



FLORIDA STATE UNIVERSITY COLLEGE OF MEDICINE

Research Workshop Series #2 *Introduction to Research*





Outline

- Research Definitions
 - Human Subjects Research
 - Quality Improvement
 - Clinical Research
- Clinical Research Approaches
- Research Terminology
- Research Design & Methodology
- Questions & Discussion



What is research?

As defined by the DHHS 45.CFR 46.102(d):

- A systematic investigation
- Designed to contribute to generalizable knowledge
- Must meet both conditions to be categorized as research



What is NOT research?

Examples:

- Surveys for evaluating the performance of faculty, staff, and students, or other studies for internal institutional use only
 - NOT research – activity is for internal use, not generalizable
- Oral history of New Orleans jazz artists and memories of post-WWII era
 - NOT research – not systematic or generalizable intent



Human Subjects Research

As defined by 45 CFR 46(f):

Human Subject:

- Living individual about whom an investigator (professional or student) conducts research

Human Subject Research Includes:

- Data through intervention or interaction with the individual, or
- Identifiable private information



Types of Human Subjects Research

- Case Studies (3+ subjects)
- Retrospective Chart Reviews
- Observational Studies
- Behavioral Research
- Interventional Studies
- Secondary analysis of publically available data



Human Subjects Research

Examples:

- Interviewing cancer survivors about coping techniques
- Questionnaires about dating behaviors among college students
- Surveys about shopping preferences in rural communities
- Moderate exercise activities and venipuncture of individuals to determine blood levels of electrolytes
- Music therapy intervention to determine whether it affects pain levels in a hospital environment



NOT Human Subjects Research

Examples:

- Research utilizing a human cell line available from the American Type Culture Collection or a similar depository
 - NOT human subjects because the cell line and accompanying information is publically available
- Researcher contacts the director of a battered women's shelter and asks for information on the average length of stay of women who use the shelter
 - NOT human subjects because even though there is interaction between a researcher and an individual, the research is not "about" the director



Quality Improvement (QI) vs Research

Systematic and continuous actions that lead to measurable improvement in health care services and the health status of targeted patient groups (HRSA)

Similarities

- QI is systematic
- Leads to improvement in healthcare
- QI targets patient groups

Differences

- QI is not generalizable
- Institution-specific



IRB Disclaimer

- Institution-specific requirements may vary.
- Please check with your institution's IRB and review policies for determining whether your project is considered to be human subjects research or QI.

***Refer to decision tree handout*



Clinical Research

NIH defines clinical research as:

- Patient-oriented research
 - Research conducted with human subjects for which an investigator directly interacts with human subjects
- Epidemiologic and behavioral studies
- Outcomes research and health

NIH defines clinical trials as:

- A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes (9/2016).



How can clinical research advance medicine?

- Provide information about disease trends and risk
- Improve knowledge of efficacy and adverse effects of medical interventions
- Can impact human health and longevity
- Can provide novel approaches to disease prevention
- Help translate basic research into new treatments and information to potentially benefit patients



Approaches to Conduct Clinical Research

- **Community-based participatory research (CBPR)** – A collaborative approach to research that equitably involves all partners in the research process and recognizes the unique strengths that each brings
- **Comparative-effectiveness research (CER)** - compares effectiveness of different methods or practices on patient outcomes; designed to inform health-care decisions by providing evidence on the effectiveness, benefits, and harms of different treatment options



Approaches to Conduct Clinical Research

- **Implementation Science** –focuses on understanding how programs are implemented, translated, replicated, and disseminated in “real-world” settings. It expands the focus of traditional research from discovering *what* works to also discovering *how* the implementation works in *specific contexts*.
- **Translational research** - Research process of turning observations in the laboratory, clinic and community into interventions that improve the health of individuals and the public — from diagnostics and therapeutics to medical procedures and behavioral changes; ‘translate’ findings bench to bedside.



Emerging Clinical Research Trends

- Precision Medicine
- Structural, Molecular, Cell biology
- Health informatics
- Telemedicine
- Bioengineering
- Population health and “big data”





INTRODUCTION TO RESEARCH

PART II

Adapted from:

Burge, S. K. *All About Conducting Research*. Department of Family & Community Medicine University of Texas Health Science Center at San Antonio.



RESEARCH TERMINOLOGY

HANDOUT REVIEW



Research Designs

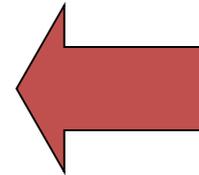
- Prospective
- Retrospective
- Observational
- Interventional



Retrospective vs. Prospective

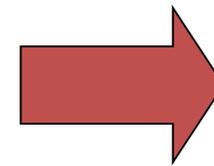
Retrospective

- Uses existing records or information



Prospective

- Generates new information





Retrospective vs. Prospective



Retrospective

- Examine school records of adults who abuse drugs and those who do not to determine how many had learning disorders during childhood.

Prospective

- Identify children with learning disorders (LD) and a comparison group of children with no LD, and follow them over time to determine how many will develop problems with drug abuse.



Retrospective Design

Advantages

- Some data is not available otherwise
- Less expensive than prospective
- Data is more accessible
- Less time consuming

Disadvantages

- Critical data may be absent
- Controls may not be in place (biases are hard to rule out)
- Measurement is limited



Prospective Design

Advantages

- Measurement of data is consistent with purpose of study
- More controls for bias can be put in place

Disadvantages

- Investigator is dependent on subject cooperation
- Time consuming
- Resource heavy



Observational Design

- The investigator *does not* alter events or situations under study
- Study can be prospective or retrospective
- Descriptive studies
- Analytical studies
 - Cross-sectional
 - Case Control
 - Cohort



Observational Design

Advantages

- Less expensive
- Can use existing data
- No change to subjects' environment

Disadvantages

- Cannot rule out many alternative explanations



Interventional Design

- Investigator intentionally alters study environment or situation
- Prospective
- Examples:
 - Pre/Post intervention
 - Experimental vs. Control
 - Experimental vs. Placebo
 - Crossover



Interventional Design

Advantages

- Allows investigator to rule out alternative explanations
- Investigator has much control study environment & research procedures

Disadvantages

- Subject selection
- Subject attrition
- Expensive
- Ethically inappropriate for some questions



Research Methods

Qualitative

- In-depth research of non-numerical data
- *Benefit* – Flexible design & comprehensive data

Quantitative

- Systematic process of obtaining numerical data
- *Benefit* - Utilize data to generalize results to a population

Mixed-Methods

- Combines the strengths of quantitative and qualitative research by utilizing both methods
- *Benefit* – Multiple forms of data



Thank you!

Questions & Discussion

* *Human Subjects Training:* [CITI Instructions](#)