MHRP

Good Participatory Practices for vaccine clinical trials

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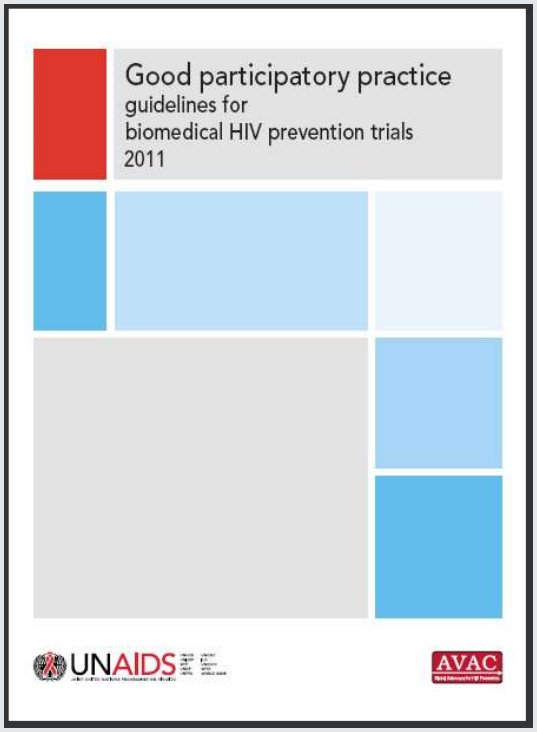
U.S. MILITARY HIV RESEARCH PROGRAM

AVAC

Global Advocacy for HIV Prevention

Good Participatory Practice Guidelines: Implications for research sponsors



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Executive Director

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Sr Program Manager

Objective of the GPP guidelines

The Good Participatory Practice (GPP) guidelines for biomedical HIV prevention trials:

Set global **standard practices** for stakeholder engagement. They provide trial funders, sponsors, and implementers with **systematic guidance** on **how** to effectively engage with stakeholders in the design and conduct of biomedical HIV prevention trials.

GPP: Where the story began

PrEP research controversy:

2004 – Cambodia trial not initiated

2005 – Cameroon and Nigeria trials discontinued

GPP History

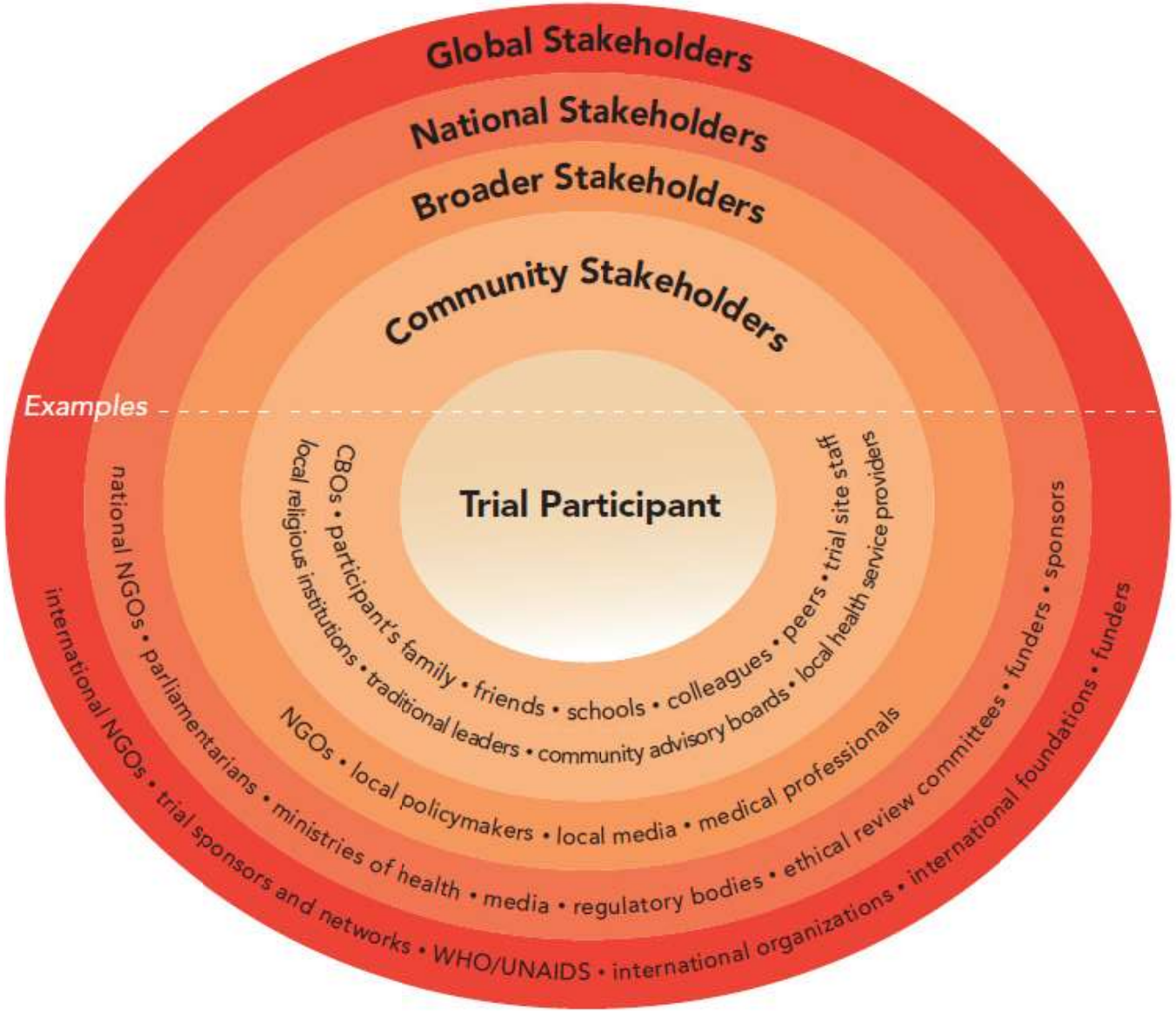
2004 PrEP Controversies

2007 GPP launched

Guidelines development

- Recognized need for effective partnerships between **research teams** and **stakeholders**
- Other aspects of clinical trial conduct are informed by guidelines; stakeholder engagement should be, too
- 1st edition (2007) – developed by international, multidisciplinary working group, with global input from stakeholders
- 2nd edition (2011) – developed after feedback from global consultations and piloting

Consideration of Stakeholders



GPP is woven into the lifecycle of a trial

What is GPP *Not*?

- Not recruitment
- Not retention
- Not a CAB
- Not participant-trial site interactions
- Not about a single trial
- Not a “nice to have”
- Not **GCP**, but..
- **It IS core to the research and development process**

Did You Say GCP?

GCP ≠ GPP

Research Investigator

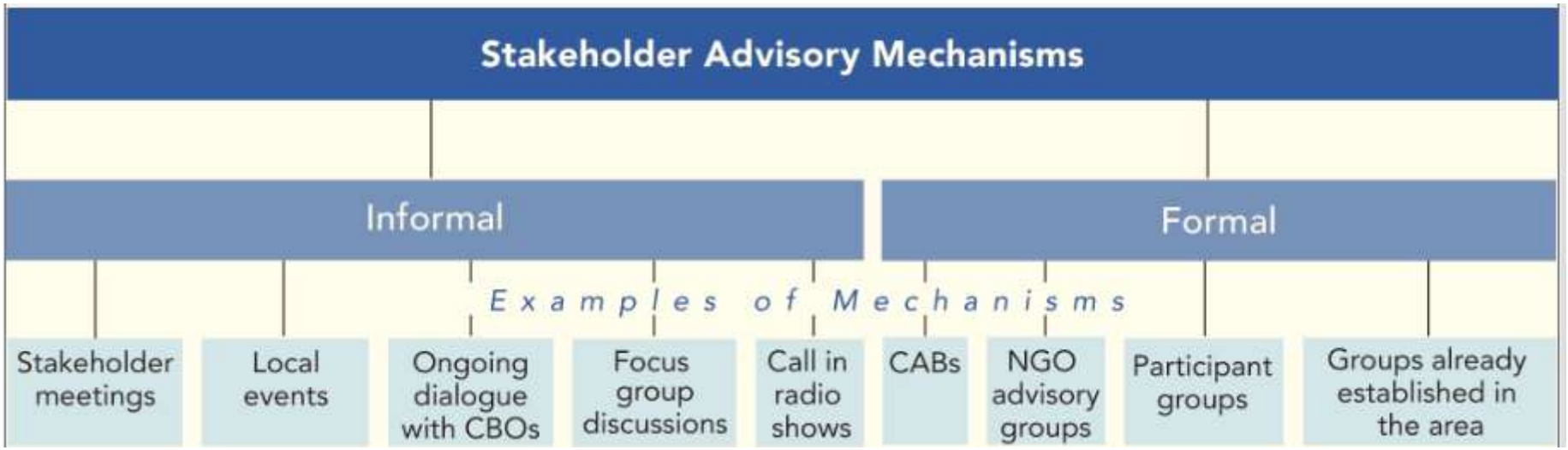
GCP

Trial participants

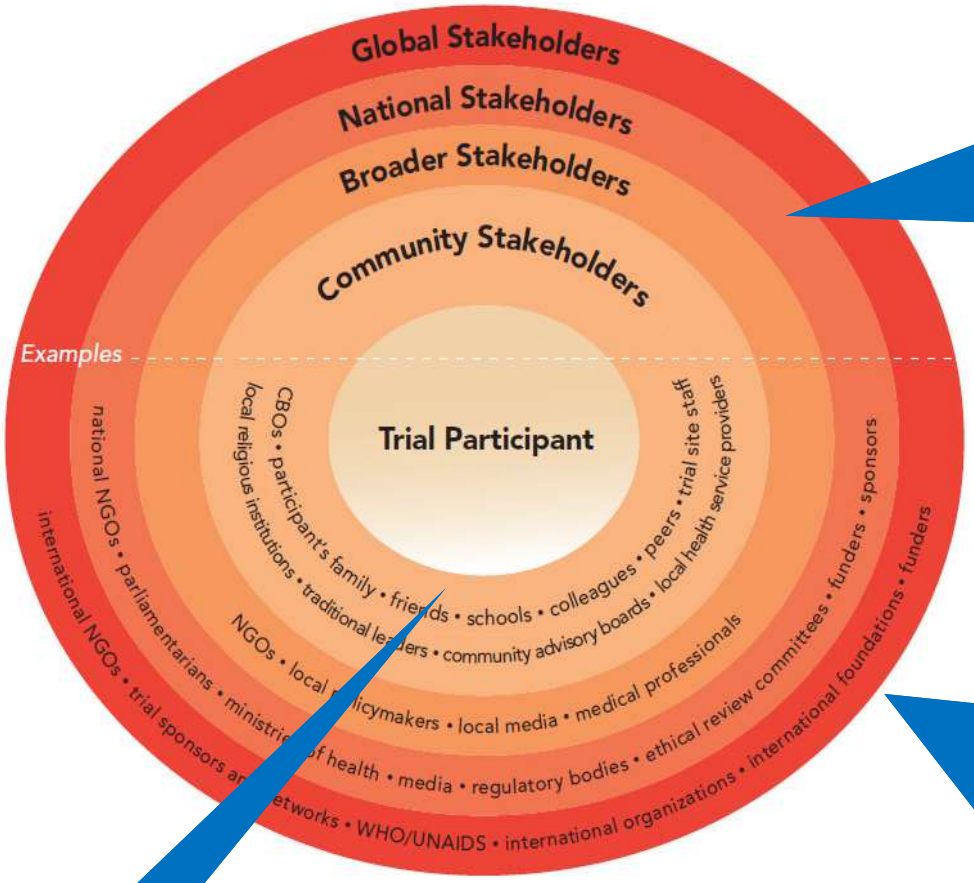
Research teams (and trial sponsors and funders)

GPP

Not Just a CAB



Implementation Globally

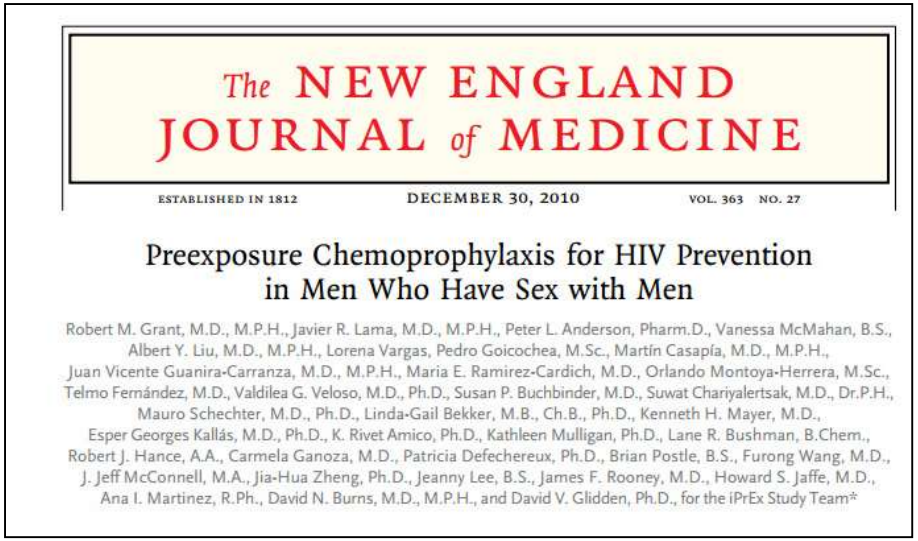


- National GPP plan and N-CAB in Thailand
- National CAB Forums, incorporation into ethics review processes in South Africa
- Incorporation into ethics guidelines in Uganda

- Adaptation to other fields, e.g., TB, Ebola
- "Global" GPP/CE Forum, Q3 2015
- Endorsement by Presidential Bioethics Commission
- Global consultations, e.g., proposed ECHO trial, MTN-017
- Stakeholder Engagement CoP

- GPP training, tools for sites
- FACTS 001
- iPrEX
- ASPIRE – results prep
- IAVI partner research centers

GPP in Publication

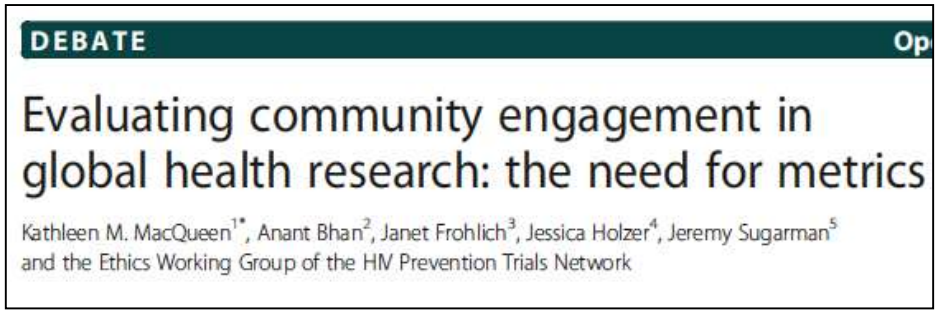


The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812 DECEMBER 30, 2010 VOL. 363 NO. 27

Preexposure Chemoprophylaxis for HIV Prevention in Men Who Have Sex with Men

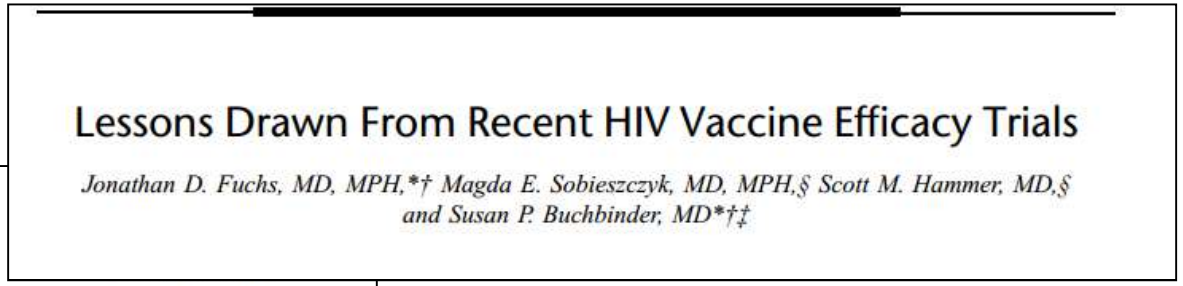
Robert M. Grant, M.D., M.P.H., Javier R. Lama, M.D., M.P.H., Peter L. Anderson, Pharm.D., Vanessa McMahan, B.S., Albert Y. Liu, M.D., M.P.H., Lorena Vargas, Pedro Goicochea, M.Sc., Martín Casapía, M.D., M.P.H., Juan Vicente Guanira-Carranza, M.D., M.P.H., Maria E. Ramirez-Cardich, M.D., Orlando Montoya-Herrera, M.Sc., Telmo Fernández, M.D., Valdilea G. Veloso, M.D., Ph.D., Susan P. Buchbinder, M.D., Suwat Chariyalertsak, M.D., Dr.P.H., Mauro Schechter, M.D., Ph.D., Linda-Gail Bekker, M.B., Ch.B., Ph.D., Kenneth H. Mayer, M.D., Esper Georges Kallás, M.D., Ph.D., K. Rivet Amico, Ph.D., Kathleen Mulligan, Ph.D., Lane R. Bushman, B.Chem., Robert J. Hance, A.A., Carmela Ganoza, M.D., Patricia Defechereux, Ph.D., Brian Postle, B.S., Furong Wang, M.D., J. Jeff McConnell, M.A., Jia-Hua Zheng, Ph.D., Jeanny Lee, B.S., James F. Rooney, M.D., Howard S. Jaffe, M.D., Ana I. Martinez, R.Ph., David N. Burns, M.D., M.P.H., and David V. Glidden, Ph.D., for the iPrEx Study Team*



DEBATE Op

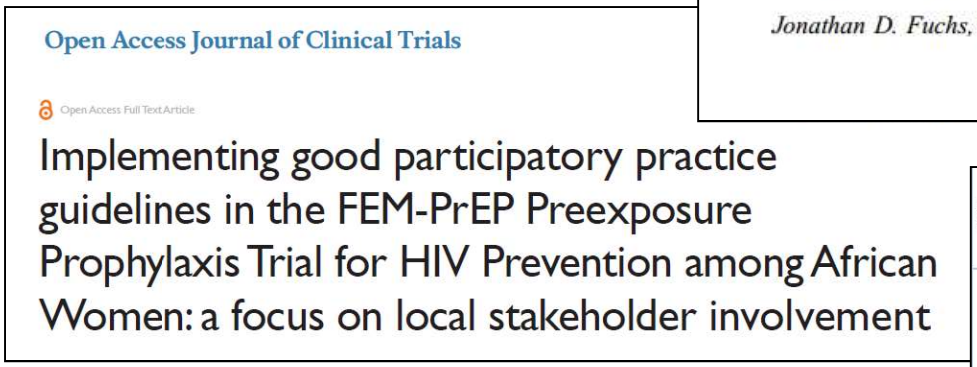
Evaluating community engagement in global health research: the need for metrics

Kathleen M. MacQueen[1*], Anant Bhan[2], Janet Frohlich[3], Jessica Holzer[4], Jeremy Sugarman[5] and the Ethics Working Group of the HIV Prevention Trials Network



Lessons Drawn From Recent HIV Vaccine Efficacy Trials

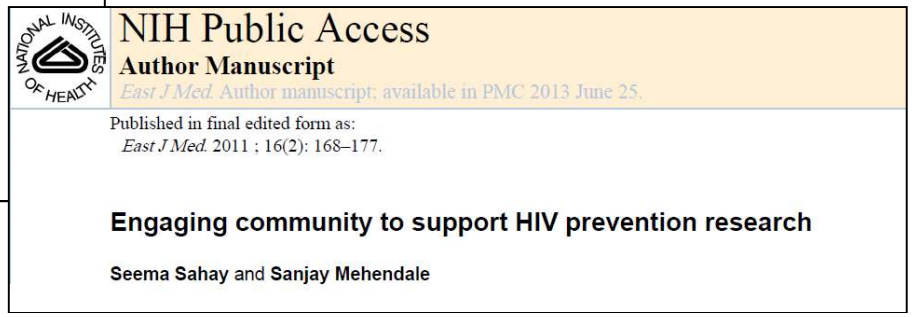
Jonathan D. Fuchs, MD, MPH,† Magda E. Sobieszczyk, MD, MPH,§ Scott M. Hammer, MD,§ and Susan P. Buchbinder, MD*†‡*



Open Access Journal of Clinical Trials

Open Access Full Text Article

Implementing good participatory practice guidelines in the FEM-PrEP Preexposure Prophylaxis Trial for HIV Prevention among African Women: a focus on local stakeholder involvement



NIH Public Access

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East J Med. Author manuscript; available in PMC 2013 June 25.

Published in final edited form as:

East J Med. 2011 ; 16(2): 168–177.

Engaging community to support HIV prevention research

Seema Sahay and **Sanjay Mehendale**

GPP Guidelines Structure

Section 1:
The importance of Good Participatory Practice

The importance of Good Participatory Practice defines the key terms used in the document and describes the realities of and the underlying determinants of the HIV epidemic, the context of conducting biomedical HIV prevention trials, and why a participatory approach is necessary to effectively conduct trials.

Section 2:
Guiding Principles of GPP in Biomedical HIV Prevention Trials

Guiding Principles of GPP in Biomedical HIV Prevention Trials outlines the set of principles that serve as the foundation of the relationships among trial funders, sponsors, and implementers and other stakeholders.

Section 3:
Good Participatory Practices in Biomedical HIV Prevention Trials

Good Participatory Practices in Biomedical HIV Prevention Trials describes optimal practices for trial funders, sponsors, and implementers to follow when designing, conducting, and concluding biomedical HIV prevention trials. Under 16 topic areas, this section outlines expected stakeholder engagement activities that take place at each stage of the research life-cycle.

Section 1:
The Importance of Good Participatory Practice

- Who are Stakeholders?
- What is Stakeholder Engagement?
- The Wider Context of HIV
- The Dynamics of Biomedical HIV Prevention Trials
- Rationale for GPP Guidelines
- Applying GPP

Section 2:
Guiding Principles of GPP in Biomedical HIV Prevention Trials

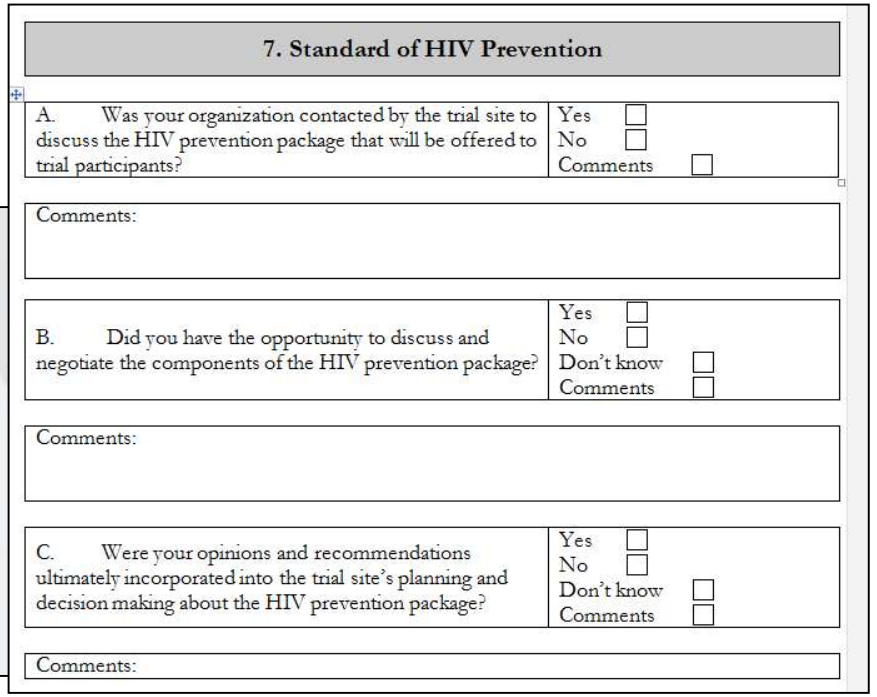
- Respect
- Mutual Understanding
- Scientific and Ethical Integrity
- Transparency
- Accountability
- Community Autonomy

Section 3:
Good Participatory Practices in Biomedical HIV Prevention Trials

- Formative Research Activities
- Stakeholder Advisory Mechanisms
- Stakeholder Engagement Plan
- Community Education Plan
- Communications Plan
- Issues Management Plan
- Site Selection
- Protocol Development
- Informed Consent Process
- Standard of HIV Prevention
- Access to HIV Care and Treatment
- Non-HIV-Related Care
- Policies on Research-Related Harms
- Trial Accrual, Follow-Up and Exit
- Trial Closure and Results Dissemination
- Post-trial Access to Trial Products or Procedures

Implementation tools

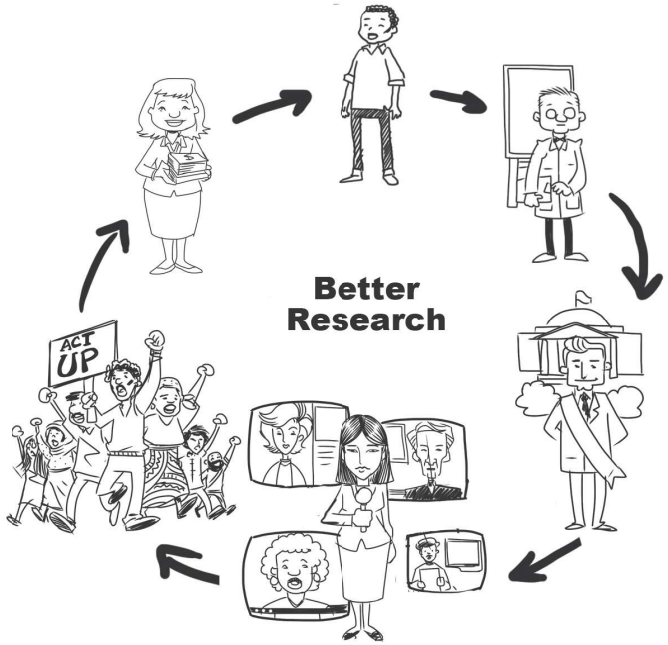
- GPP Blueprint
- Trial site binder/file
- Planning templates
- Assessment toolkit



7. Standard of HIV Prevention	
A. Was your organization contacted by the trial site to discuss the HIV prevention package that will be offered to trial participants?	Yes ☐ No ☐ Comments ☐
Comments:	
B. Did you have the opportunity to discuss and negotiate the components of the HIV prevention package?	Yes ☐ No ☐ Don't know ☐ Comments ☐
Comments:	
C. Were your opinions and recommendations ultimately incorporated into the trial site's planning and decision making about the HIV prevention package?	Yes ☐ No ☐ Don't know ☐ Comments ☐
Comments:	

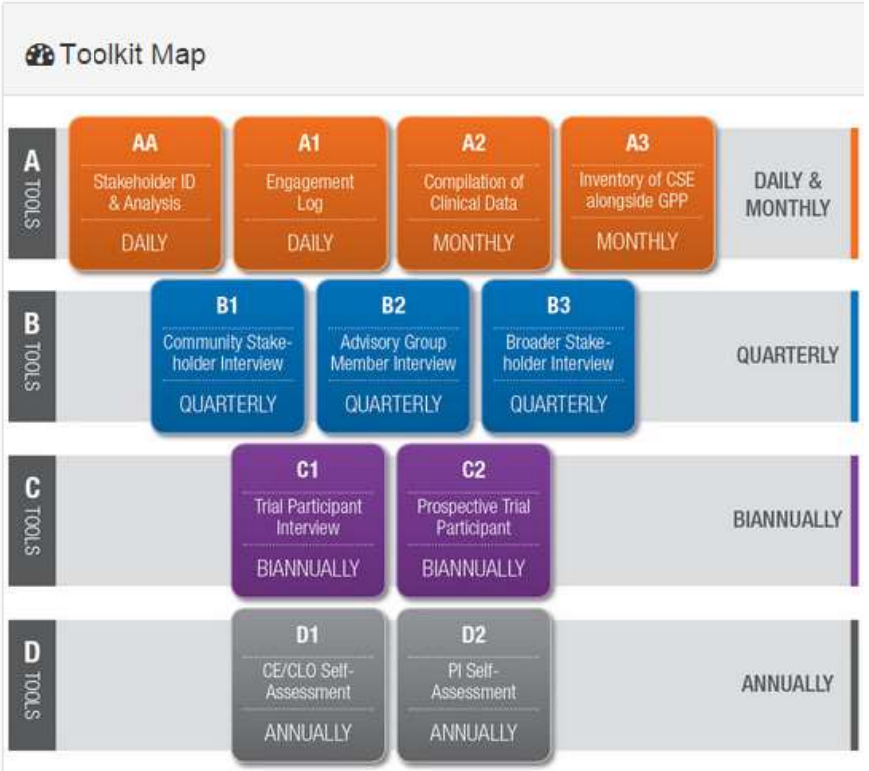
Online training curriculum

- Designed for multiple audiences, adaptable
- Primary focus on trial implementers
- Aids in strategy, work plan development
- Interactive asynchronous content
- Moderated by GPP experts



Monitoring and Evaluation Toolkit

- Set of tools for monitoring engagement activities
- Online database for data entry and standardized reporting
- Developed with TB Alliance, input of working group
- Piloted with multiple trial sites
- Introduced Sept 2014
- Official launch Q3 2015



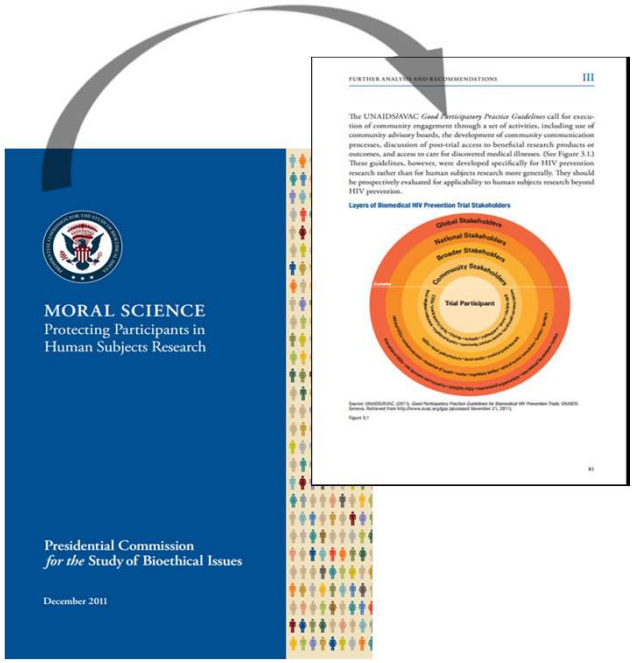
Implementation: National

- Uganda – incorporating GPP into national ethics guidelines
- Training for IRB members

- Zambia – national stakeholder consultations
- Thailand – national awareness through site trainings

Implementation: Global

- US Presidential Bioethics Commission recommendation, 2011
- Adapted version for TB drug trials, 2012; Ebola trials, 2015
- GPP Online Training Course
- Abstract driven session at HIV R4P conference, 2014
- Combined Community Engagement Forum, Sept 2015



Summary

- Good Participatory Practices, 2nd Edition have provided a key framework for ethical HIV prevention research
- GPP: inclusive, early, and durable stakeholder engagement
  - **GPP is woven into the entire lifecycle of a research effort**
- Future:
  - Need to generalize for other infectious diseases, especially those seen in outbreaks.
  - Applicability for non-communicable disease research?
  - Sufficient engagement of behavioral and social change research?

Resources

- GPP for HIV Prevention: http://www.avac.org/good-participatory-practice
- Training & Implementation Tools: http://www.avac.org/gpp-tools
- Online Training Course: http://www.avac.org/gpp-online-training-course
- GPP for TB: http://www.cptrinitiative.org/resources/gpp-tb-resource-document/
- Stakeholder Engagement Toolkit: http://www.avac.org/resource/stakeholder-engagement-toolkit-hiv-prevention-trials