



# Stakeholder Engagement in HIV Cure Research

HIV Cure Research Training Curriculum

Stakeholder Engagement Module presented by:

**Jessica Salzwedel, AVAC**

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The HIV CURE research training curriculum is a collaborative project aimed at making HIV cure research science accessible to the community and the HIV research field.

# Session Objectives

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Describe:

- Lessons learned from HIV prevention research
- What is stakeholder engagement
- Why engagement is important for HIV cure research



# How Can We Define Stakeholders?



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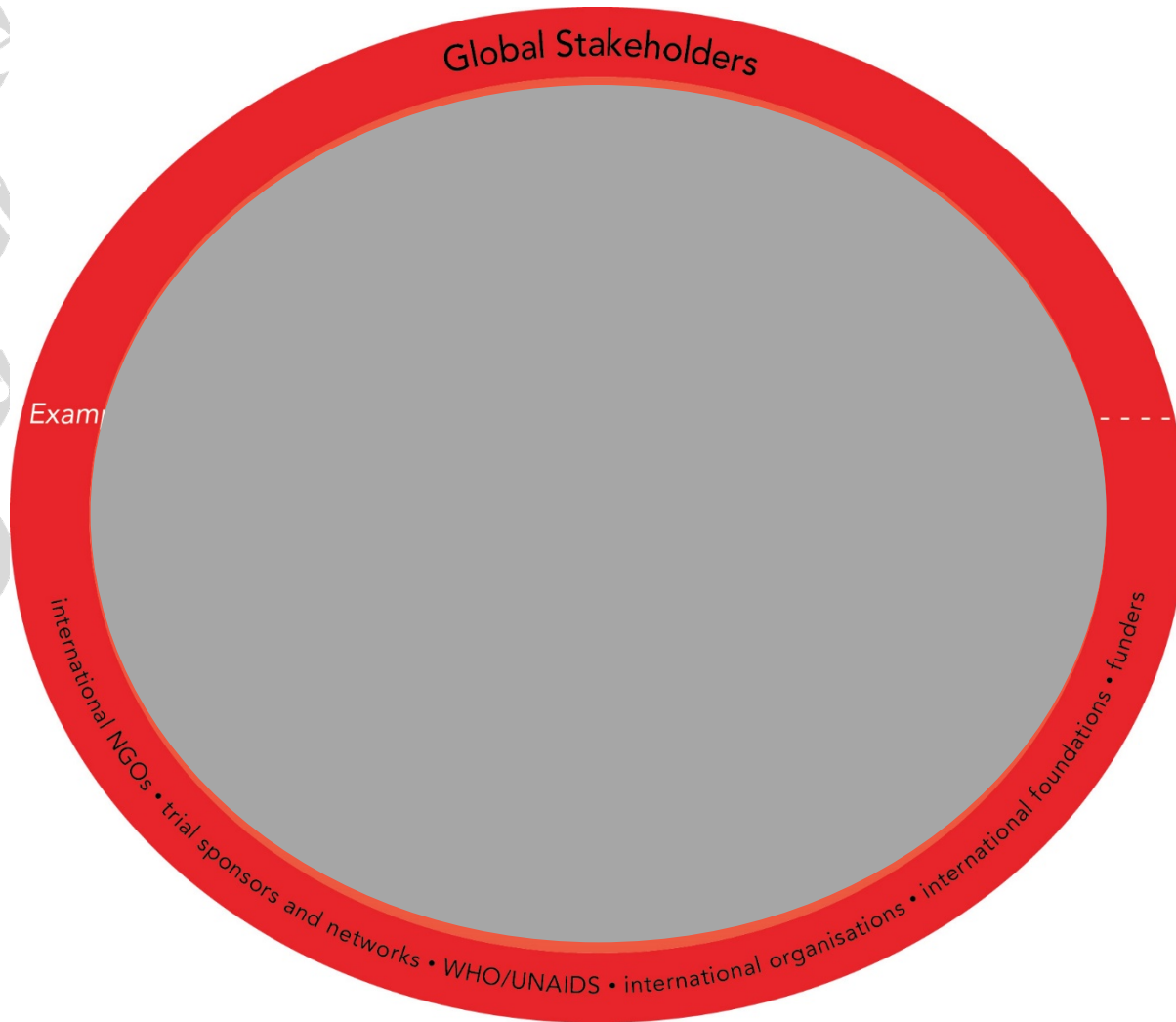


- Global Stakeholders
- National Stakeholders
- Broader stakeholders
- Community Stakeholders
- Trial Participants/Potential Participants



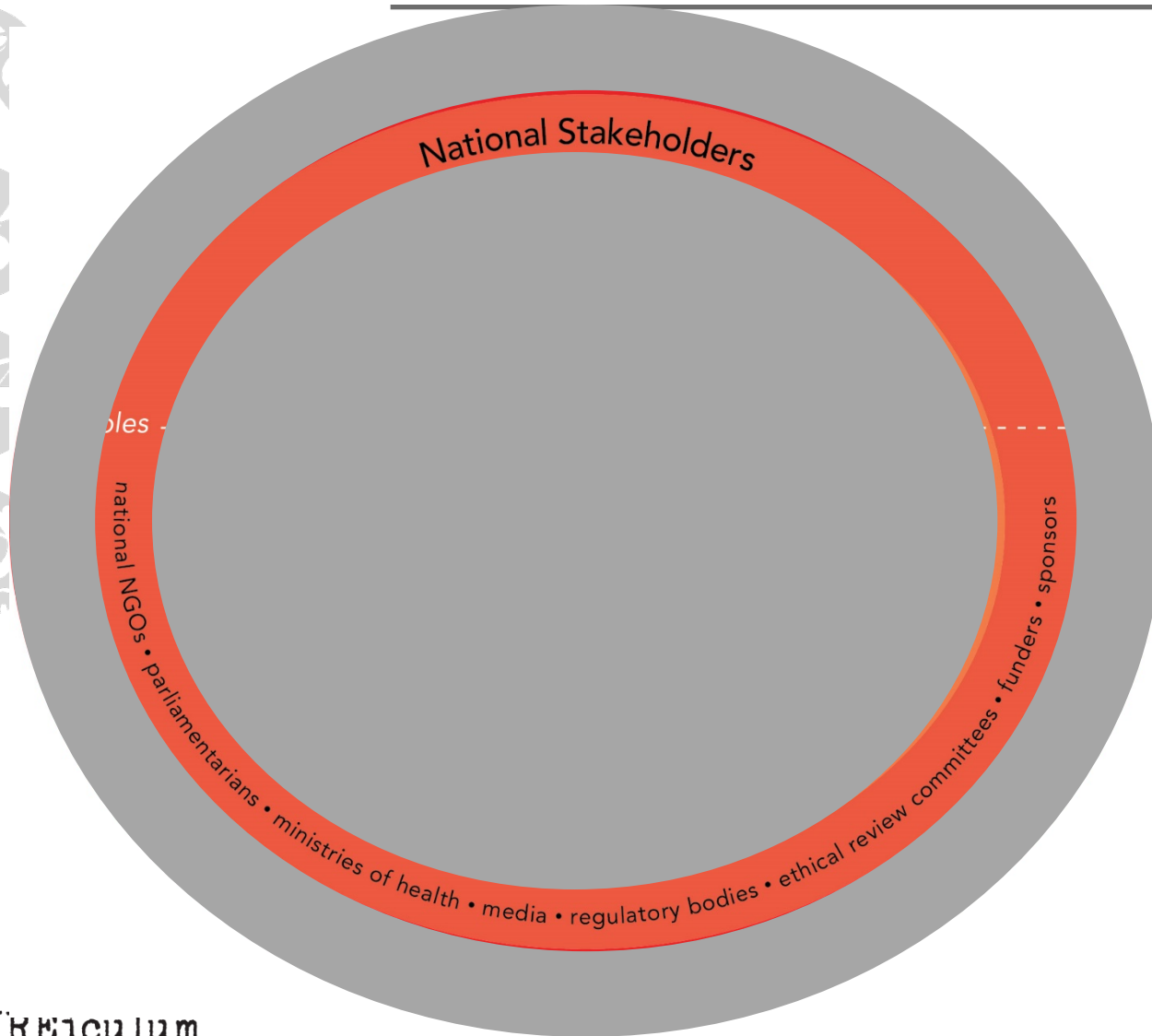
# Global Stakeholders

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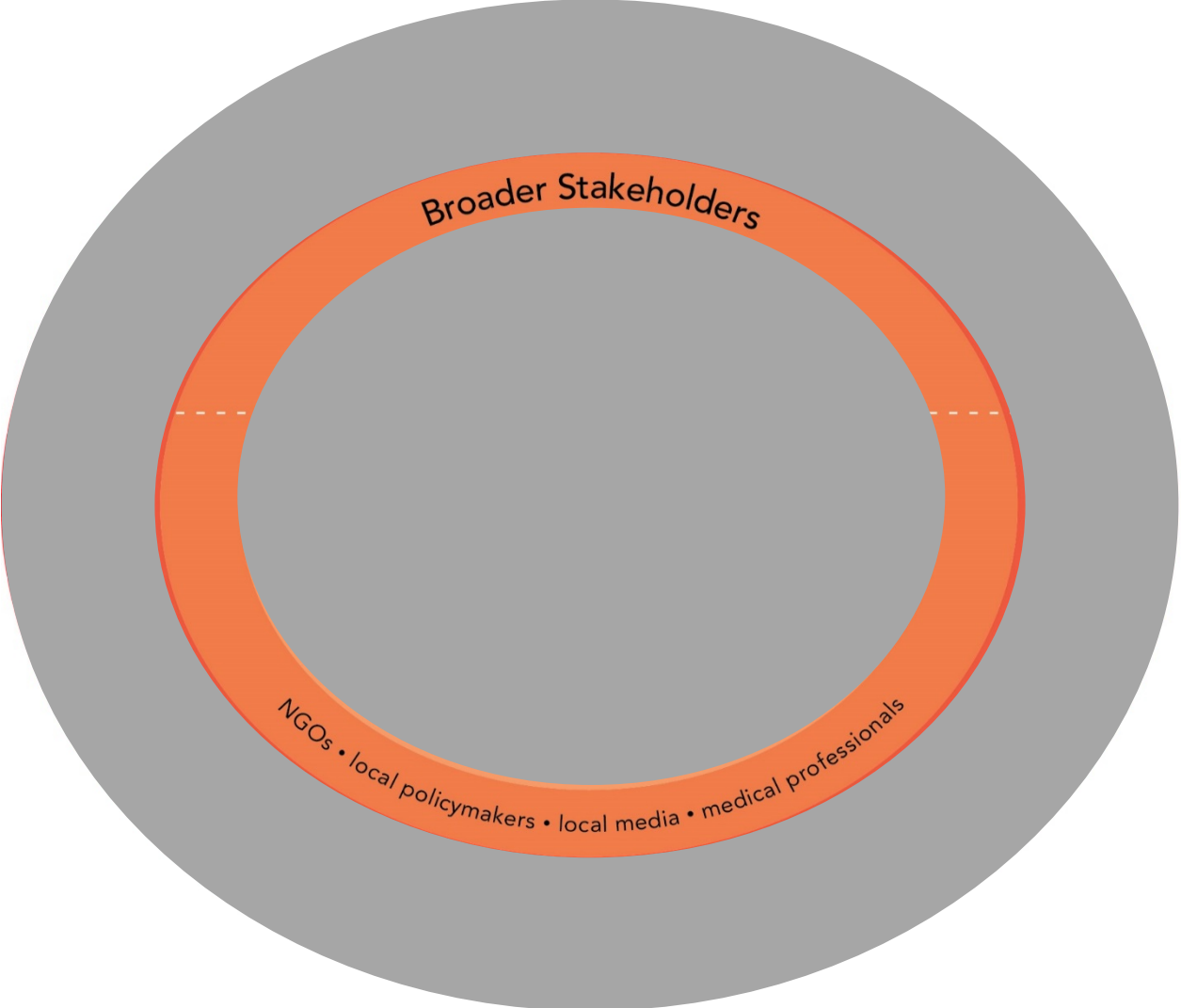
International  
NGOs, Trial  
sponsors,  
WHO/UNAIDS,  
International  
Foundations,  
Fundors

# National Stakeholders



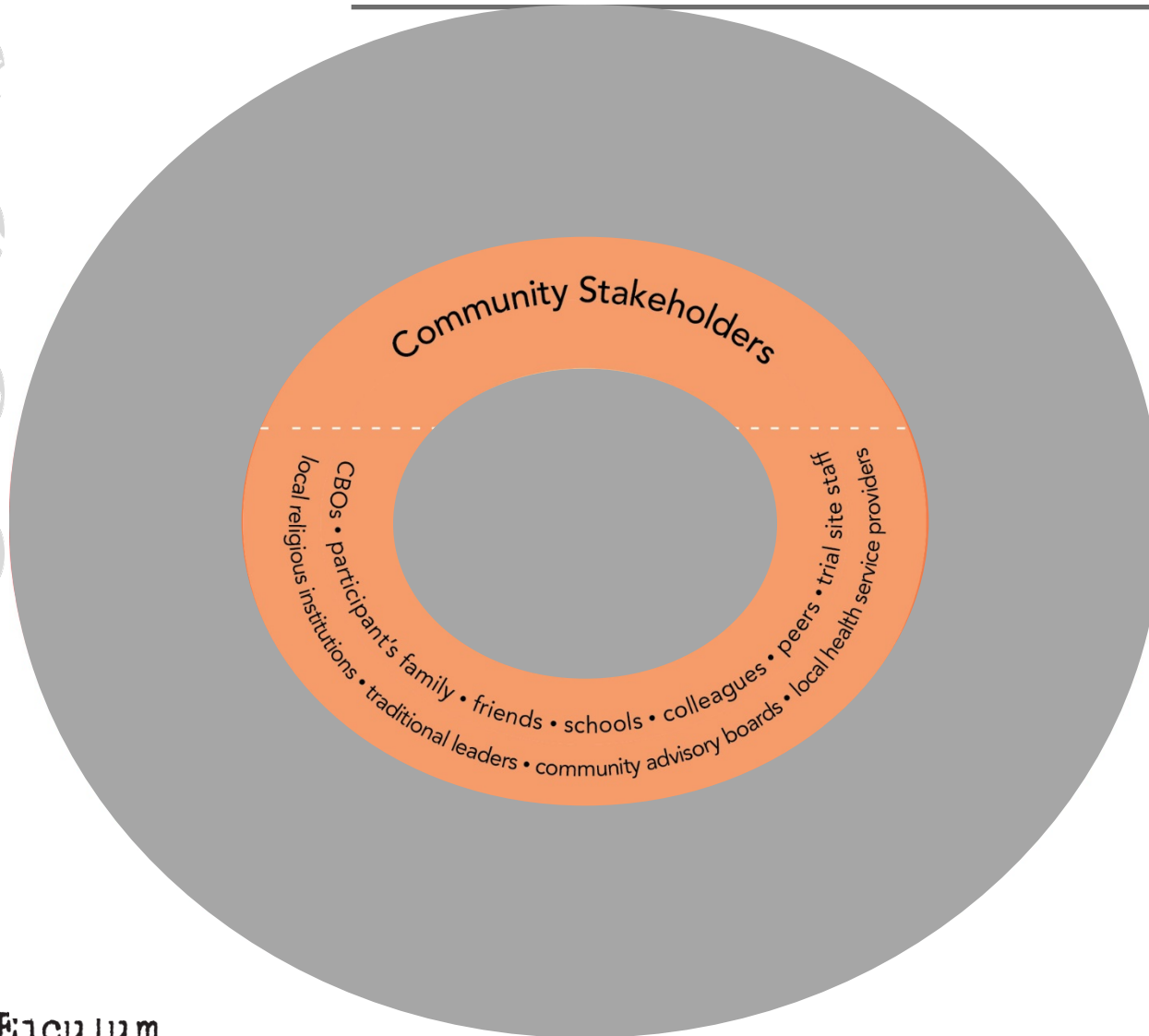
National  
NGOs,  
Ministries of  
Health,  
Regulatory  
Bodies, Ethical  
Review  
Committees

# Broader Stakeholders



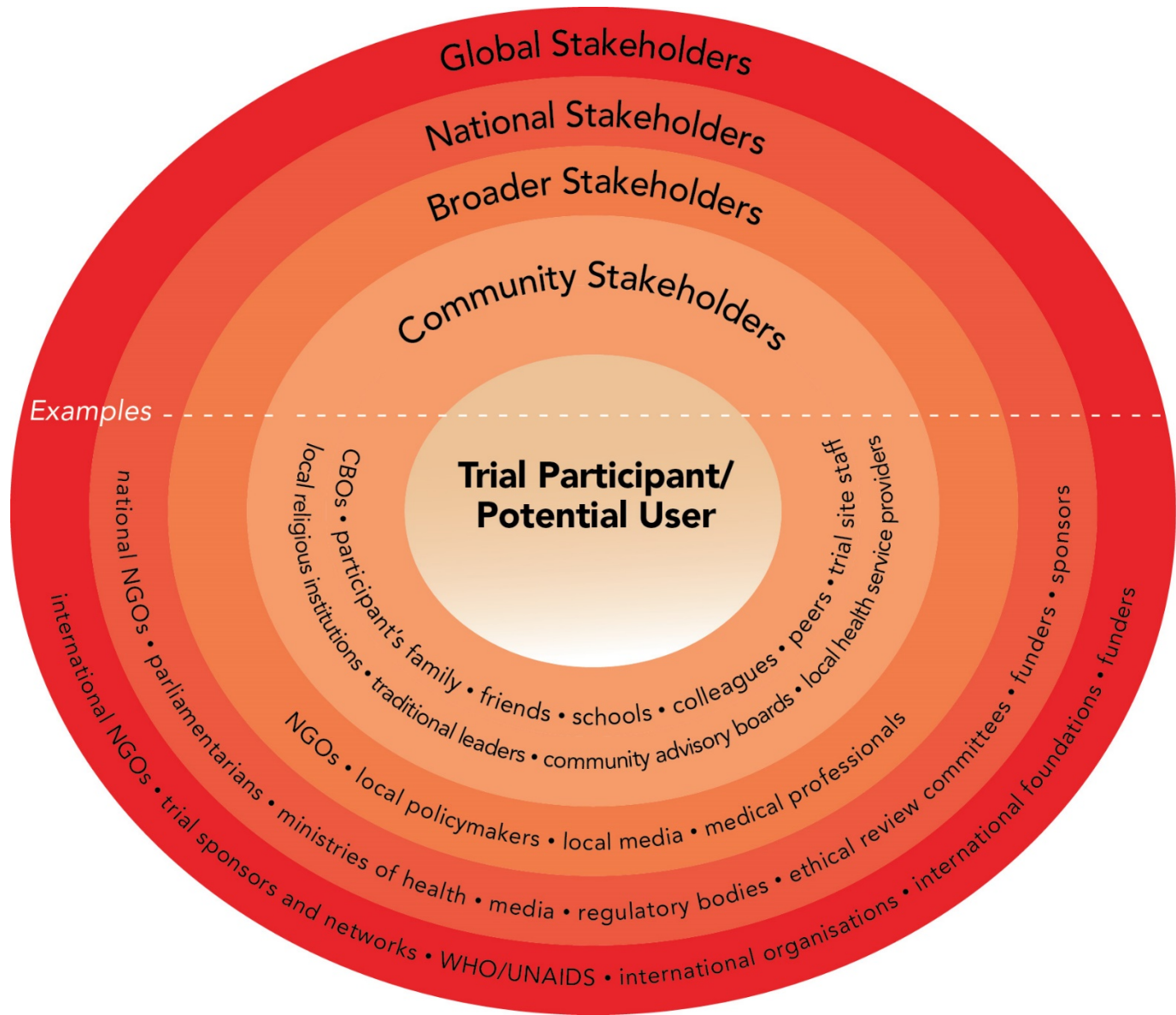
NGOs, Local  
Policymakers,  
Local Media,  
Medical  
Professionals

# Community Stakeholders



CBOs,  
participant  
family, friends,  
schools, peers,  
trial site staff,  
local health  
service  
providers,  
community  
advisory boards,  
traditional  
leaders







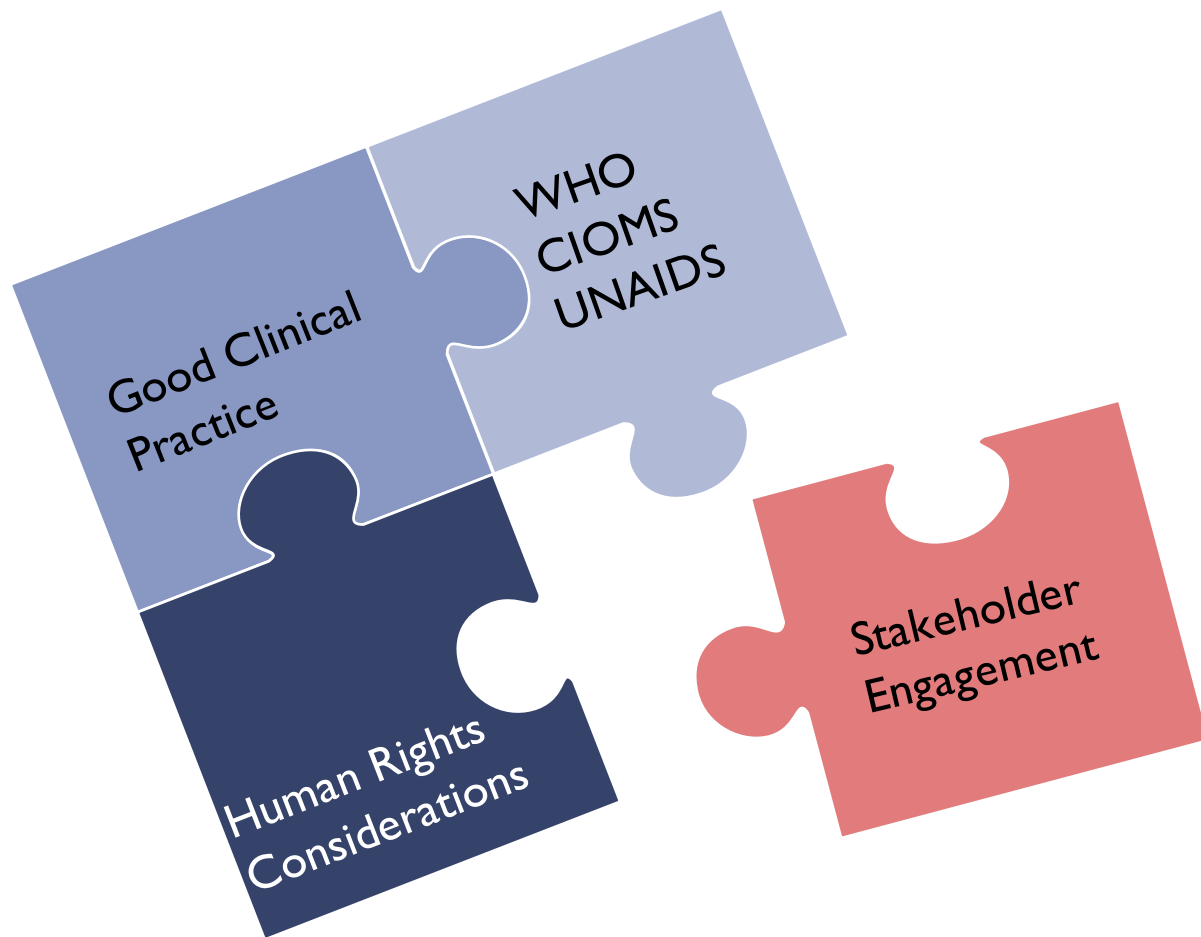
# How Can We Define Community?



# How Can We Define Community?

- “A group of people with diverse characteristics who are linked by social ties, share common perspectives, and engage in joint action in geographical locations or settings.” (MacQueen, 2001)
- “who is included and who is excluded from membership” (Institute of Medicine, 1995)

# Where Does Engagement Fit?



# GCP is NOT GPP



**Research Investigator**



**Research teams  
(and trial sponsors and funders)**



**GCP**



**Trial Participants**



**GPP**



**Stakeholders**

# Why Do We Engage Beyond the Participant?

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- PrEP Research trial controversy
- 2004- Cambodia trials were not initiated
- 2005- Cameroon and Nigeria trials discontinued





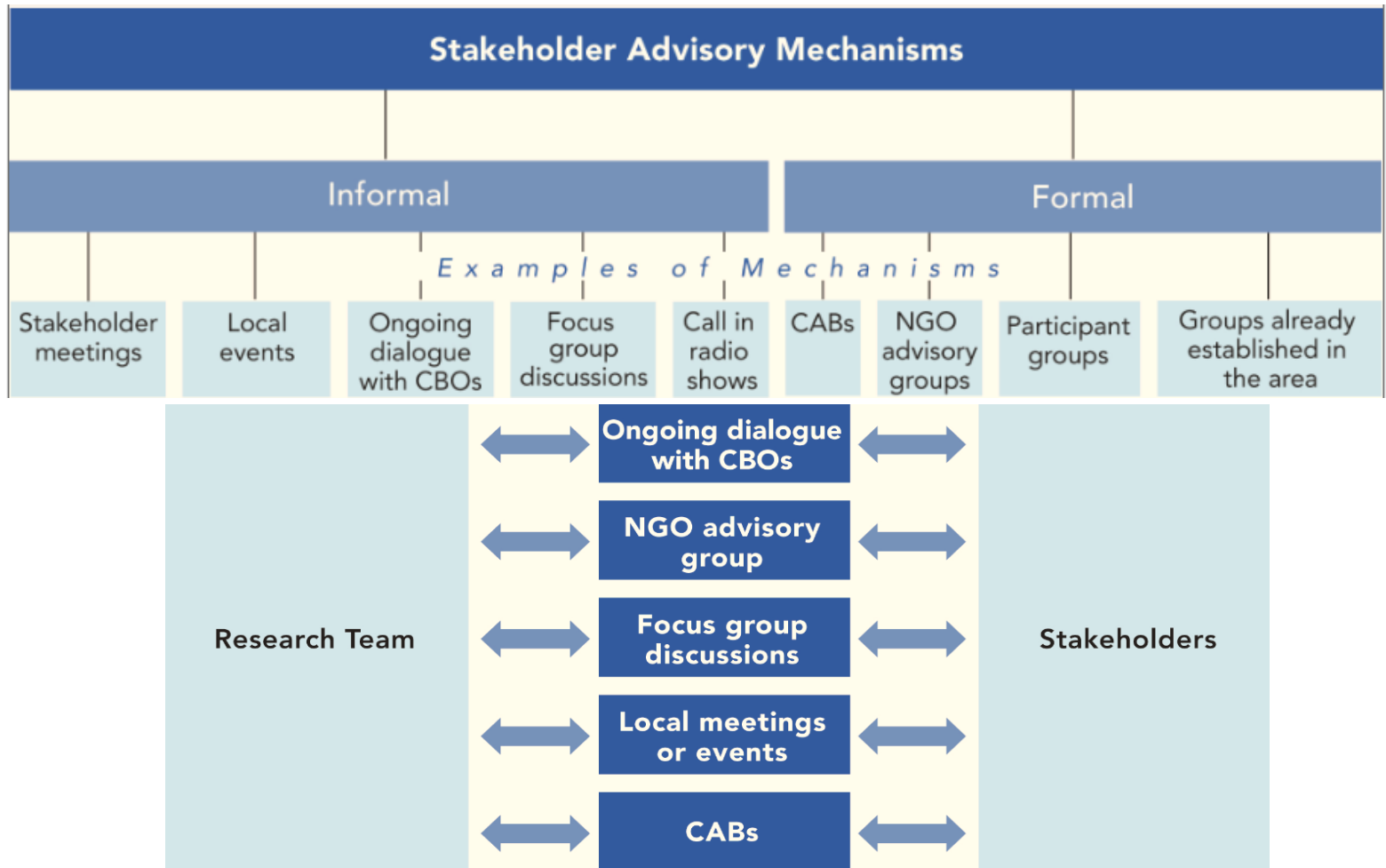
# What Principles Make **Good Engagement?**

# Guiding Principles of Engagement





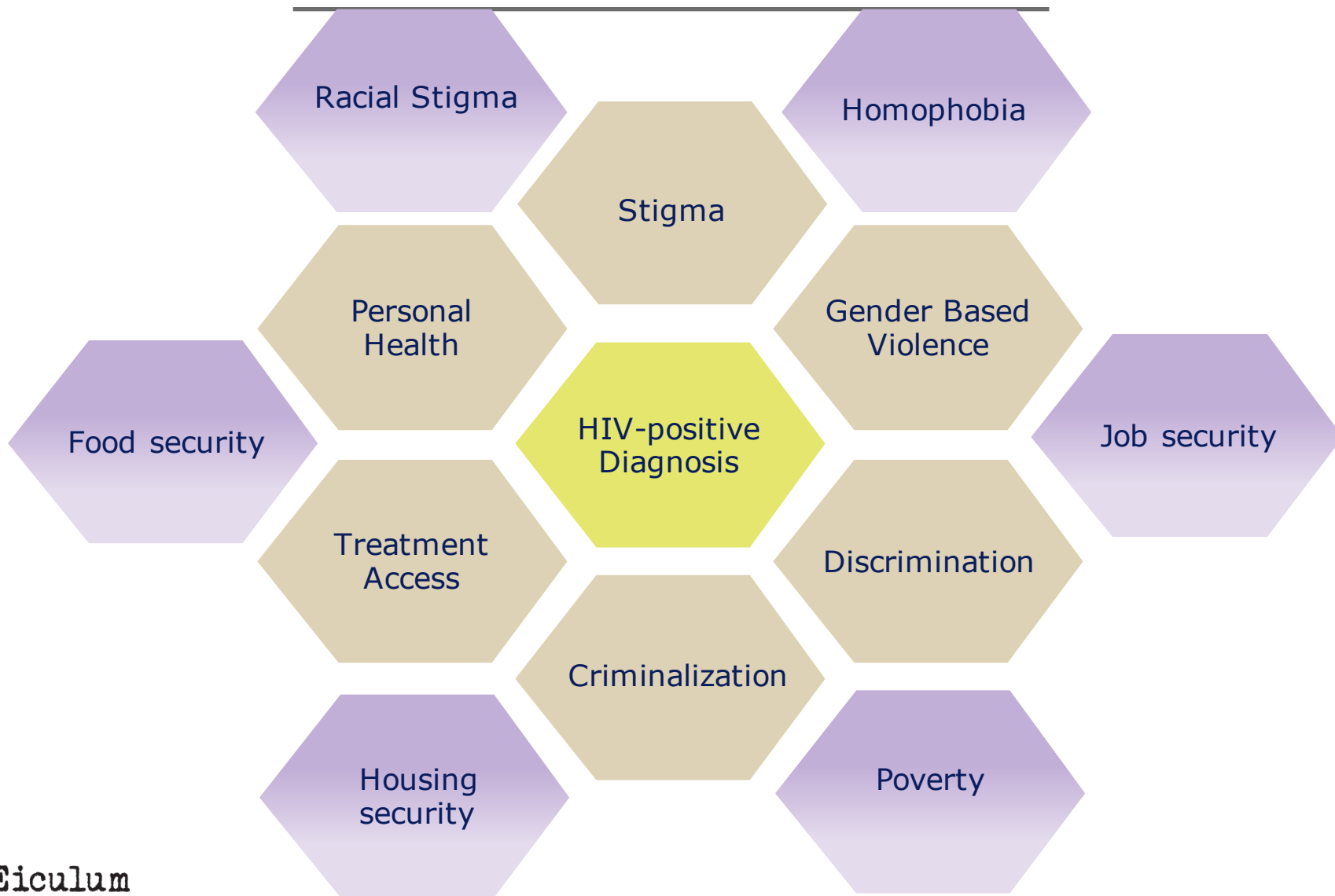
# How Do We Engage?





# Why is Engagement Important?

# Landscape of Engagement





# Research in the Age of Fast Media

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- Headlines aren't always accurate



- Potential to spread rumors



- Potential to erode trust



*“Cure for HIV possible **within three years** as scientists snip virus from cells”  
-Telegraph, 2016*

# Research in the Age of Fast Media- Lesson from Prevention

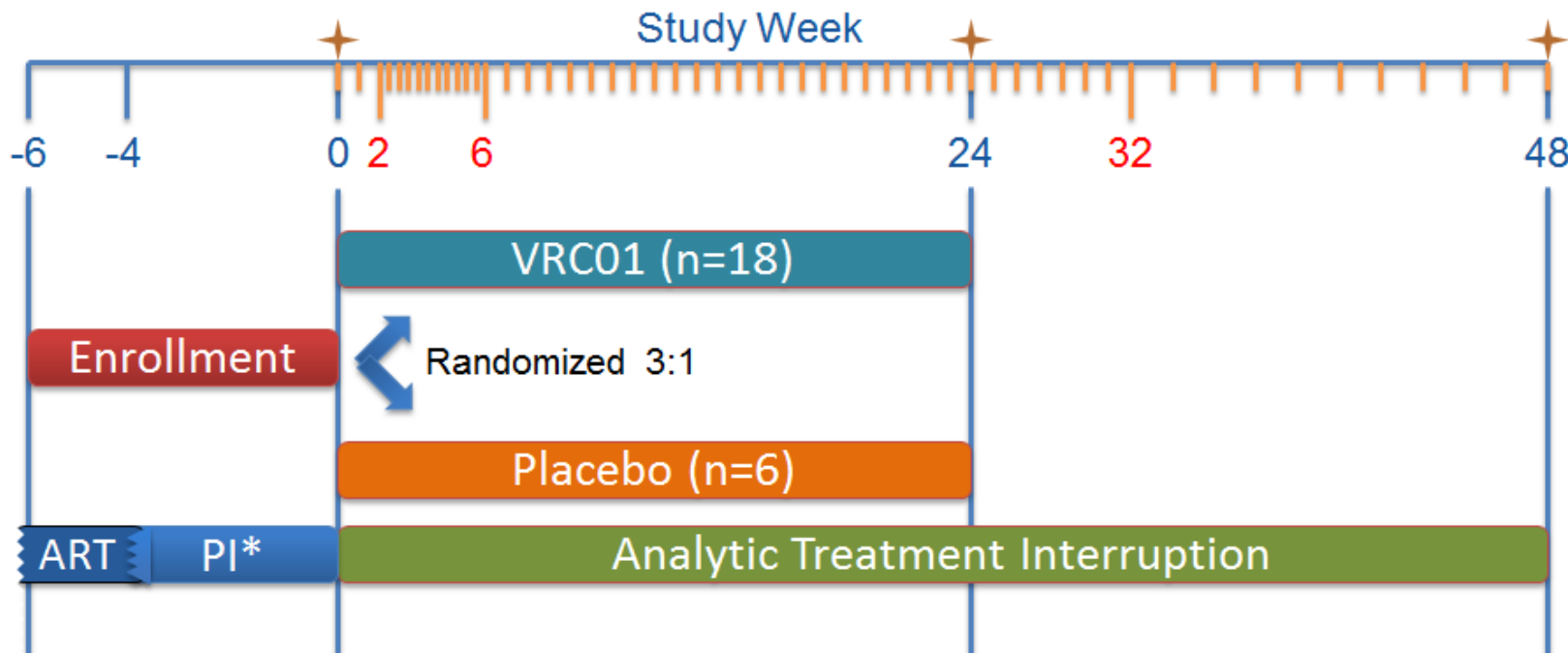


- In December 2009 MDP 301 announced flat trial results
- A Zambian blogger based in the UK published false information about the trial that was picked up by local Zambian media
- Years after this incidence researchers had challenges securing approval for microbicide research



# HIV Cure Research Has **New Language**

# Sample Protocol



Volunteers from Health Center

- > 20-50 years old
- > Started on ART during AHI (FI-FIII)
- > Prescribed ART for  $\geq 24$  mo
- > HIV-1 RNA < 50 copies/mL
- > CD4 > 400 cells/mm<sup>3</sup>

\*4-week PI substitution for subjects prescribed NNRTI

Primary Endpoint:

- > Virologic control (RNA < 50 copies/mL)

Secondary Endpoints:

- > HIV Reservoirs
- > Inflammatory markers
- > CD4 count

- ★ Optional:
- LP
  - Gut biopsy
  - Lymph node biopsy

= HIV RNA Assessment  
Any positive HIV RNA prompts repeat quantitative testing every 3 days until negative or ART resumed



# Engagement in **HIV Cure Research**





# Formative Research Activities

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Allows the research team to:

- gain informed understanding of local populations
- socio cultural norms
- local power dynamics
- local perceptions
- channels of communication
- site selection



## SearchHIV

- Conducting research in Cape Town, Guangzhou and Chapel Hill
- Develop a theoretical framework about HIV cure research and early implementation
- Determine HIV cure stakeholder perspectives on cure research

## APSEC

- Assessing motivations and barriers that influence willingness to participate in HIV cure clinical trials
- Explore factors associated with perceived tolerance and acceptability of various HIV cure clinical trial designs



# Stakeholder Engagement Plan

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- Communication component
  - Policies and strategies to increase broad awareness of the trial and facilitate accurate dissemination of research
- Education component
  - Key to building research literacy and empowering community stakeholders as decision-making agents



# Informed Consent Process

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- Comprehension should be assessed throughout the research process



- Forms, materials and techniques to assess understanding should be locally appropriate



- Strategies to pilot tools of consent



- Partner consent process

Participant first hears about the research

Participant first sees informed consent documents

Participant signs documents. Enrolls in trial



Participant talks to physician about study

Participant talks to partner, friends, family

Participant receives 1<sup>st</sup> comprehension exam

# Access to HIV Care

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- HIV care includes all psychosocial, psychological and clinical components of HIV care
  - Alternative regimens
  - Counseling –e.g. partner disclosure
- HIV care and treatment guidelines vary by country and should be considered
  - long term logistics planning should be considered
  - Access guidelines should be updated with national guidelines



# Policies on Trial Related Harm

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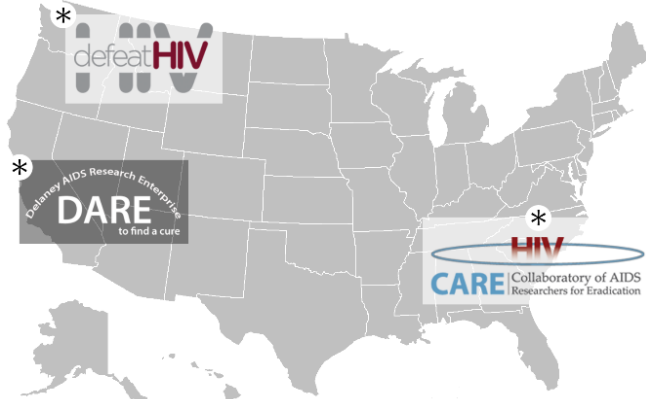
How research teams will treat and compensate trial participants

- **Physical harms-** include any negative physical event
- **Social harms-** non medical consequences such as
  - Social isolation
  - Stigma or discrimination
  - Employment or housing loss
  - Difficulties in personal relationships



# Why is Stakeholder **Engagement Important?**

# Research is Happening







# Engagement in HIV Cure Research

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- **Education and transparency** are key goals that stakeholder advisory mechanisms must strive to incorporate
- Critical that all stakeholders, **including health care providers**, understand how early phase cure related research can benefit future populations
- **Developing comprehensive engagement plans** that reflect sociocultural norms and stakeholder needs are crucial to advancing research aims

# Questions

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A large, semi-transparent grey virus icon with a circular center and several protruding spikes of varying lengths, each ending in a small rounded tip. It is positioned on the left side of the slide, partially overlapping the text.

**For additional information  
visit: [www.avac.org/CUREiculum](http://www.avac.org/CUREiculum)**

# Acknowledgements

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University of California  
San Francisco

