The Importance of Research

Keith C. Norris, M.D.
University of California, Los Angeles

Loretta Jones, M.A.
Healthy African American Families II

Aziza Lucas-Wright, M. Ed.
Healthy African American Families II

University of California, Los Angeles
Clinical & Translational Science Institute
Community Engagement & Research Program
Workshop Audience & Objectives

Audience
This workshop is aimed for members of community organizations, and organizations that provide services to communities, who are interested in learning more about medical research.

Objectives
By the end of this session, participants will be able to:
1. List two reasons for the importance of clinical research
2. Identify at least two different types of clinical research
3. Explain the function of the Institutional Review Board
“When it is dark enough, you can see the stars.”

- Ralph Waldo Emerson
• Seatbelts
• Parachutes
• Penicillin
• Aspirin
• Vaccines
Any systematic investigation, including research development, testing and evaluation, designed to develop or contribute to knowledge.

45 CFR 46.102(d)

“re-search” - search and search again

★ Principal investigator’s allegiance is to the protocol

★ Physician’s allegiance is to patient (even if through evaluation of systems)
What is Clinical Research?

Provide demographic data
• To determine racial health disparities (e.g. infant mortality, cancer, heart disease, diabetes)
• To determine health risk factors (e.g. smoking)

Determine effect of actions
• To know if a program or special treatment is effective and/or safe (e.g. educational programs, medical treatments, access to care, risk management)

Determine health care policy
• Resource allocation
• Guidelines for care, treatment, etc…
Why Clinical Research?

To collect data that is:

- Minimally biased
- Comprehensive (large #'s)
- Uniform methods
- Rigorous

To answer health-related questions in a manner that is scientifically valid
Types of Clinical Research

• Quality of Life
• Screening
• Prevention
• Treatment

*A more comprehensive list of clinical research modalities, and more information on clinical research is included in the Resource section of your workbook.*
In Research, What is a Human Subject?

A living individual about whom an investigator (whether professional or student) conducting research obtains:

• data through intervention or interaction with the individual, or
• identifiable private information or records.

15 CFR 27.102(f)
Patient/Participant Protection in Clinical Research

- Institutional Review Board (local)
- Maintaining regulatory compliance (federal)
- Informed Consent Process
All research needs IRB approval. Some may be exempt from consent forms. Even survey/education types of “research” may need full IRB approval if issues of high sensitivity and patient privacy are involved (e.g. substance abuse, HIV/AIDS, mental disorders, telemedicine)

The IRB is your friend!!!
To Improve Health Outcomes

- To increase racial/ethnic participation in clinical research
- To reduce gender/age disparities in clinical research
- To evaluate novel approaches to improving health outcomes
- To improve health care systems
Ethics in Clinical Research

Four different perspectives on identification and evaluation of risks and benefits

*Subject  *Community  *Researcher  *Regulator
Acknowledgements

This presentation is supported in part by: NIH-NIMHD Grant U54MD007598 (formerly U54RR026138), P20MD00182, NIH/NCATS Grant # UL1TR000124, NIH-NIMHD Grant U54RR022762 and CDC #99IPA06350.