RESEARCH OPPORTUNITIES IN MEDICAL TRAINING
Principles, Pitfalls and Pearls

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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.

*Testing whether laughter IS the best medicine*
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

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

For a very brief period, medieval scientists were known to have dabbled in the merits of cardboard armor.
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
- RN’s
- MD’s
- Pharmacists

... anywhere!

... anyone!
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)

- Tutorials, design templates, progress tracking

ProtocolBuilder

- Tutorials, design templates, progress tracking
Web Resources

- CenterWatch: Clinical Trial Resources  https://www.centerwatch.com/
- Food and Drug Administration (FDA)  www.fda.gov
- Office for Research, UVA School of Medicine  https://med.virginia.edu/office-for-research/
- 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
"Yes ... I believe there's a question in the back."
References

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