Research 101

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History of Ethics

Prior to 1906, when the Pure Food and Drug Act was passed, there were no regulations regarding the ethical use of human participants in research. There were no consumer regulations, no Food and Drug Administration (FDA), no Common Rule, and no Institutional Review Boards (IRBs). What follows is a brief discussion of why federal rules and regulations were established and why IRBs became a necessity.

SOURCE: Claremont Graduate University http://www.cgu.edu/pages/1722.asp

Nuremberg Code

The most dramatic and well-known chapter in the history of research with human participants opened on December 9, 1946, when an American military tribunal opened criminal proceedings against 23 leading German physicians and administrators for their willing participation in war crimes and crimes against humanity. Among the charges were that German Physicians conducted medical experiments on thousands of concentration camp prisoners without their consent. Most of the participants of these experiments died or were permanently crippled as a result.

SOURCE: Claremont Graduate University http://www.cgu.edu/pages/1722.asp

Result of the Nuremberg Code

- As a direct result of the trial, the Nuremberg Code was established in 1948, stating that "The voluntary consent of the human participant is absolutely essential," making it clear that participants should give consent and that the benefits of research must outweigh the risks.
- Although it did not carry the force of law, the Nuremberg Code was the first international document which advocated voluntary participation and informed consent.

SOURCE: Claremont Graduate University http://www.cgu.edu/pages/1722.asp

Declaration of Helsinki

- In 1964, the World Medical Association established recommendations guiding medical doctors in biomedical research involving human participants. The Declaration governs international research ethics and defines rules for "research combined with clinical care" and "non-therapeutic research." The Declaration of Helsinki was revised in 1975, 1983, 1989 and 1996 and is the basis for Good Clinical Practices used today.

SOURCE: Claremont Graduate University http://www.cgu.edu/pages/1722.asp

Issues addressed by the Declaration of Helsinki

- Research with humans should be based on the results from laboratory and animal experimentation
- Research protocols should be reviewed by an independent committee prior to initiation
- Informed consent from research participants is necessary
- Research should be conducted by medically/scientifically qualified individuals
- Risks should not exceed benefits

SOURCE: Claremont Graduate University http://www.cgu.edu/pages/1722.asp

The Belmont Report

- The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research prepared the Belmont Report in 1979. The Belmont Report attempts to summarize the basic ethical principals identified by the Commission in the course of its deliberations. The Report is a statement of basic ethical principles and guidelines that should assist in resolving the ethical problems that surround the conduct of research with human participants. The Belmont Report established three basic ethical principals - *respect for persons, beneficence, and justice* - which are the cornerstone for regulations involving human participants.
- SOURCE: Claremont Graduate University http://www.cgu.edu/pages/1722.asp

Respect for Persons

- Individuals should be treated as autonomous agents.
- Persons with diminished autonomy are entitled to protection.
- This principle is the basis for informed consent:
  - The consent process must include three elements: Information, Comprehension, and Voluntary participation
  - Participants, to the degree that they are capable, must be given the opportunity to choose what shall or shall not happen to them

SOURCE: Claremont Graduate University http://www.cgu.edu/pages/1722.asp

Respect

- For potential and enrolled participants
- For community
- For research partners
- Trust and trustworthiness
- Joint development of guiding principles, agreements, and conflict resolution
- Community and Research dissemination
- Recognition of both community and research biases, stereotypes, and politics

SOURCE: Claremont Graduate University http://www.cgu.edu/pages/1722.asp

Informed Consent

- Respects research participants rights to make decisions that are consistent with their values, interests, and preferences
- Community can help design innovative ways to enhance informed consent, help manage misinformation and rumors, and disseminate information to community
- Challenge if trust in community partners leads participants to pay less attention to risk to themselves

Beneficence

- Human participants should not be harmed
- Research should maximize possible benefits and minimize possible risks

This principle addresses the assessment of risks and benefits

- The nature and scope of risks and benefits must be assessed in a systematic manner

- SOURCE: Claremont Graduate University http://www.cgu.edu/pages/1722.asp

Social or Scientific Value

- Scientific or health decision-making value
- Developing community capacity
- Sustainability increases value to community and research
- Challenges when studies that have value for community are not considered valuable from the scientific or social perspective

Source: Chen, D., Gelberg, L., Jones, L., Hogan, V.,

Favorable Risk-Benefit Ratio

- Risks and potential benefits to community as a whole should be considered
- Determining appropriate risks, benefits, and risk/benefit ratio in communities that lack access to healthcare services
- Risk to individual participants must be justifiable by potential benefit to individual and/or by benefit of findings to society

Scientific Validity

- Research must be scientifically valid to be ethical
- Community should have a role in deciding the design of a study- certain designs may not be acceptable, thus the study may not be done
- Community input can increase validity of interpretations

Justice

- The benefits and risks of research must be distributed fairly.
- This principle insures fair selection of participants:
  - There must be fair procedures and outcomes in the selection of research participants

SOURCE: Claremont Graduate University http://www.cgu.edu/pages/1722.asp

Fair Subject Selection

- Should be based primarily on scientific goals-focus on particular racial/ethnic or particular community may be justifiable as fair when chosen for reasons of justice
- Hiring and training community members for outreach, recruitment, & data analysis can increase fairness and community capacity

Independent Review

- Enhance public accountability and minimize influence of potential conflicts of interest
- Independent community review enhances transparency and accountability to community
- Community IRB: same functions as University IRB's

Two Basic Approaches Exist For Ensuring Compliance With Human Participants Regulations:

- The Food and Drug Administration (FDA) uses inspection and audits.
- Department of Health and Human Services (DHHS) components rely on assurances of compliance that are negotiated with institutions by the OPRR office for protection from research risks.

Assurance

- Assurance is a written document negotiated with either a university, drug company, or community that has an IRB (Institutional Review Board)
- DHHS regulations mean you adopt federal policy
- Each institution adopts internal audits or self assessments, procedures, and practices
- Investigators are the most frequent source of non-compliance with human participant regulation

So, What is an IRB?

- An institutional review board (IRB), also known as an independent ethics committee or ethical review board, is a committee that has been formally designated to approve, monitor, and review biomedical and behavioral research involving humans. They often conduct some form of risk-benefit analysis in an attempt to determine whether or not research should be done.

SOURCE: http://en.wikipedia.org/wiki/Institutional_review_board

Why an IRB?

- In the United States, the Food and Drug Administration (FDA) and Department of Health and Human Services (specifically the Office for Human Research Protections) regulations have empowered IRBs to approve, require modifications in planned research prior to approval, or disapprove research. IRBs are responsible for critical oversight functions for research conducted on human subjects that are 'scientific', 'ethical', and 'regulatory'.

- SOURCE: http://en.wikipedia.org/wiki/Institutional_review_board

IRB's Can Differ Across Institutions:

- There are several kinds of IRB's-some institutions have one board that reviews everything.

- Others have several, i.e., medical, behavioral, and animal, each with a focus on what level of trials.

Why is Research Important?

- By 1980, average life expectancy in America had reached 74 years—25 years longer than at the beginning of the 20th century. However, African Americans, Hispanic Americans, American Indians, Asian Americans, and Native Hawaiians/Other Pacific Islanders, who represented 25% of the U.S. population, continued to experience significant health disparities, including shorter life expectancy and higher rates of diabetes, cancer, heart disease, stroke, substance abuse, infant mortality, and low birth weight.
- 36 years later, these disparities in health still exist…

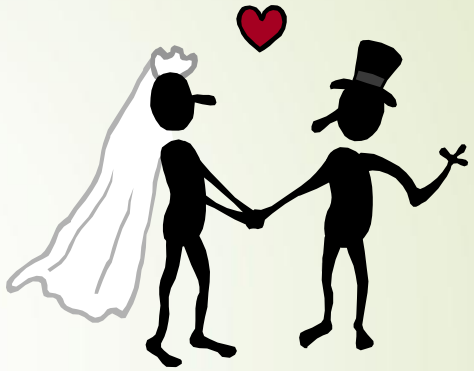
https://report.nih.gov/nihfactsheets/viewfactsheet.aspx?csid=124

Why Engage Community?

- To enhance the validity and quality of the research by incorporating the knowledge of the people involved;
- To bridge "cultural gaps" that may exist between the partners involved;
- To incorporate cultural, social, and economic factors that may influence health;
- To facilitate the design of culturally sensitive and linguistically appropriate measures and methods;
- To provide resources and opportunities for the communities involved.

Community Engagement

(The New Way - Is it Love?)



- The locus of control and ownership are collaborative
- Leverages built ownership into action
- Promotes organic development of thought, building networks, and cultivating leadership

Defining Community

- Geography
- Population
- Gender
- Race
- Boundaries
- Shared Interests

How is this done?

Circle of Influence Model for Collaborative Research © 2002

Source: This model was developed by L. Jones, M.A., D.S. Martins, M.D., Y. Pardo, R. Baker & K. C. Norris, M.D.

Partnership

"We need to build this partnership. It's going to take some time…is everyone committed to this?"

What are the Ingredients Needed for Partnership?

Respect

Trust

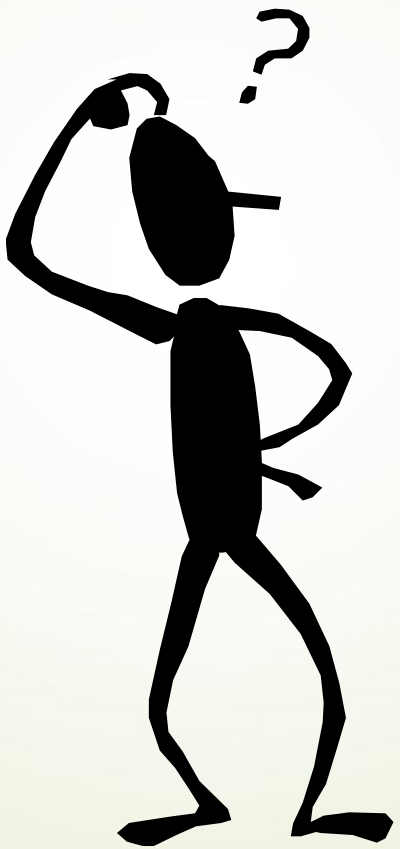
Transparency

Words to Remember:

- Improvisation
- Resiliency
- Connectedness to others
- Spirituality
- Emotional Vitality
- Gallows Humor
- Healthy Suspicion of the Message *and* the Messenger

Joe White, Ph.D February 23, 2006 African American Mental Conference, Los Angeles, CA

Questions?



THANK YOU!

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