

# 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](http://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](http://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)