

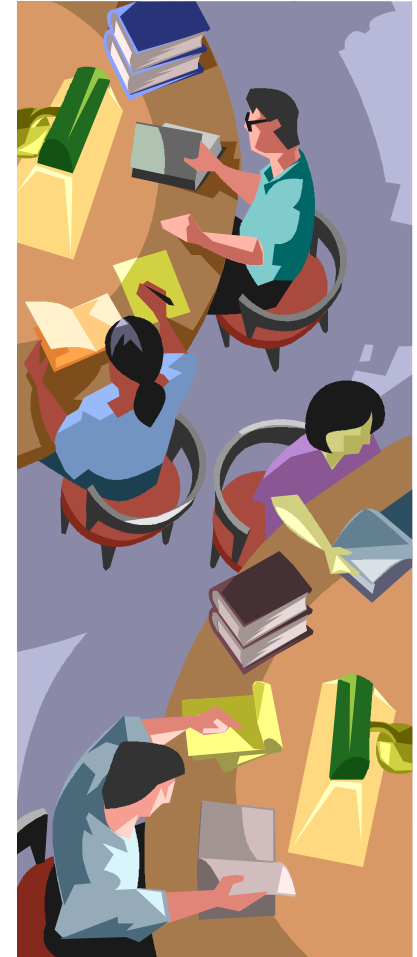
The Importance of Research

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Workshop Audience & Objectives

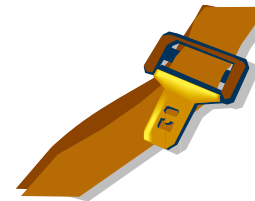
Audience

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.



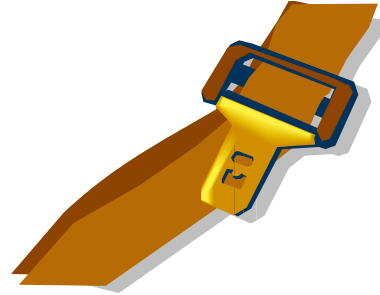
“When it is dark enough,
you can see the stars.”

- 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**



Patient/Participant Protection in Clinical Research - cont'd

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

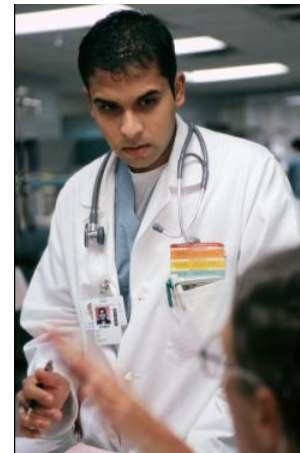
Four different perspectives on identification and evaluation of risks and benefits



***Subject**



***Community**



***Researcher**



***Regulator**