The Importance of Research

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Audience

This workshop is aimed at 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 knowledgeable of the importance of conducting research, and the different types of clinical research.
• Be introduced to the protections in place for research involving human participants.
“When it is dark enough, you can see the stars.”

- Ralph Waldo Emerson
Successful Research

- Seatbelts
- Parachutes
- Penicillin
- Aspirin
- Vaccines
What is Research?

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!!!*
Role of Clinical Research in Enhancing Wellness and Health Care Outcomes

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