Development of Clinical Research

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WHY?

- The joy of abstraction and contributing to generalizable knowledge
- Constructive channeling of criticism and skepticism
- Means of connecting to other disciplines, institutions, national-international dialogue
- Credential for promotion/program accreditation, source of income, add luster to our institution

HOW

- It starts with observations and ideas
- Do not think of clinical work and clinical research as separate activities
- Don’t re-invent the wheel
  - Refer to published articles (journal clubs)
- Seek mentorship and consultation

A paradox

- The best evidence is from randomized controlled trials

- An RCT requires pilot data, time, large numbers of cases, and financial support

Practical Designs

- Case report – case series
- Case-control
- Naturalistic longitudinal follow-up

Wilson’s paradox

- “Unfunded research is a hobby”
  - DE Wilson

- “It takes money to make money”
  - anon

Necessary Steps

- IRB (consent/ consent waiver)
- Transmittal Procedures and ORA/OSP for external applications (lead time)
- http://ovprc.howard.edu/

(link) “Human Participant Use”

- Forms
  - A1 > Minimal Risk
  - B1 Chart Review
  - C1 Other Minimal Risk Studies
  - D1 Exemption

Submissions for External Funding

- Link “Forms, Tools, and Checklists”
  - “Application to Seek Off Campus Funds”
  - Your application/budget
  - “Investigator Assurance Form”
  - “Conflict of Interest Form”

Office of Sponsored Programs – Research Administration: ora.howard.edu; 238-2580

Dana Hector – Manager, signing authority

Support for research activity

- Trainee effort (reciprocity)
- New faculty award/seed grant
- GCRC/CTSA
- Foundations (grantsnet.org)/other government (DOD)
- NIH
  - K series
  - R03 and R21
  - R01

Review Considerations

- Significance
- Approach
- Innovation
- Investigator
- Environment

- IMPACT

Outline for a Proposal/Report

I. Statement of a Problem (Background)

II. Specific Aims
   a. To… statements (determine, test, evaluate); subsidiary hypotheses

III. Methods
   a. Design
   b. Participants
      1) Recruitment (consent)
      2) Inclusion
      3) Exclusion
   c. Procedures (assessments)
   d. Analysis (Refers back to aims, hypotheses)

IV. Results (Just the facts)

V. Conclusions

I. Statement of a Problem

A. Argues significance (often by alternating between bad news and good news)
B. General to specific, integrates themes
C. What we know, what we need to know
D. Sets up objectives, aims

In Precis to Aims, amplified in Background/Significance

I. Specific Aims

A. Can be embedded in a general aim or goal

B. Specific enough to indicate methods including analysis

C. To… statements (determine, test, evaluate); subsidiary hypotheses

D. 3 optimal

Methods: Design

- Time context
  - Cross sectional
  - Retrospective
  - Prospective
- Naturalistic (Observational)
- Experimental –controls, factors
- Trial – control-comparison group, randomization, blinding

Methods II

- Participants
  - Recruitment; Process of Informed Consent
  - Inclusion and Exclusion criteria
- Assessments
- Procedures
- Analysis
  - reflect back to aims/hypotheses
  - Define variables;
    - continuous/ categorical
    - dependent/independent (predictor)
  - Tests
    - Is dependent measure continuous or categorical
    - Univariate/multivariate

Resources

- Individual mentors
- GCRC resources (consultation on stats, regulatory, conferences)
- Georgetown, Howard, VA, Medstar network (GHUCCTS)