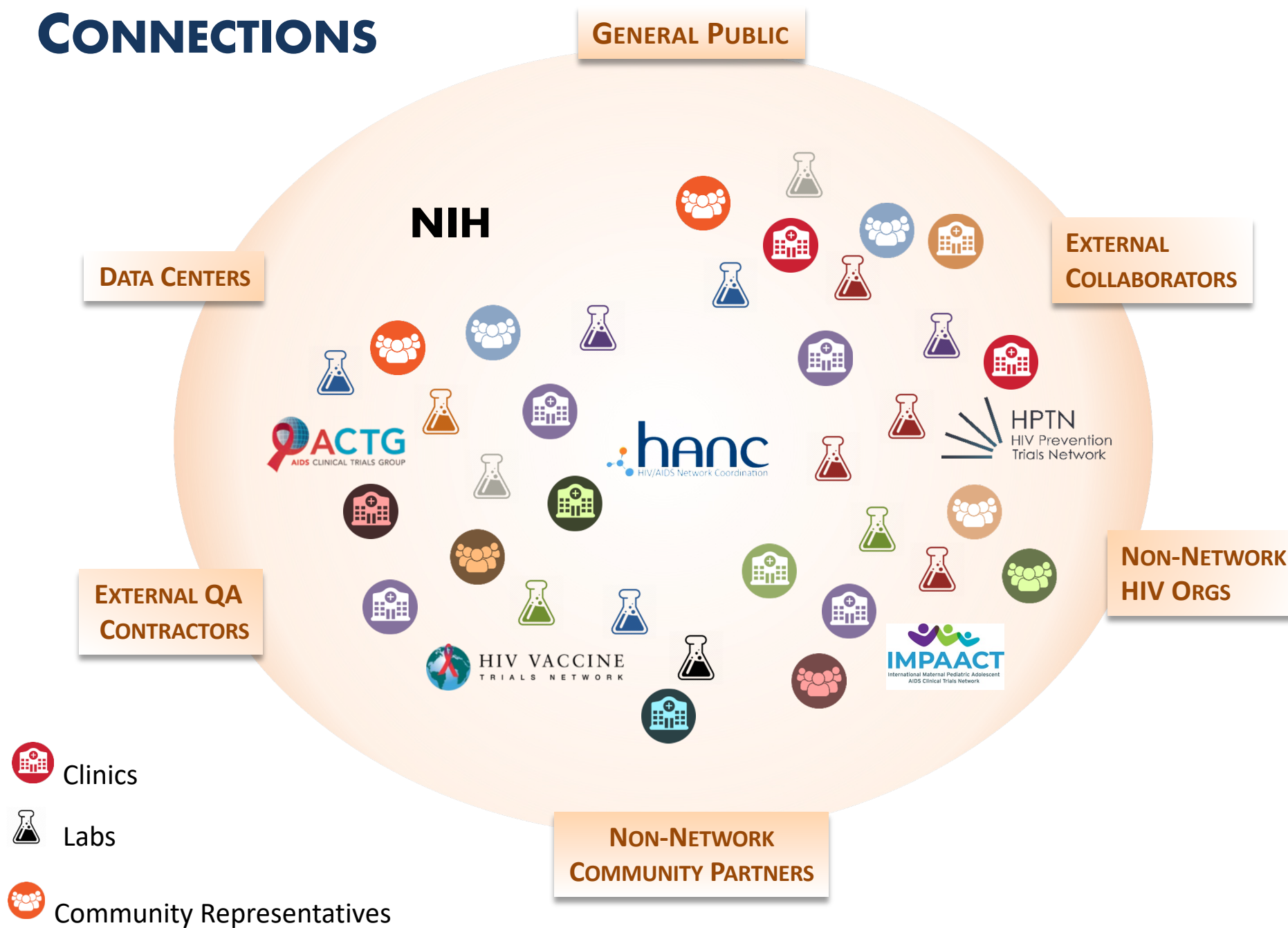


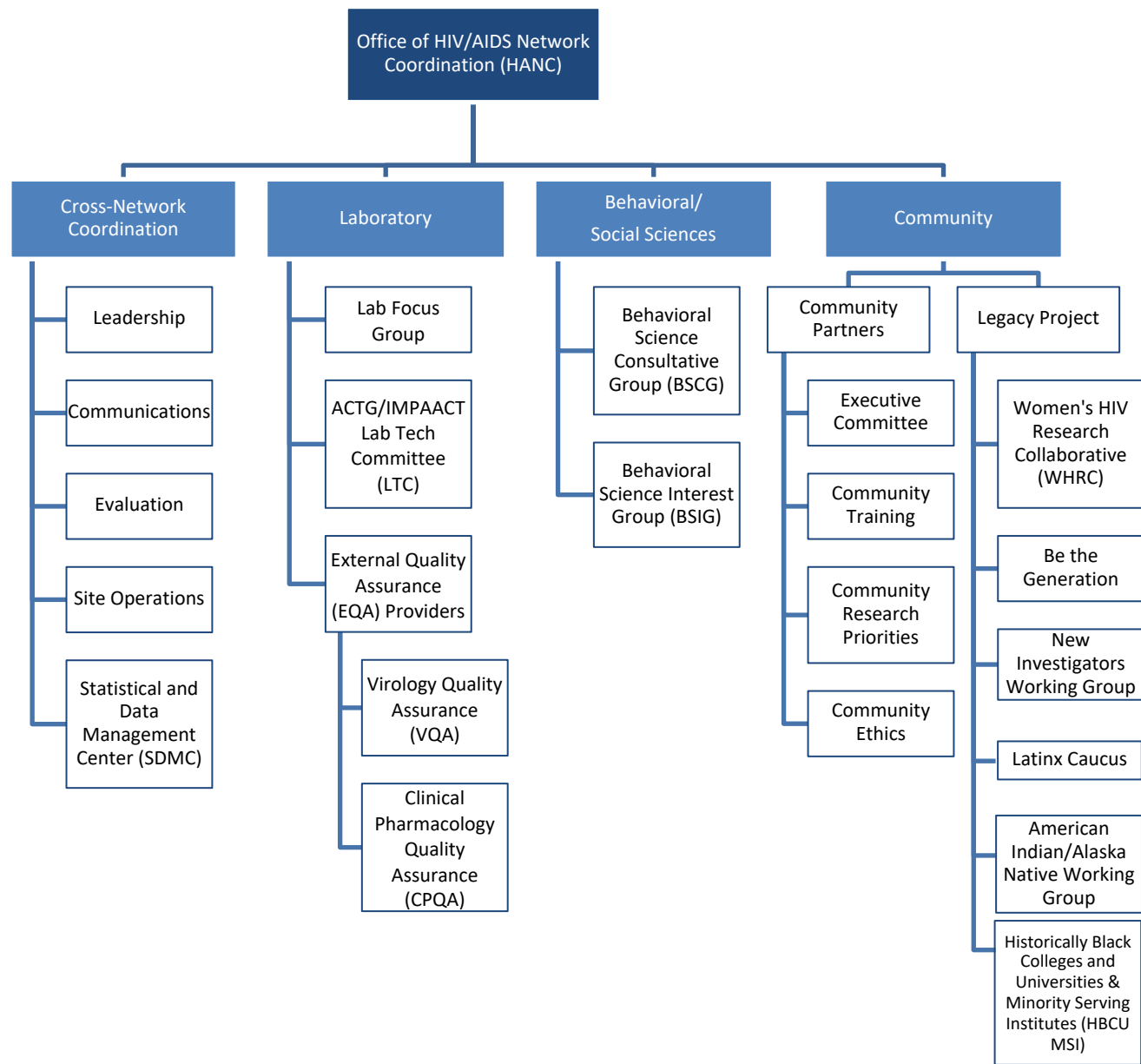
Original image from AVAC



HIV VACCINE
TRIALS NETWORK

CONNECTIONS







Resources for Inclusive Community Involvement

Featured on this page are a list of resources covering various aspects of community engagement in clinical research.

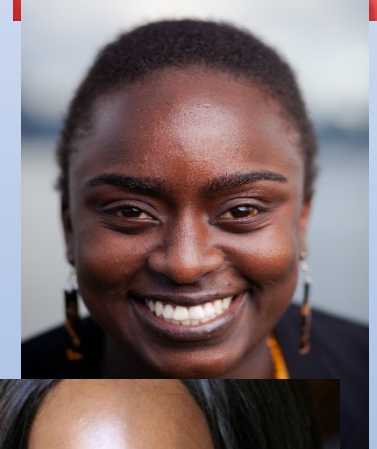
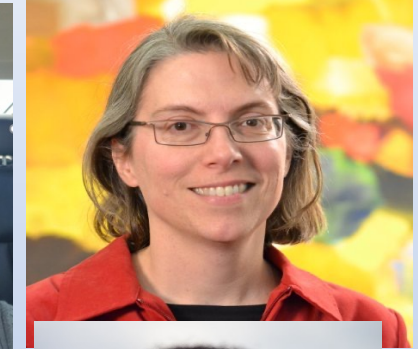
On This Page:

- [Bill of Rights and Responsibilities for HIV Research](#)
- [Community Engagement Resource Highlights](#)
- [DAIDS CAB and CWG Directory](#)
- [Guidance for Gender-Inclusive HIV Research Practices](#)
- [How to Critically \(and Quickly\) Read a Protocol](#)
- [Long-Acting Antiretroviral Injectables Info Sheet](#)
- [NIAID HIV Language Guide](#)
- [PHOENix Study Community Engagement](#)
- [Recommendations for Community Engagement](#)
- [Representative Studies Rubric](#)
- [TB Resources for Communities](#)
- [National Women and Girls HIV/AIDS Awareness](#)

Community Resources

www.hanc.info

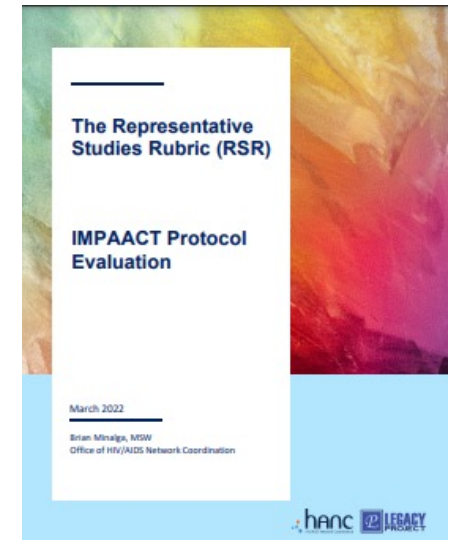
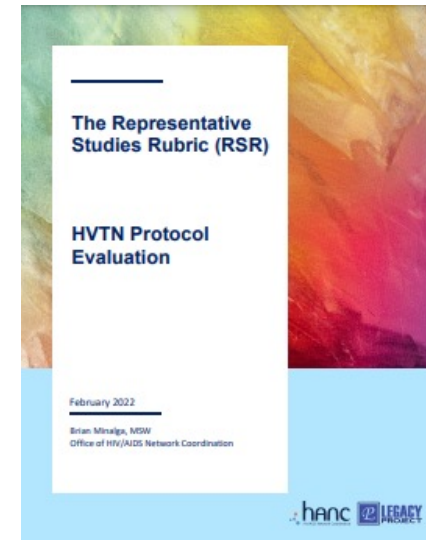
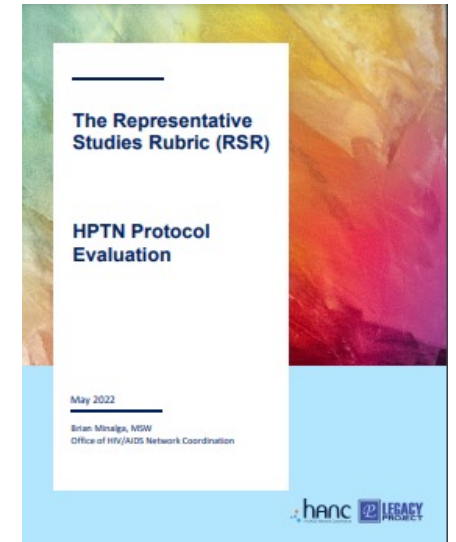
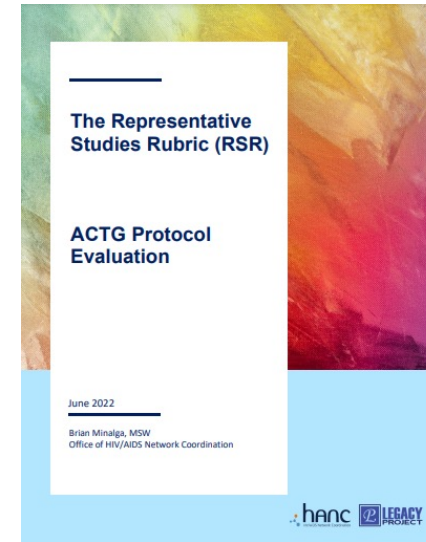
Cure-Specific Resources: the WHRC



The Representative Studies Rubric (RSR)

Addressing Inclusion:

- Age
- Drug use
- Ethnicity
- Gender
- Pregnancy
- Race
- Sex assigned at birth





Recommendations for Community Engagement in HIV/AIDS Research



A guide for communities and researchers

November 2020



Division of AIDS, National Institute of
Allergy and Infectious Diseases,
National Institutes of Health

Community Resources

How to Critically (and Quickly) Read a Protocol

- Outlines and explains the most important components of a study protocol
- Empowers CABs and community members to advocate
- Available in English, Portuguese, and Spanish

Community Resources

Bill of Rights and Responsibilities for HIV Research

- Outlines the rights and responsibilities for participants in a clinical trial
- Empowers research participants act on their own behalf and in partnership with study staff
- For use by clinical research sites along with informed consent forms

Mentorship Program

- To support site staff and CABs in an effort to rebuild and reenergize CABs.
- In addition to the Recommendations for Community Engagement document, CP can offer more specific and/or hands-on orientation, consultation, or training.
- Pool of experienced CAB liaisons that sites across the networks can reach out to for mentorship (ex. how to run a CAB meeting, develop your program, schedule trainings, identify critical training needs, prepare bylaws, organize a CAB).
- These individuals who agree to volunteer as mentors would be valuable resource.



Red Ribbon Registry (R3)

www.redribbonregistry.org

A database that connects potential study participants (volunteers) with local clinical studies to strengthen the connection between the community and the doctors and scientists working on clinical research studies.

HANC's role:

- Facilitate expansion of the R3 to additional network studies.
- Maintain the *R3 Resources* page on the HANC website to support ACTG, HPTN, and IMPAACT sites.
- Develop processes and workflows to facilitate various communications between external stakeholders and R3 internal team, including processes for regulatory approval of site-developed advertising materials and requests for communications to volunteers.
- Conduct training sessions for site administrators and users.






HANC Webinar Library


- Behavioral Science (4)
- Community Engagement (6)
- Outreach & Marketing (3)
- Health Disparities (6)
- HIV & Substance Use (3)
- HIV Genetic Sequencing (4)
- Lab (6)
- COVID-19 (9)
- MPV (1)
- TB (5)
- Zika (1)
- National HIV Awareness Days (6)
- Women (4)
- Hot Topics (7)

THE LANCET

CORRESPONDENCE | VOLUME 395, ISSUE 10325, P628, FEBRUARY 12, 2022

Research on transgender people must benefit transgender people

Brian Minalga  Cecelia Chung  J D Davids  Aleks Martin  Nicole Lynn Perry  Alic Shook

Published: February 12, 2022  DOI: [https://doi.org/10.1016/S0140-6736\(21\)00806-3](https://doi.org/10.1016/S0140-6736(21)00806-3)

NATIONAL WOMEN & GIRLS HIV/AIDS AWARENESS DAY

March 10, 2022

The Women's HIV Research Collaborative celebrates these recent advancements in research focused on cis and trans women. Follow us on [Facebook](#) for more!

A SHOT FOR PREVENTION

No pills? No problem! A [bi-monthly shot](#) has been approved for HIV prevention in the US and is under review in many other countries. To the more than [550 transgender women](#) and [3,200 cisgender women](#) who participated in these studies, we have you to thank!



HOPE FOR A CURE

Diagnosed with HIV in 2013, a multiracial American woman is showing signs of HIV remission! She is the first woman in the world to do so after receiving a [rare treatment for hepatitis C](#). She and [other women](#) are giving scientists clues that may someday lead to a widespread cure for HIV.

A RING FOR PREVENTION

With its first approval in Zimbabwe, a [monthly vaginal ring](#) has become the first approved biomedical HIV prevention method designed specifically for cisgender women! [Advocacy continues](#) to make it available for all who need it.



TRANSGENDER WOMEN



Two major research networks are launching their very first studies designed exclusively for transmasculine people! Learn more about the [1 Am study](#), and stay tuned for the "Get It Right" study. Both studies are looking at gender-affirming hormones and HIV.

HIV VACCINE RESEARCH

Thousands of women have participated in studies trying to discover an HIV vaccine. The search continues in the [Mosaico study](#), which is fully enrolled with about 3,800 people, including transgender women.



PREGNANCY & BREASTFEEDING

Pregnant and breastfeeding people are too often excluded from research, leaving them and their doctors unsure what to do when drugs are needed for treatment and prevention. Thankfully, [new guidance](#) has been issued to accelerate the inclusion of pregnant and breastfeeding people in HIV research.



JOURNAL of COMMUNITY ENGAGEMENT and SCHOLARSHIP

The Meaningful Involvement of People with HIV/AIDS (MIPA): The Participatory Praxis Approach to Community Engagement on HIV Surveillance

Authors: Andrew Spieldenner, Martin French, Venita Ray, Brian Minalga, Cristine Sardina, Robert Suttle, Marco Castro-Bojorquez, Octavia Lewis, Laurel Sprague

REPRESENTATION MATTERS

By Pedro Goicochea, MSC, MA and Tasia Baldwin, MSC, MA on behalf of the Latinx Caucus*

SOC ARXIV SocArXiv Papers

Lessons Learned from Community Engagement Regarding Phylodynamic Research with Molecular HIV Surveillance Data

AUTHORS

Diana M. Tordoff, Brian Minalga, Alfredo Trejo, Alic Shook, Roxanne P. Kerani, Joshua T. Herbeck

BE THE GENERATION

TO END THE AIDS EPIDEMIC

Thank you!



Conversation



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Background

- As a whole HIV clinical research is not representative of the HIV epidemic.
- Cisgender White men make up 6% of the global epidemic but 51% of participants in RCTs for new ARVs.*
- Underrepresented populations suffer the consequences of exclusion:
 - Cisgender women, transgender people, pregnant people, and PWID globally
 - Black, Indigenous, and Latinx people in the US and territories

*Pepperrell, T., Hill, A., Moorhouse, M., Clayden, P., McCann, K., Sokhela, S., Serenata, C., & Venter, W. (2020). Phase 3 trials of new antiretrovirals are not representative of the global HIV epidemic. *Journal of virus eradication*, 6(2), 70-73.

The RSR: 12-Item Questionnaire


1-7: Eligibility

1. Age
2. Cisgender women
3. Gender non-binary individuals
4. Persons who inject drugs
5. Transgender men
6. Transgender women
7. Pregnancy

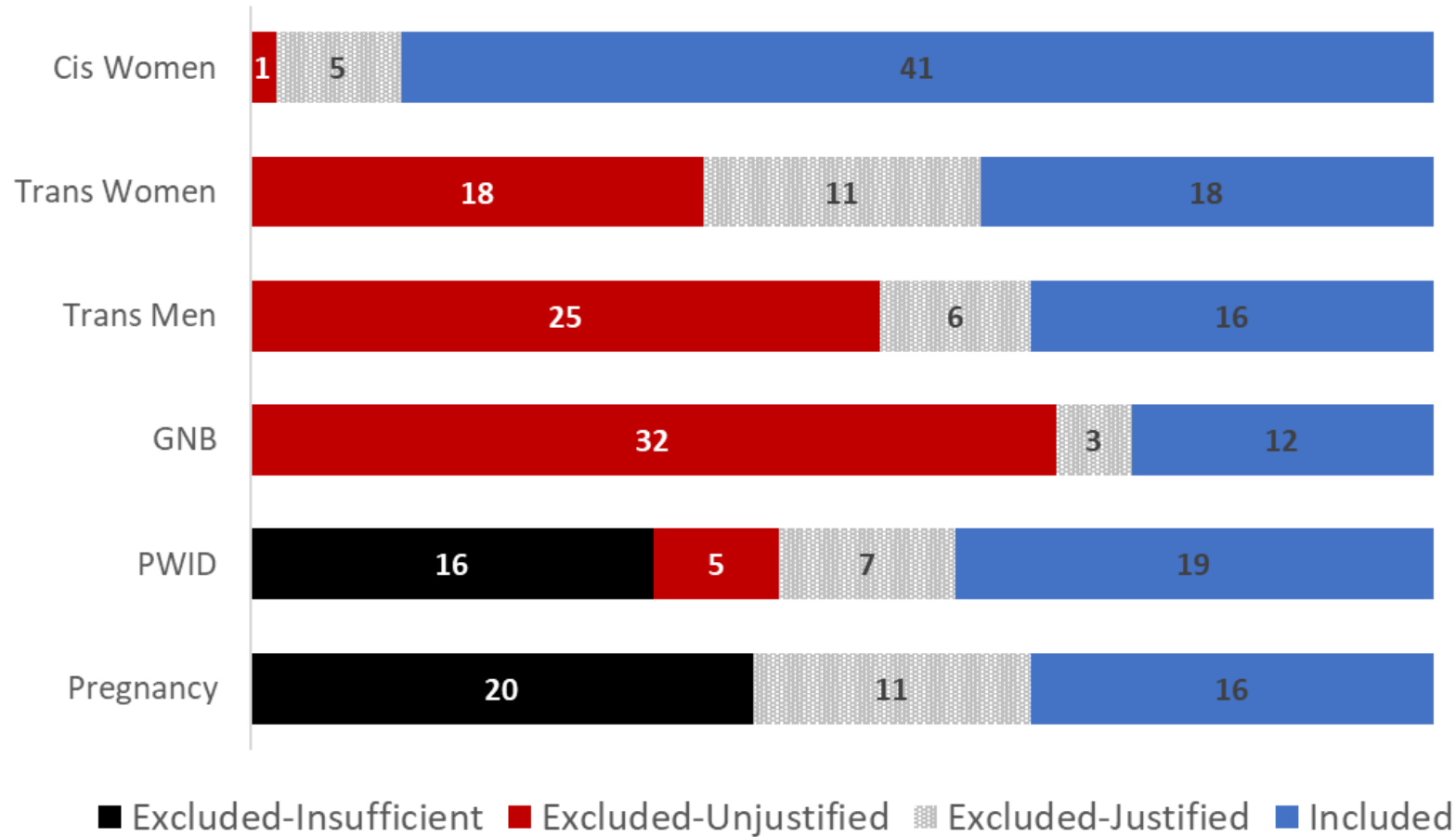
8-12: Processes to Support Representation

8. Enrollment Goals (incl. ethnicity & race)
9. Community Engagement
10. Statistical Analysis: Gender & Sex
11. Defining Gender & Sex
12. Language (stigma)

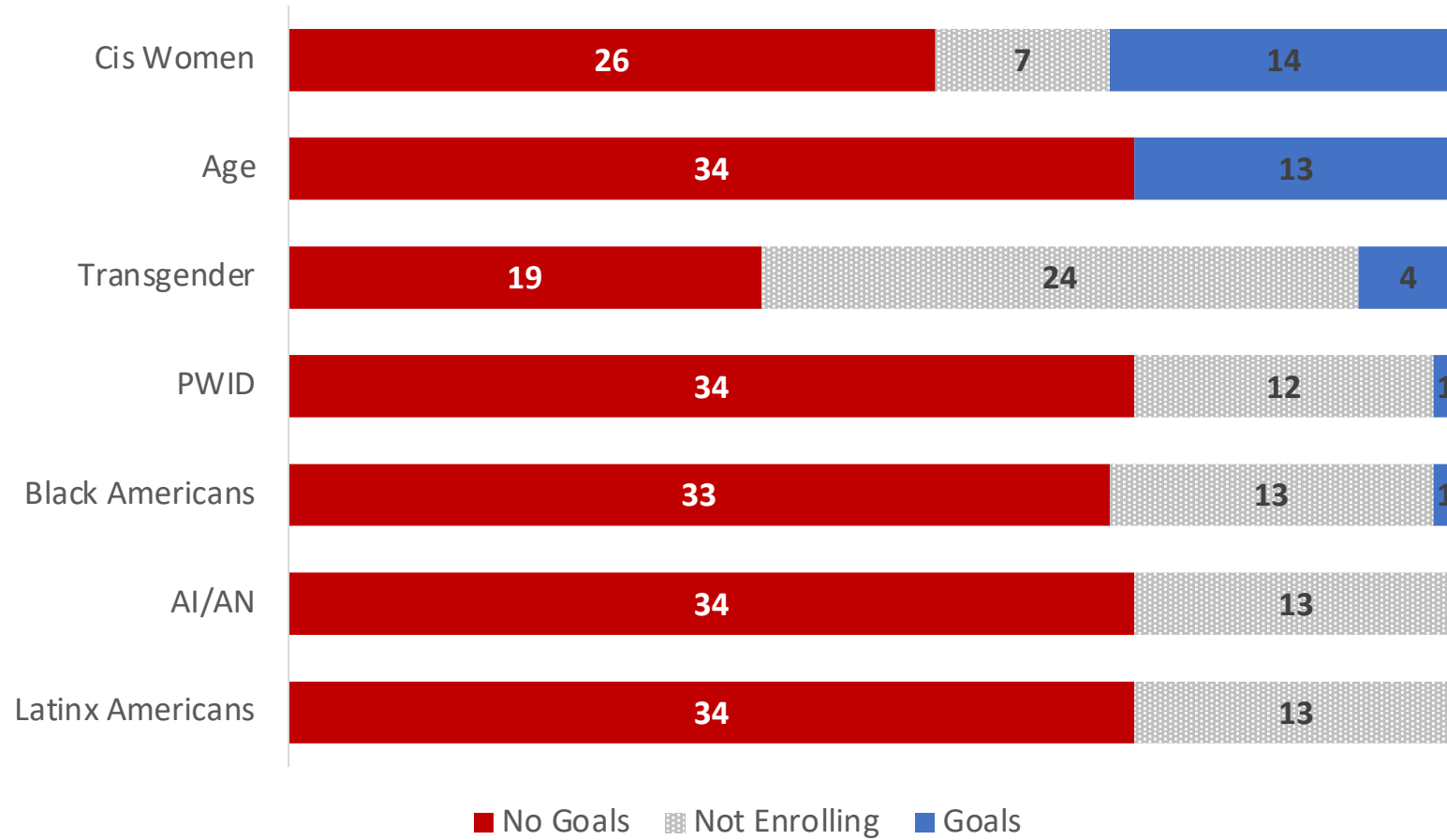
Protocol Analysis (47)

- AIDS Clinical Trials Group (21)
 - International, Maternal, Pediatric, Adolescent AIDS Clinical Trials Network (10)
 - HIV Prevention Trials Network (5)
 - HIV Vaccine Trials Network (5)
 - HPTN/HVTN (3)
 - Microbicide Trials Network (2)
 - COVID-19 Prevention Network (1)
- 
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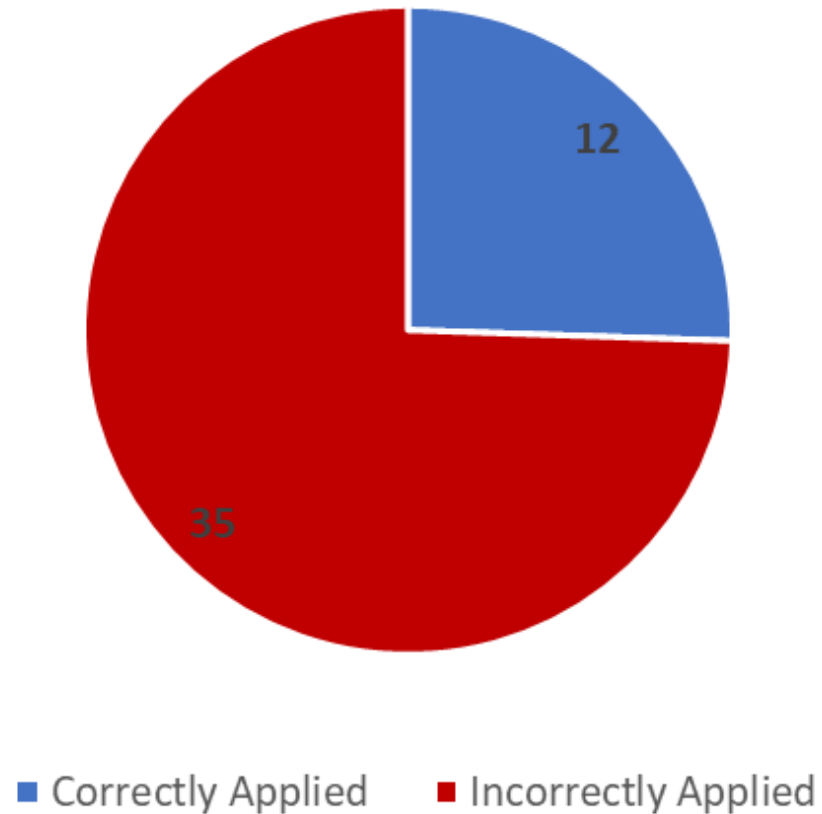
Inclusion/Exclusion of Underrepresented Populations



Specific and Measurable Enrollment Goals



Application of CNTWG Guidance: Defining Study Populations by Gender Identity and Sex Assigned at Birth



NIAID HIV Language Guide

- All 47 protocols included at least one instance of stigmatizing language

HIV-infected / HIV-uninfected

Infection / infect

Risk / low-risk / high-risk / at-risk (referring to participants)

Subjects (referring to participants)

Target (referring to participants)

Conclusions & Next Steps

- Institutionalized barriers are ongoing and may perpetuate the underrepresentation of certain populations
 - Proactive implementation of the RSR for all future protocols
 - RSR Working Group
 - RSR pilots
 - Revise protocol templates
 - Publish findings and promote the RSR for use in all clinical trials
- 