

Student Research as a Masters Capstone Project – How to Navigate the Development of the Research Question and the IRB

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Goals and Objectives

- Explain why research is incorporated in graduate education
- Discuss pros and cons of student directed research
- Utilize framework in guiding students to formulate the research question
- Critique research proposals
- Describe the IRB process
- Discuss methods utilized to present research findings

Why research projects?

- Important to clinical practice
- Important to the profession
- Important to consumers of the medical literature
- Important to adult learners
- Important to personal and professional growth

• *Blessing, D. Physician Assistant's Guide to Research and Medical Literature. 2nd ed. Philadelphia: FA Davis and Company. 2006*

Why student research?

- Pros -
 - In our experience, the students formulate great research questions.
 - It becomes their work, not something they are doing for the faculty.
 - It (should) inspires faculty to develop their own research.
 - Develops their skills for life-long learning and, perhaps, life-long research activities
- Cons
 - Grandiose ideas
 - Time away from clinical rotations

The Seton Hall University Experience

- 3-year curriculum
- Initially Research Methods/Biostatistics in one semester and Research Project in the following semester
- Now a 3 semester experience
- Research course sequence is during “clinical” phase of the program
- Research groups consisting of 3 to 5 students

Sample SHU Student Projects

- Classes taken at PA School – Which are most helpful to practicing PAs?
- The comparative effect of academic versus clinical credentials in admission to PA programs: a randomized trial.
- Awareness of reduced morbidity associated with early detection of testicular cancer via TSE among men aged 18 – 25 years at SHU
- Age related compliance with the use of chronic medication

Sample SHU Student Projects - continued

- The role of socioeconomic status on utilization of prenatal care
- Cultural competency of graduate allied health students training in an urban setting

Presenting The Findings

- **Manuscript**
 - JAAPA, *Perspective*, others
 - Schoolwide/Departmental publishing
- Task: Writing a manuscript suitable for submission to a peer-reviewed professional journal
 - whether or not it is eventually submitted
 - JAMA guidelines is the default documentary style

Presenting The Findings

- **Poster presentations**
 - AAPA Annual Conference
 - Plan ahead, meet all deadlines and requirements
 - Usually preceded by a call for abstracts in January
 - Schoolwide/Departmental Research Colloquia
- Use a university or hospital Media Center
- Commercial printers – Kinko's, AlphaGraphics, others

[Poster Title]

YOUR LOGO HERE

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Developing a Research Question

Gary J. Bouchard, Ph.D., PA-C

The Research Problem

- “The formulation of a problem is often more essential than its solution, which may be merely a matter of mathematical or experimental skill. To raise new questions, new possibilities, to regard old questions from a new angle, requires creative imagination and marks real advance in science”

– Albert Einstein

The research “hourglass”

Casual Observations
Problems – general
Questions – more specific
Hypotheses – most specific
Individual studies

THE STUDY

Your findings
Internal validity
Truth Within the study
External validity
TRUTH in the universe

Adapted from Trochim WMK

Problem A

- An automobile blows a tire on a lonely country road. There is no jack in the trunk.
- The travelers define the dilemma by asking the question “Where can we find a jack?”
- They begin to walk several miles back to the last service station they passed to borrow a jack.

Problem B

- A **second** automobile blows a tire on the same lonely country road. They also have no jack in the trunk.
- The travelers define the dilemma in a different way, by asking the question “How can we raise the automobile without a jack?”
- They enter a nearby barn which houses a pulley system used for lifting heavy bales of hay. They raise the car with the pulley, change the tire, and resume their journey

- From Getzels JW (1979)

Problem Finding

- Problems are found through **scholarship** and **experience**
- Prior studies/ literature review
 - Extend or refine prior studies
- Work environment
 - Practical problems in the field
- Personal interest
- Mentor or preceptor interest
- Requests for proposals (RFPs)

- Unexpected differences
- Unexpected similarities
- Strange, striking, or new phenomena

From Research Problem to Research Question

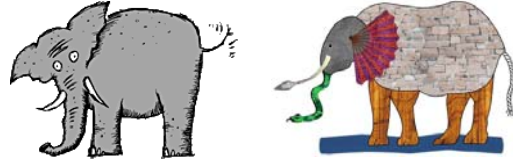
- Problems must be refined before they become research questions
 - From general to specific
 - Answerable using observable data
 - Relates two or more variables
 - Must flow logically

- Research problem:
 - “There is an increased incidence in post-operative infections in an ambulatory surgery pavilion as compared to similar procedures performed in a main operating suite.”
- Research questions
 - “Is there a significant difference in the pre-operative scrub procedures between the two settings?”
 - “Is there a significant difference in perioperative use of antibiotics between the two settings?”
 - Others?
- Research hypothesis
 - Highly specific
 - Features completely operationalized variables

A FINER research question

- FINER
 - Feasible
 - Burdens on time, resources, staff
 - Interesting
 - Novel
 - Some room for replication studies
 - Ethical
 - Human subjects have extensive protections in research
 - Relevant
 - Timeliness, seriousness, the "so what?" consideration

THE BLIND MEN AND THE ELEPHANT - JG Saxe



It may take several narrowly defined studies to fully comprehend all of the complexities of a problem.

Don't try to study an entire elephant in a few months!

• Group Activity

- Each group to develop a question

Institutional Review Board

Joseph L. Monaco, PA-C, MSJ

Institutional Review Board

- The purposes of the IRB
 - Protection of subject rights
 - Assess for sound research design

History

- **Nazi Medical War Crimes**
 - Experiments unprecedented in scope and the degree of harm and suffering
 - "Crimes against humanity"
 - August 1947 verdict, the judges included a section called "Permissible Medical Experiments."
 - Nuremberg Code

History

- **The Tuskegee Syphilis Study: 1930-1972**
 - Knowing violations of vulnerable research participants' rights
 - Studied natural course of untreated syphilis
 - 400 black men
 - 10 year mortality 2x higher than controls
 - Never provided with PCN in the 1940s
 - Resulted in federal regulatory controls for human experimentation

History

- **The Jewish Chronic Disease Hospital Study: 1963**
 - Studied whether the body's inability to reject cancer cells was due to cancer or debilitation
 - Foreign, live cancer cells were injected into patients with chronic debilitating diseases.
 - Oral consent, only; did not include consent for the injection of cancer cells because the researchers felt subjects would be unnecessarily frightened
 - The researchers were found guilty of fraud, deceit, and unprofessional conduct.

History

- **The Willowbrook Study: 1963 – 1966**
 - Willowbrook State School, S.I., N.Y.
 - Study undertaken to understand the natural history of infectious hepatitis
 - newly admitted children were deliberately infected with the hepatitis virus; researchers justified the deliberate injection of these children b/c most would acquire the infection while at Willowbrook due to overcrowding, and unsanitary conditions
 - Willowbrook closed its doors to new patients, claiming overcrowded conditions; the hepatitis program had its own space at the institution and was able to continue to admit new patients; parents were unable to admit their children to Willowbrook unless they agreed to their participation in the studies
 - Raised important questions about the adequacy and freedom of consent,

History

- Belmont Report in 1979
 - National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research at the request of the Secretary of the Department of Health and Human Services (DHHS)
 - 3 principles formed the foundation for the conduct of research,
 - obtaining informed consent
 - respect for privacy and confidentiality
 - and risk/benefit assessment

Elements of Informed Consent

- **A valid consent is based on these critical elements:**
 - **COMPETENT:** The participant must be competent to begin the informed consent process. If due to age, illness, incapacity, or any other reason, special provisions apply, the participant may not be included in the research.
 - **DISCLOSURE:** All relevant information must be provided to the potential participant. The information must be sufficient to allow the potential participant to decide whether to participate. The following information must be provided: the purpose of the study; nature of the procedure; reasonable alternatives to the proposed intervention; and risks, benefits, and uncertainties of each possible intervention.
 - **COMPREHEND:** The participant must understand the information. The research team must evaluate the potential participant's ability to understand the proposed intervention in the study.
 - **AGREE:** The participant must agree to the proposed intervention in the research study.
 - **VOLUNTARY:** The participant's must agree w/o being coerced in any manner coercion.
 - **WITHDRAW:** Participants must be able to freely terminate involvement in the study at any time without penalty.

To Learn More....

- <http://cme.cancer.gov/clinicaltrials/learning/humanparticipant-protections.asp>
- Can complete a tutorial and receive a "Human Participants Protection Education for Research Teams" certificate

- IRB proposal

– Each group to complete a section of a proposal.

- Questions?

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