



# ***Session 7: Science in Action:*** **Women, HIV Research, and Clinical Trials**

*May 7, 2025, 9am PT / 12pm ET*

*Together, we can change the course of the HIV epidemic...one woman at a time.*

#onewomanatatime

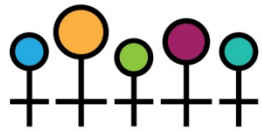
[www.thewellproject.org](http://www.thewellproject.org)

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# About The Well Project

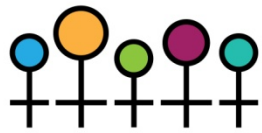
- Non-profit organization with a mission to change the course of the HIV/AIDS pandemic through a unique and comprehensive focus on women and girls across the gender spectrum
- Leverages technology to improve health outcomes and increase quality of life for women and girls living with HIV
- Our focus: education and information, community support, advocacy and leadership, collaborative engagement, and women-focused HIV research
- Access our resources and join our community at [www.thewellproject.org](http://www.thewellproject.org)



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# About *WATCH! 2.0*

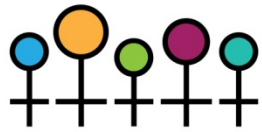
- Treatment advocacy webinar series, based on our successful 2015 series *A Place at the Table: WATCH!*
- 7 monthly sessions; 1 hour each
- Capacity building and training for women living with HIV and with reasons for HIV prevention across the gender spectrum
- Series topics will include advocacy basics, treatment and prevention, sexual and reproductive health, aging, research
- Participation in live sessions encouraged; recordings of sessions will be available to those unable to attend
- Certificates of completion will be issued to participants upon finishing the series and required evaluations/post-tests based on content of each episode
- *This episode is supported by a grant from Merck*



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# A Note on Gender and Language

- We are proud to be a resource that welcomes and focuses on women across the gender spectrum – that means all women who identify as such – as well as all people who can benefit from our materials and support networks
- We not only acknowledge and affirm but celebrate the existence of our community members of trans and nonbinary experience
- The language we use on our website and in our programs reflects this affirmation; our commitment is to grow ***stronger*** in this practice and ***more inclusive*** in our language



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# Agenda

- Welcome
- Women, Clinical Trials, and HIV
- Barriers and Successes in Participation
- HIV Research and the Current Administration
- Q&A
- Closing

# Today's Presenters



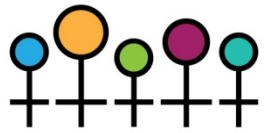
**Danielle Campbell, MPH**  
Charles R. Drew University  
of Medicine and Science;  
iSTRIVE Lab, UCSD



**Olivia G. Ford**  
***Moderator***  
The Well Project

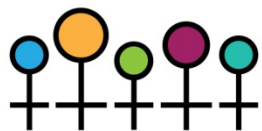


**Connie L. Johnson, MA**  
Growing Into Greatness



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# Poll Question



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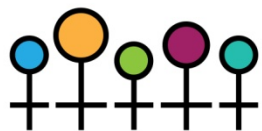
# Clinical Trials and Women Living with HIV

- In the US, more than 1 in 5 people living with HIV (22%) are women
- Almost 3 in 4 US women diagnosed with HIV in 2022 were Black and/or Latina
- Globally, women make up just over half of all people living with HIV
- But in many HIV studies ...

***Less than 1 in 5 people being studied is a woman***







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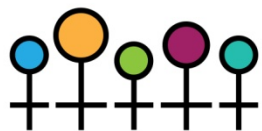
# Clinical Trials and Women Living with HIV

- Most information on effectiveness and safety of HIV drugs is based on research done in men
- Some HIV drugs may act differently in women's bodies; studies need to be designed to answer questions for women:
  - Correct drug doses for women
  - How gynecologic problems affect women living with HIV
  - What side effects are more likely to affect women
  - How do drugs fit into women's lifestyles?
  - Whether HIV increases risk of certain cancers
  - Does a diet and exercise program work in women with HIV?
- Only way to get this information is for ***more women living with HIV to participate in clinical trials***

# What Are Clinical Trials?

*Clinical trial:* Describes many different types of **research studies on people (“human subjects”)**





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# Five Main Types of Clinical Trials

## **Treatment trials** study ...

- New drugs, combinations of existing drugs, or types of therapies

## **Prevention trials** look for ...

- Better ways to prevent disease, with drugs or behavior changes

## **Diagnostic trials** test ...

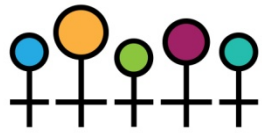
- Best way to find disease or changes within the body

## **Natural History trials** study ...

- Natural course of disease in the human body

## **Quality of Life trials** study ...

- Ways to improve aspects of life for people living with illnesses

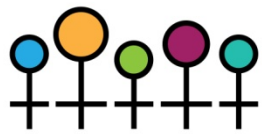


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# Clinical Trials to Find an HIV Cure

## **HIV cure (HIV remission) trials** study ...

- Ways to control HIV over a long period without HIV drugs
- Remission: a person no longer shows signs or symptoms of a disease



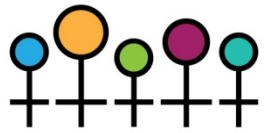
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# Basic Components of Clinical Trials

- **Investigators:** the scientists and/or healthcare providers managing clinical trials
- **Participants** (may also be called **volunteers** or **study subjects**): people who join clinical trials
- ***ALL clinical trials are voluntary***
  - You never have to participate in a clinical trial unless you want to
  - This is a human right protected by international laws
- Each clinical trial has a **study protocol**, which describes:
  - Goals of the study
  - How long the study will last
  - Who is allowed to participate (**inclusion and exclusion criteria**)
  - What tests and procedures are required of each participant

# Informed Consent

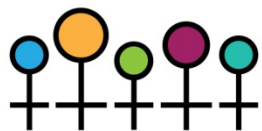
- Participants must sign an “informed consent” form
- Consider taking the form with you and talk about it with your healthcare provider, family, friends
- Ask if translation is available if your native language is not the one spoken by the people describing the study
- Important that you truly understand the study and what you will be asked to do
- Ask study staff any questions
  - Their job is to make sure that you understand what you are agreeing to do when you sign this document



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# Compensation

- You may be paid for travel expenses to and from the study site and for your time
- Child care may also be provided
- You can ***choose to leave (drop out of) a study*** at any time, for any reason

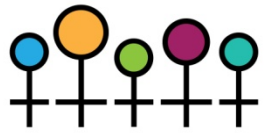


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# Stages of Treatment Trials

- ***Phase I: Is the drug safe?***
  - Small number of participants (usually <100) to find a safe dose
  - Usually short (a few days to a few weeks)
- ***Phase II: Is the drug effective?***
  - Larger number of participants (usually 100-300) to see if it works
  - Usually lasts 6 months - 1 year
- ***Phase III: Is the drug safe and effective in larger groups of people for longer periods of time?***
  - Generally lasts 2-3 years
- ***Phase IV or Post-Marketing studies: What are the long-term results of using the drug?***
  - Done after drug has been approved for sale
  - Gets more information about drug's best use, long-term side effects

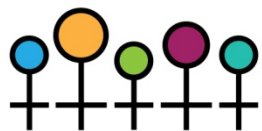




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# Clinical Trials and People Living with HIV

- **Important for people – and especially women – living with HIV to be involved early in research**
  - Results more useful when people affected by what is being studied are included in designing the study
  - Reveals important information for researchers to know before study begins signing up participants
- **2020 study on HIV cure trial participation**
  - Men and women consider different factors when deciding to participate in a clinical trial



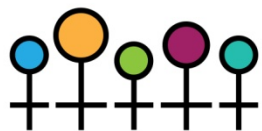
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# Women of Trans Experience in Research

Women of trans experience (trans women) are profoundly affected by HIV, yet marginalized in HIV research and data

Slow improvements (until recently) upon long record of ...

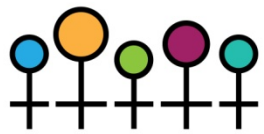
- **Miscategorizing:**
  - Trans women as MSM (i.e., not asked about gender identity)
  - Trans women as subset of cisgender MSM (i.e., study title about MSM, also enrolls trans women)
  - Heterosexual cisgender male partners of trans women as MSM



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# Women of Trans Experience in Research

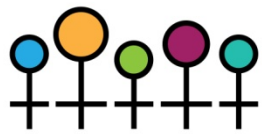
- **Inadequate inclusion:**
  - Including trans women in a study and failing to describe them in results
  - Including trans women and failing to include questions specific to their experiences
- **Consequences of miscategorization:**
  - erases important identities
  - can advance assumptions about sex, gender, and behavior
  - may result in misallocating desperately needed funds away from trans women
- Lack of research specifically focused on **areas of need** for trans women



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# What Has Kept Women Out of Studies?

- For many years, The Well Project founder Dawn Averitt, and other community advocates have ***called for trials to include more women and people of color***
- Historically, women were kept out of many types of clinical trials (not just HIV studies)
  - Concern that women might become pregnant while on a trial of an experimental drug that could harm a baby
  - In 1993, US regulations were changed and women were encouraged to participate in clinical trials, but progress has been very slow



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# What Has Kept Women Out of Studies?

- Distrust of medical establishment/clinical researchers in Black, Latine, indigenous, and other communities of color
  - Past unethical trials, history of mistreatment and exploitation in US research and scientific advancement
    - Henrietta Lacks; J. Marion Sims; Tuskegee + Guatemala STI studies
  - US government has established strong guidelines to protect participants
- Lack of information about the studies, including safety
- Stigma
- Lack of support — child care, transportation, other support

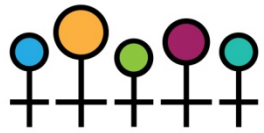
# The GRACE Study

An HIV clinical trial needed to be designed to ***overcome barriers*** for women and people of color

- Providers, advocates worked with Tibotec (now Janssen)
- Result was the GRACE (**G**ender, **R**ace, **A**nd **C**linical **E**xperience) study
  - Began in 2006
  - Designed to identify differences in Prezista's effectiveness, safety, side effects between men and women over 48 weeks
  - Largest US treatment trial to focus on women living with HIV
  - First to focus on women who had experience taking HIV drugs
  - Specifically designed to enroll women and people of color

# Successful Recruitment

- GRACE was ***successful in overcoming barriers to having women participate***
  - Reached goals for recruiting participants on schedule
  - Enrolled 67% women, 84% people of color
  - Showed it was possible to recruit large numbers of women, Black and Latine people into clinical trials
- Some of the new strategies were:
  - Selecting study sites (clinics, medical centers) that were accessible to women and people of color
  - Raising awareness among people they hoped to enroll
  - Providing support for participants and study sites

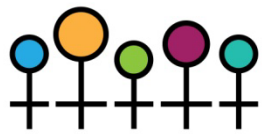


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# The Bottom Line

- It is important for more women to get involved in HIV clinical trials – and for more trials to be designed with women, people of color in mind
- There are many women's health issues that still need to be studied in women living with HIV
- You can help by ***getting involved and participating and helping others understand clinical trial participation***

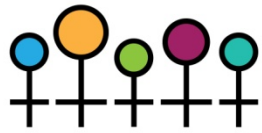




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# What Has the US Administration Done?

- Executive Order removing recognition of gender identity; defining sex as “immutable binary biological classification”
- Executive Order removing DEI offices and content
- Rescinding Biden administration orders related to gender, LGBTQ+ civil rights/equity, and DEI
- Executive Order Establishing “Make America Healthy Again Commission”
- Executive Order Implementing President’s “Department of Government Efficiency Workforce Optimization Initiative” & HHS Reorganization
- Cancellation of increasing number of NIH grants
  - \*Delays/layoffs in HIV/AIDS Clinical Trials Networks (ACTG, HPTN HVTN, IMPAACT)
  - Adolescent Trials Network terminated in March 2025
- Removal of public health information and data
- US global health: foreign aid review; stop work order; dissolution of USAID, including personnel; cancellation of most awards



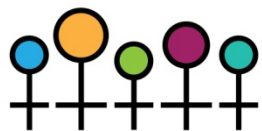
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# The Representative Studies Rubric (RSR)

- Developed by a working group led by HIV/AIDS Network Coordination (HANC), representing HIV research institutions/networks
- Evaluates whether clinical trials are designed to enroll representative study populations – particular focus on age, ethnicity, drug use, gender, pregnancy, race, sex assigned at birth
  - Operationalizes legal requirements, ethical and other guidance for researchers to reflect real-world diversity in clinical trials
- 2023: DAIDS requires study teams to submit RSR questionnaires
- 2024: All Networks consistently using RSR in development of all new study protocols
- 2025: DAIDS halts this requirement following EOs

# What Can We Do?

- Convene with women's health advocates around the globe
  - What should we be doing to continue legacy of women's work in research?
- Continue to use language that gives credence to people's existence
  - Publish in journals that support that effort!
- Call out institutions buckling under perceived threat ("obeying in advance")
- ***What do you think we need to do?***



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# Learn More!

*Scan the QR code for **more resources** on this topic from The Well Project, and to access the **video and survey** following this session!*



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