

RESEARCH OPPORTUNITIES IN MEDICAL TRAINING

Principles, Pitfalls and Pearls

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WESTERN
RESERVE
HOSPITAL

Proudly Physician Owned

Objectives

- ✓ Understand benefits of conducting research
- ✓ Discuss relevant opportunities
- ✓ Develop hypotheses and scholarly goals
- ✓ Explore resources at WRH
- ✓ Learn about current clinical trials at WRH

General Principles

- Strict scientific and ethical guidelines
 - Subject participation is voluntary
- Well-defined procedures and outcomes
- Contributes to a body of knowledge without reproducing established findings

Research vs. Treatment

National Institute of Health (NIH) definitions:

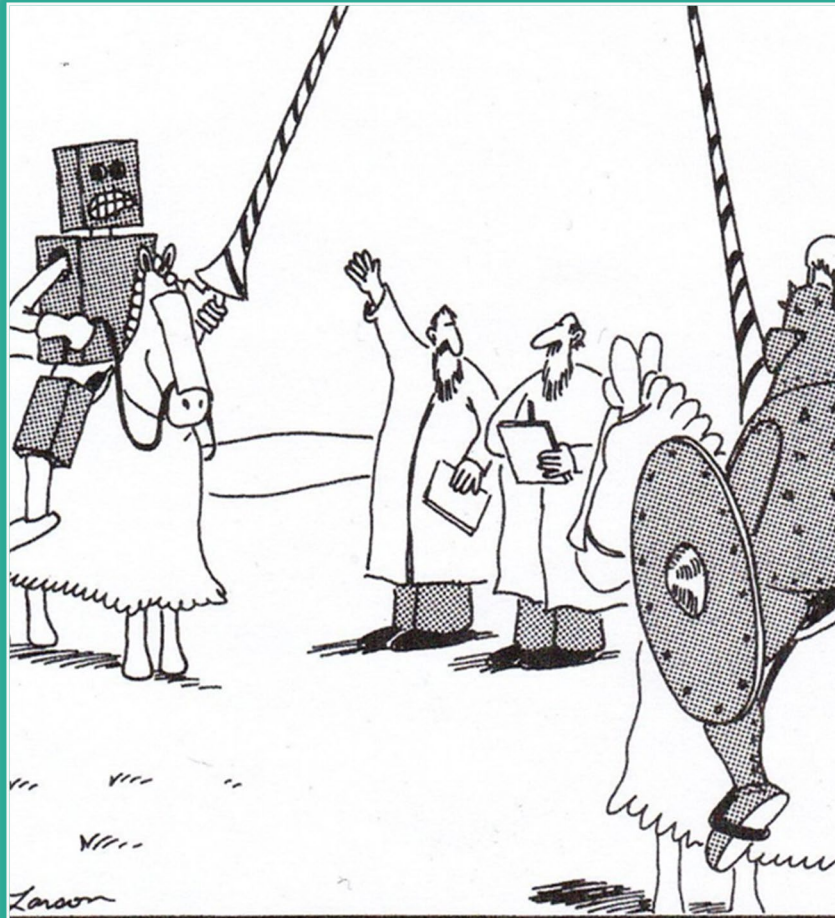
- ❖ **Research** is a systematic investigation to establish fact.
- ❖ **Treatment** is the care provided to improve a situation.



Why You Should Do Research

- Professional growth and enrichment
- Develop awareness of current literature
 - Identify leading centers, innovators, trends
- Gather info about your clinical practice
 - Identify inefficiencies, measure outcomes
 - Quality Assessment Performance Improvement (QAPI)
- Enhance your evidence-based approach
- Also . . . **IT'S REQUIRED ;)**

Areas of Investigation

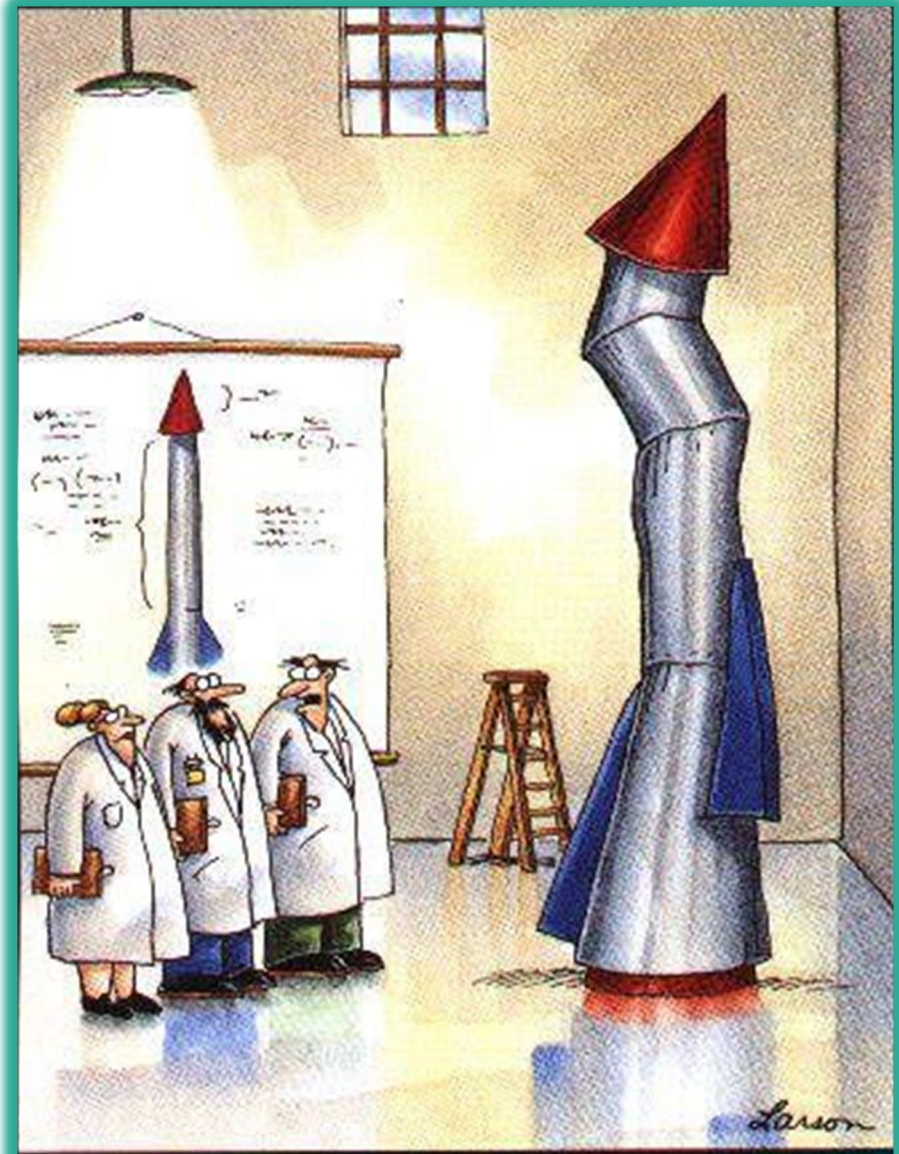


For a very brief period, medieval scientists were known to have dabbled in the merits of cardboard armor.

- Diagnosis
- Management
- Prevention
- Quality of Life
- Screening
- Treatment
 - i.e, Phase III drug trials

Study Types

- Descriptive
 - Case report*
 - Case series
- Exploratory
 - Retrospective*
 - Prospective
- Experimental
 - Clinical trials
 - Laboratory



"It's time we face reality, my friends. ...
We're not exactly rocket scientists."

Where do questions come from?

- Outpatient clinics
- Hospitals
- Surgical practices
- ED's

... anywhere!

- RN's
- MD's
- Pharmacists

... anyone!



Knowing how it could change the lives of canines everywhere, the dog scientists struggled diligently to understand the Doorknob Principle.

Dr. Ignaz Semmelweis (1818-1865)

- Hypothesized that lack of antisepsis after autopsies caused puerperal (childbed) fever at his hospital
- Findings led to antisepsis in medical practice
- Died of the same disease
- "I think with the greatest admiration of him and his achievement and it fills me with joy that at last he is given the respect due to him."
-Joseph Lister



WRH Resources

➤ WRH Research Site

www.westernreservehospital.org/education/resources/research.aspx

- Medical Librarian
 - Judy Knight
- Biostatistician
 - David Goddard
- GME Coordinators, Research fellow
- Attending physicians
- IRB's
 - Lake Erie College of Osteopathic Medicine (LECOM)
 - Western Internal Review Board (WIRB)



ProtocolBuilder[®]

- Tutorials, design templates, progress tracking

Web Resources

- **CenterWatch: Clinical Trial Resources** <https://www.centerwatch.com/>
- **Code of Federal Regulations (CFR)** www.access.gpo.gov/nara/cfr/
- **Collaborative Institutional Training Initiative (CITI)**
<https://about.citiprogram.org/en/homepage/>
- **Food and Drug Administration (FDA)** www.fda.gov
- **National Institutes of Health (NIH)** <https://www.clinicaltrials.gov/>
<https://ohsr.od.nih.gov/>
- **Office for Research, UVA School of Medicine**
<https://med.virginia.edu/office-for-research/>
- **Office of Human Research Protections** www.ohrp.osophs.dhhs.gov
- **Society of Clinical Research Associates** www.SOCRA.org

PEARLS



- Find topics of personal interest
- Start with case reports & retrospective studies
- Set goals
 - Publication, presentation at meetings, WRH poster contest
- Take advantage of all resources
 - Seek advice early
 - Identify personnel who need to be "in the loop"
- Meet regularly with mentor to discuss progress
- Adhere to all protocol and regulatory details

PITFALLS

- Going it alone
- Re-inventing the wheel
- Setting unrealistic goals
- Failing to disseminate findings



Clinical Research at WRH

- Traditionally, experimental research is associated with larger academic medical centers.
- Why smaller hospitals should do research:
 - To offer most current treatments
 - Access to a more diverse population
 - Be recognized as innovative
 - Revenue
 - To address local needs and interests

ORIGINAL CLINICAL RESEARCH

(INVESTIGATOR-INITIATED TRIALS)

Writing a Proposal

- Develop question/hypothesis
- Conduct literature review
- Design protocol & budget
- Submit proposals
- If approved:
 - Protocol, IRB, consent, regulatory compliance, data management, etc.
 - Standard Operating Procedures (SOP)

Sources of funding

- Government
- Professional societies
- Foundations
- Local Charities
- Private Industry

Clinical Trial Site Requirements

- Internal
 - Experienced researchers and coordinators
 - Cooperation within hospital
 - Lab, radiology, pharmacy, medical groups, etc.
 - Physicians willing to be investigators
 - Institutional Review Board (IRB)
 - Approves, monitors study design for safety & quality
 - Administrative support
- External
 - Collaboration with an academic center or sponsor

Personnel

Investigators

- Principal Investigator
- Sub-Investigators
- Research assistants
 - RN's, BN's, MA's
- Statisticians

Trained for specific roles with appropriate certifications

- *Good Clinical Practice (GCP)*
- *Association of Clinical Research Professionals (ACRP)*

Administration

- Research Coordinator
- Clinical Research Associate (CRA)
- Departmental staff
 - Pharmacists
 - Lab managers
 - Radiology
- Administration
 - Budgeting
 - Billing
 - Existing policies
 - Job descriptions and hiring



Interventional Drug

- SP-102
- Non-opioid injection
- For sciatic back pain caused by herniated disc
- Similar to standard epidural steroid injections

WRH as a site

- 20 screenings
- 2 enrollments

Design

- RCT
- 400 subjects
- 35 research sites
- 6 months duration
- Endpoints
 - Pain relief
 - Function
 - Side effects
 - Safety

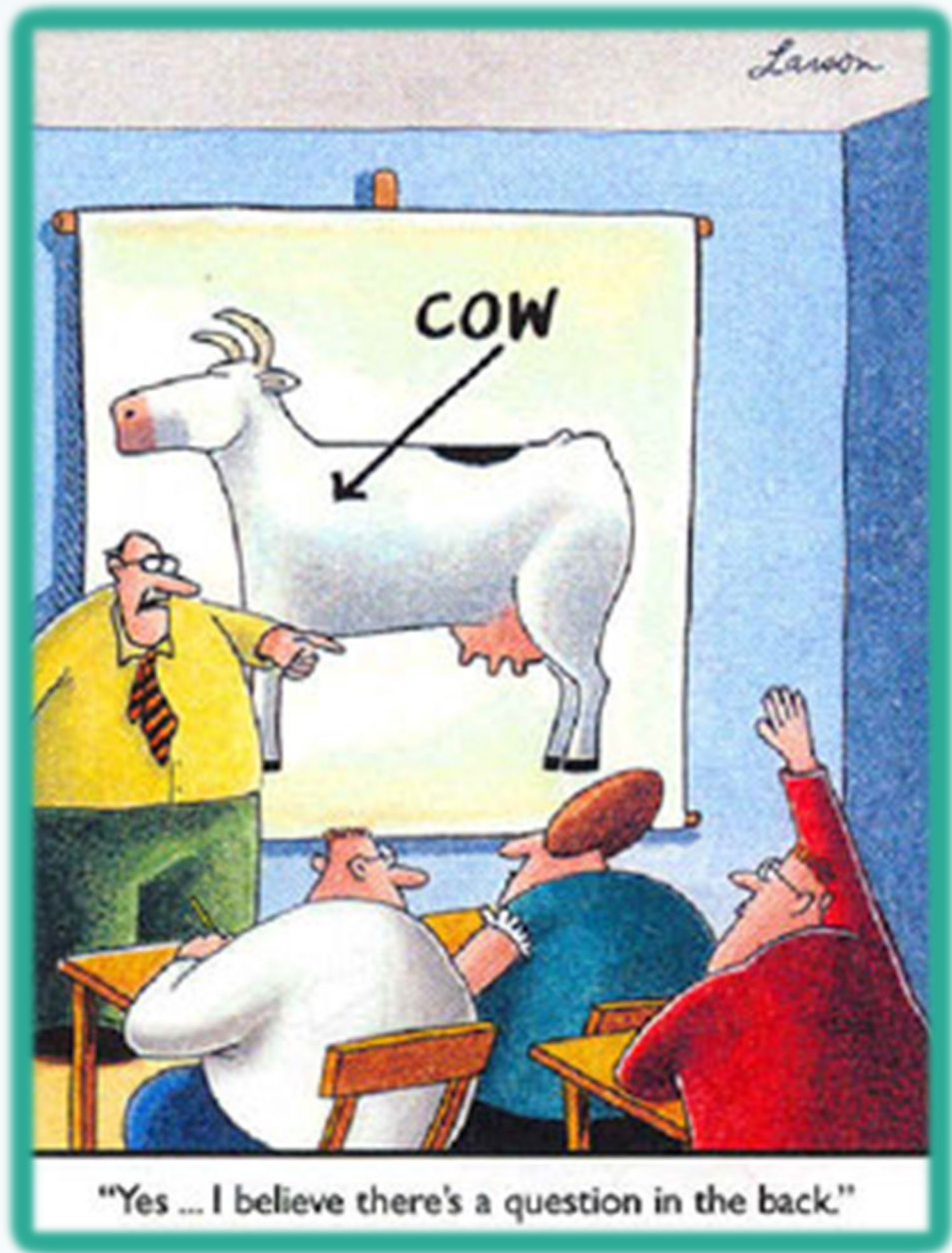
<https://www.clinicaltrials.gov/ct2/show/NCT03372161>

ReliaTack™ Articulating Reloadable Fixation Device

- Principle Investigator:
Dr. Gemma
- A fixation device for hernia repair
- Sponsor:  **Medtronic**



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"Yes ... I believe there's a question in the back."

References

- <https://www.socra.org/publications/past-socra-source-articles/setting-up-a-clinical-research-program-in-the-community-hospital-setting/>
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- J Oncol Pract. 2010 Jan; 6(1): 45–47. Basic Steps to Building a Research Program Allison Baer, RN, BSN, Naftali Bechar, MD, Gary Cohen, MD, and Susan Devine, CCRP
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