



HIV VACCINE  
TRIALS NETWORK

## Taking the journey: creating the trial participants' Bill of Rights and Responsibilities

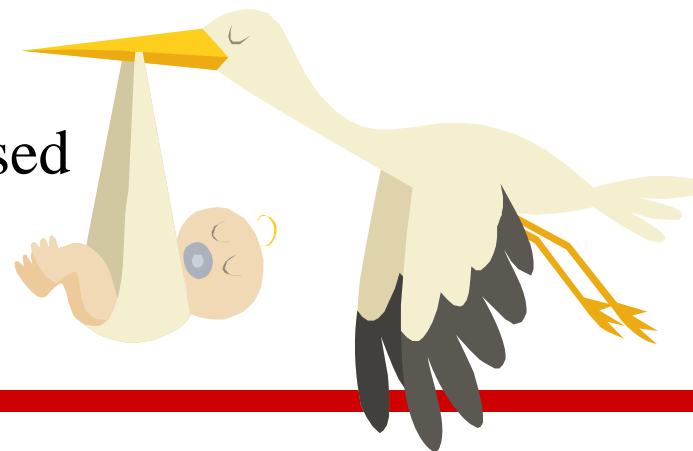


### Authors

**Butch McKay – Birmingham; John Bunting – Baltimore; Tom Gibson – Denver**

In the beginning . . .

- HIVNET and AVEG initiate concept of the PBOR
- HVTN forms task force to draft a PBOR
- Ethics Working Group is born
- Birthing problems arise and are addressed





## Taking the journey: creating the trial participants' Bill of Rights and Responsibilities

- Ethics Working Group (EWG) submits PBOR draft to Community Advisory Boards across the Network
- Global CAB recommends **Responsibilities** be added to the document – creating the **PBORR**
- DAIDS supports concept of PBORR
- Challenges in language and cultural differences
- Local CABs from around the world work toward consensus





## Treatment for study related injuries

- Complex questions and no easy answers
  - How are injuries defined?
  - Who pays and how much?
  - What expenses are covered?
  - What about issues such as lost wages, child care, and living expenses?
- Insurance issues
- Appeal to Congressional Black Caucus



VS





HIV VACCINE  
TRIALS NETWORK

## Taking the journey: creating the trial participants' Bill of Rights and Responsibilities

### Uses and Value of PBORR

Informed consent	Best practice
Community education	Recruitment tool
Assurance of fair treatment	

### Survey Results

"Reinforces, reiterates, and clarifies commitments and freedoms."

"Handout at meetings with and presentations to CBOs on doing ethical research"

"Helped because this explained that the study is using safest methods and this was not seen in protocol."





HIV VACCINE  
TRIALS NETWORK

## Taking the journey: creating the trial participants' Bill of Rights and Responsibilities

### Conclusions

The process of developing and refining the PBORR has enhanced Network discussions regarding ethical trial conduct, and the PBORR has become an important document in defining how HVTN trials are conducted. The EWG's and GCAB's initiative and leadership have provided added benefit. Over time, further revisions are expected. For example, as plans for adolescent trials move forward, implementation of the PBORR will need to be reviewed and applied to the trial population.

