Diverse participation in research: Ethical and Scientific challenges”

Karriem S. Watson, MS, MPH
Adjunct Instructor DePaul College of Health Sciences
Northwestern University School of Continuing Studies
Admin. Director of Community Engaged Research UI Cancer Center

kswatson@uic.edu or 312-413-8908
Diverse participation in research: ethical and scientific challenges

Objectives

1. Examine current trends in diverse participation in research
2. Review common barriers to diverse participation
3. Discuss ethical and scientific implications
4. Identify possible solutions & Roles of IRBs
Framing the Conversation: Why this & why now?

- Increasing health needs & widening gap of health inequities for people of color

- Funders: Industry, Academic & Federal and state funding agencies guiding WHO we should target

- Its Just RIGHT!
Global and National Trends

- Low study enrollment a National Trend
- Increasing globalization of trials due to low US enrollment
- Minorities represent almost 30% of those enrolled in clinical trials sponsored by the National Institutes of Health (NIH) (Fischer & Kalbaugh, 2011) *(Is this improvement?)*
- “In NIH studies at 7.6% of all research participants,³ and a report on industry-sponsored studies found that only 3% of those participants were Hispanics” (Fischer & Kalbaugh, 2011)
- Continued low enrollment for Cancer Trials
Common Barriers

• What do you see and hear?
Examples of Common Barriers

- Fear: (Quinn et al, 2012)
- General lack of trust in healthcare & Research (Friedman, 2009)
- Lack of diversity in investigators, FDA has documented this as barrier (FDA, 2011)
- Institutional Barriers
Ethical & Scientific Implications:

- Not serving health needs of communities we serve
- Risks may differ based on CULTURE & Genetics or interactions of Social Determinants
- Lack of TRUE understanding of how drug, device or intervention works in DIVERSE communities
- Inability offer state of the art treatment at early stage of disease (Cancer Trial Example)
Are National Trends Reflective of Local Disparities?

• “A long-awaited update from the U.S. Preventive Services Task Force (USPSTF) recommends against screening men for prostate cancer with the prostate-specific antigen (PSA) test.”

• [Link](http://www.cancer.gov/ncicancerbulletin/052912/page4)
History

- 1932-1972: Tuskegee Experiment
- 1974 IRB Required
- 1994 NIH Guidelines on the inclusion of women and minorities in clinical trials
- 1997 FDA Modernization Act required FDA and NIH to consult on inclusion of women and minorities in clinical trials
- 2014 Continued low participation of communities of color in research
EXAMPLE: BiDIL

- Drug for Heart Failure
- Original study in late 80’s and early 90s and study DID not include large percentage of blacks
- Original study results showed drug NOT effective....in Whites. BUT what about Blacks?
- New Study initiated 5/29/01 and terminated early on 7/19/04 because of significant survival benefit in the BiDil group1-3
HPV: CERVICAL CANCER and Women of Color

- “HPV strains that affect black women differ from those targeted by cancer-preventing vaccines, researchers say”
When people of color don’t participate or when RACE is NOT considered

- The findings underscore the importance of having racial and ethnic minorities represented in clinical trials that result in new therapies and preventive treatments

- “[There weren’t] enough people of African descent,” she said of the trials that led to Gardasil and Cervarix. “We may be rethinking the vaccine itself.”

- Cathrine Hoyo, MD:
  Duke University
Role of IRBs

- Consent forms: Is Longer better?
- More diverse representation on boards: presence of MORE community members
- Reports to Investigators to include tracking of diverse participant enrollment
- More focus on recruitment plans
Open Discussion
Questions??????

- Karriem S. Watson
  - ksadot@hotmail.com
  - 312-933-4825
  - Clinicaltrials.gov
  - http://tigger.uic.edu/depts/ovcr/research/protocolreview/irb/participant/studies.html