INTRODUCTION TO RESEARCH REQUIREMENTS

Identifying a Research Question, Writing your Hypothesis, and Selecting your Research Project Mentor

Annie Laurie W. Shroyer, Ph.D., M.S.H.A.

Professor and Vice Chair for Research, Department of Surgery

Goal

Support New Trainees Identifying Potential Research Project Opportunities

- **Audience**:
  - **New trainees** -- that don't yet have a scholarly project planned and/or mentor selected begin to explore research project opportunities
  - **Advanced trainees** – to serve as advisors guiding new trainees to help them identify research project opportunities

Identifying your own Research Question(s)

- Specify your overall research question (s)
  - Biomedical Research Challenges
    - High volume
    - High cost
    - Gap in Knowledge – Unsolved mystery
    - Rare diseases or Rare Treatments
  - Evaluate your question's value added
    - Answer the "SO WHAT?" – potential impact factor

HANDOUT: Take Pen to Paper

- **New Trainee Assignment**
  - List **three broad research topics** that you may be interested in at this time
  - For one of these topics, ask **one research question** that you are curious about
  - For this topic/question, the trainees in current projects will help to identify **at least one faculty member** that has clinical and/or research expertise in this field

HANDOUT: Take Pen to Paper

- **Advanced Trainee Assignment**
  - List **research project(s)** (up to 3) that you are working on currently
  - For each project, put **one research question** that you are investigating
  - For this topic/question, identify **at least one faculty member** that serves as a faculty mentor/advisor for each project for you

Selecting your Research Question

- STUDENT ⇔ INTEREST "FIT": What background, experience, and knowledge might you have as a "fit" with potential research topics?
- MENTOR AVAILABILITY: What expertise might available faculty mentor(s) have for potential research topics?
- LITERATURE BASED "GAPS": What are recent controversial topics in the literature?
- RECENT FINDINGS: What findings and problems observed in prior studies – as "hot" topics?

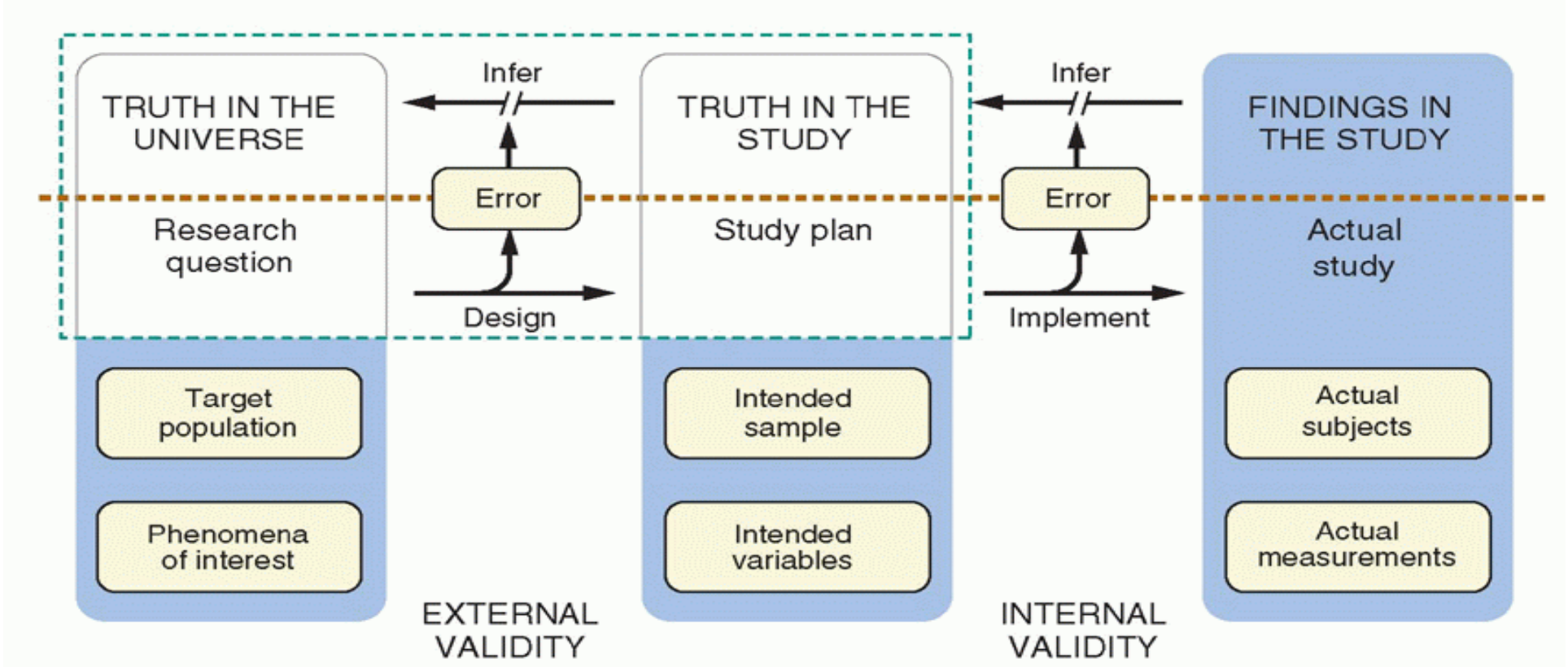
Selecting your Research Question (continued)

- IMPORTANCE: What are important , outstanding research questions to be able improve population health and/or to identify how best to diagnose and/or treat patients?
- TECHNOLOGY: What are new technologies emerging?
- PROFESSIONAL SOCIETY: What are key challenges or patterns emerging as identified at recent professional conferences?

Research Project Plan

- A **primary research question** is needed
  - Often with secondary questions
- And **a plan to answer the question**
  - By testing one or more proposed explanations (hypotheses)

Overarching View of Research



SR Cummings, WS Browner, SB Hulley

Good Research Questions

- **FINER Criteria**
  - **F**easible
  - **I**nteresting
  - **N**ovel
  - **E**thical
  - **R**elevant

- Key requirements of a good research question

FINER Criteria

- **Feasible**
  - Is your research project topic:
    - Too broad a focus? Too narrow a focus?
    - Too recent as a field of study?
  - Is there a faculty mentor available for oversight?
  - Is the research question applicable to current "real" world situations?
  - Are enough patients and/or records available?
  - Are the time and deadline requirements reasonable?

FINER Criteria

- **Interesting**
  - Finding the answer – getting at the truth – intrigues you, your colleagues, reviewers, and funding decision-makers
  - Represents an unanswered mystery

FINER Criteria

- **Novel (innovative)**
  - Generates new knowledge by providing new findings
  - Shifts paradigm of research or clinical practice
  - Refutes previous findings
  - Confirms or extends previous findings

    - *Clarify = How might your research planned be different than other existing publications and fill a "gap" in knowledge?*

FINER Criteria

- **Ethical**
  - Must be amenable to CORIHS
    - IRB approval
    - IACUC approval
    - Written exemption
  - No conflict of interest

FINER Criteria

- **Relevant (important)**
  - To improve care of patients or to healthcare broadly
  - To expand scientific knowledge
  - To support future research
    - What is the potential impact?
    - Who are the key stakeholders?
    - Will the research change decisions at the patient-level, provider-level, program management, or health policy?

Phases of Research Inquiry

- **Exploration** -- Rough Understanding of Some Phenomenon
- **Description** -- Precise Measurement and Reporting of the Characteristics of a Population/Phenomenon
- **Explanation** -- Discovery and reporting of relationships among different aspects of the phenomenon

Variables

- Independent Variable -- Possible Causes or Treatments (Intervention)
  - predictor
  - controlled variable
  - manipulated variable
  - explanatory variable
  - exposure variable

Variables

- Dependent Variable -- Possible Effect or Outcome (Results)
  - response variable
  - measured variable
  - responding variable
  - outcome
  - study endpoint

PICOS – Basic Information

- Patients
- Intervention
- Comparison
- Outcome(s)
- Study Design - Details

Patient Populations Studied

- **Inclusion Criteria** --Characteristics that define the population that will be relevant to the research question
- **Exclusion Criteria** -- Removing sub-sets of the population that may have:
  - possible competing factors impacting outcome
  - loss to follow-up
  - inability to gather high quality data

Hypothesis

- A formal and testable statement of relationships between dependent and independent variables
  - Null hypothesis (H_0) postulates no relationship or a random relationship between these variables.
  - Alternative hypothesis (H_1) postulates a relationship and may state the directionality of this relationship.

Evolution of Study Designs

- Most research studies hope for a "positive" result
  - New approach will be significantly better than the standard approach used
- Increasingly frequently, investigators seek to show that a therapy is equivalent in efficacy to a standard therapy
  - Comparing a conservative treatment with a more intensive, invasive or toxic standard therapy
  - Comparing a less costly treatment with a more costly approach

Null and Alternative Hypotheses

Easily confused for different trial design approaches

- Study design depends on type of research question:
  - Superiority trials
    - new treatment is hypothesized to be better than traditional treatment
  - Non-inferiority trials
    - new treatment is no worse than traditional treatment
  - Equivalence trials
    - Two approaches are indistinguishable

What is Need to Prove a Hypothesis?

- Confirming Evidence -- Based on Inductive Reasoning
- **Disconfirming Evidence** -- Based on Deductive Evidence
  - Data show the Null Hypothesis is likely False

Rationale

- Evaluate the test statistics for the null hypothesis using appropriate analytical approach
- Assuming the **null hypothesis is true**, the p-value is the probability of obtaining a test statistic as extreme or more extreme as the one observed
- Generally, the **alternative hypothesis is accepted** and the null hypothesis is rejected if the p-value is less than a pre-established threshold (e.g., $p \leq 0.05$ or $p \leq 0.01$)

Begin to Narrow Your Research Project Focus
What is Fun AND Feasible for you to do?

- Quantitative
  - **Interventional Study Design**
    - Randomized, Control Group, Blinded Trial (RCBT)
    - Quasi-Experimental Study
  - **Observational Study**
    - Cohort
    - Case Control
    - Cross-Sectional Analysis
- **Qualitative**
  - Exploratory Study – Case Series Report
  - Descriptive Case Report

Study Timing Choices

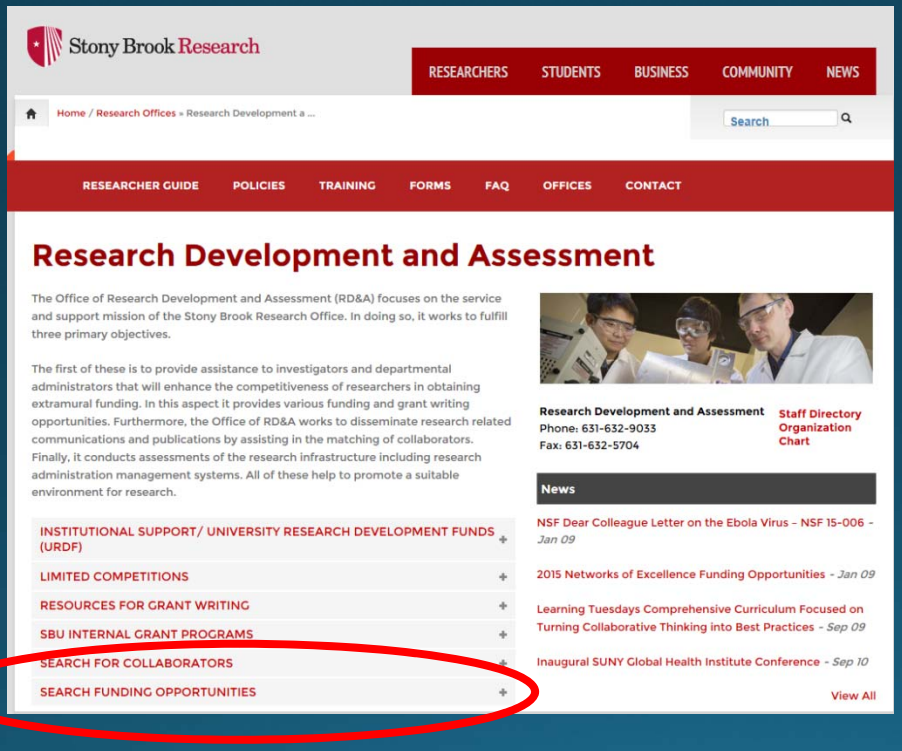
- **Prospective**
  - Sample and predictor variables defined before any outcomes measured
  - Design Proceeds Outcomes Measurement
- **Retrospective**
  - Sample and data capture occur after outcomes have occurred
  - Design Follows Outcomes Measurement

Range of Outcome(s)

- Mortality
- Morbidity (new occurrence of complication)
- Lab measure (e.g., low density lipoprotein)
- Clinical measure (e.g., pulse)
- Side effects or subsequent care required
- Quality of life
- Patient satisfaction
- Length of stay
- Cost of health care

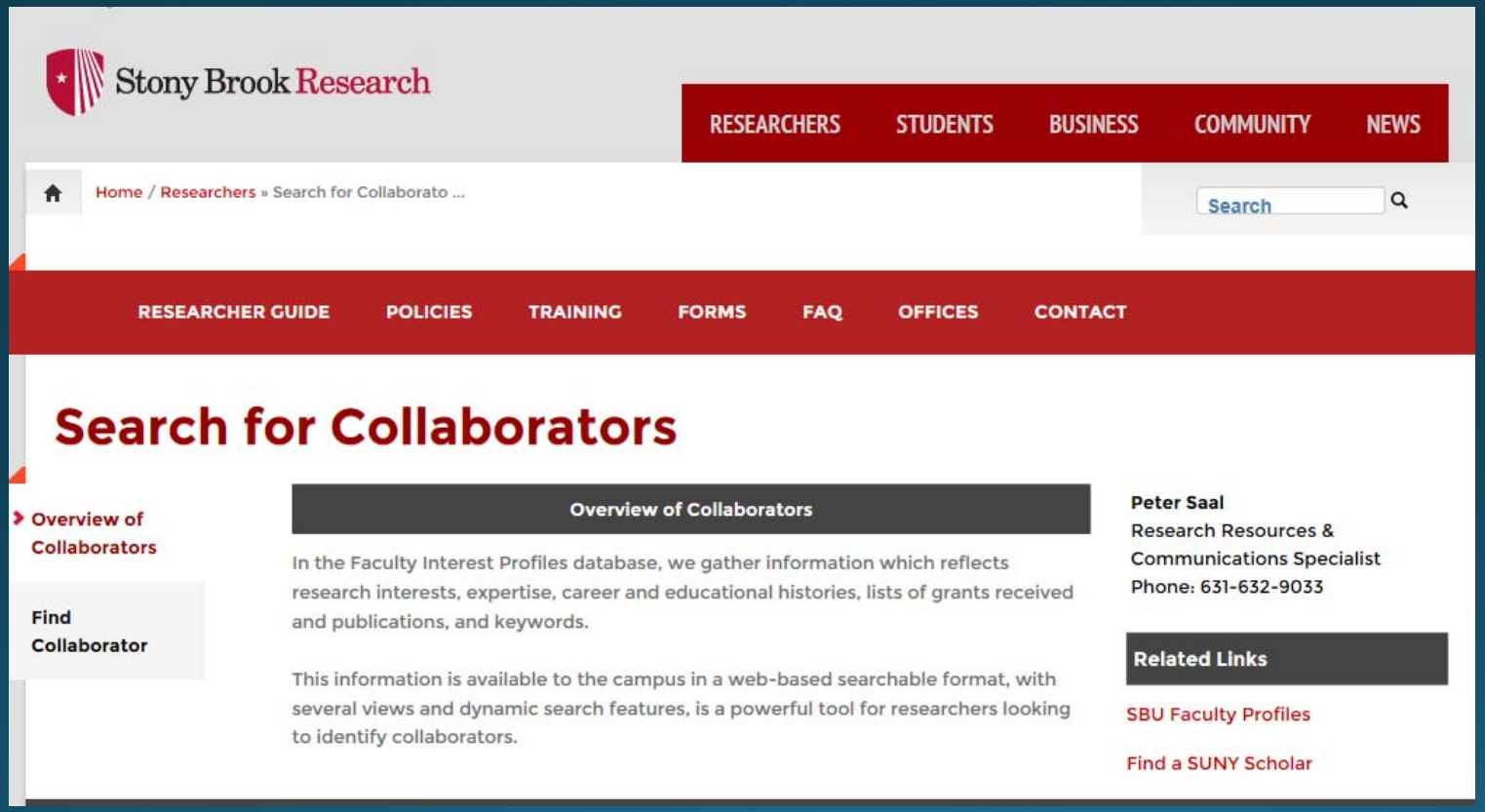
Funding Options

- Ideally, identify at least one research funding opportunity that may be appropriate for consideration.



- http://research.stonybrook.edu/rda

Faculty Collaborations



- http://research.stonybrook.edu/search-collaborators#Overview-of-Collaborators-

Mentor Agreements

- **AAMC Mentoring Agreement- Example**
- Examples of Goals/Objectives/Activities
  - Create an individualized career development plan (e.g., identified professional goals with action oriented specific career objectives as well as tentative time line planned);
  - Present at one national professional society meeting; and/or
  - Submit at a manuscript in a peer-reviewed journal.

Examples of Roles and Responsibilities in Mentoring Partnership

OVERALL GOALS

Increase potential for academic success, and thus increase number and diversity of successful senior faculty.

Increase collaboration and networking opportunities.

Provide a structured system for strengthening and assuring the continuity of organizational culture.

ROLES OF EACH

Mentee: ask for career, professional and personal advice on issues of teaching, research, promotion, tenure, and the collegial culture; be available for networking opportunities and introductions to key individuals by Mentor.

Mentor: guide Mentee in personal and professional issues; participate in open, honest, goal setting and feedback for academic career advancement; introduce Mentee to individuals who can facilitate career advancement.

Both: complete Mentoring Partnership Agreement; evaluate the partnership

GENERAL GUIDELINES

Partnership duration: clearly defined duration

"No fault" divorce clause if the partnership is not working for either party – after discussion and evaluation of the mentoring partnership together.

Contact: generally established by Mentee.

Contact frequency: recommend frequent contact for guidance, at agreed-upon intervals.

Mentoring Partnership Agreement

The Partnership will be for six months. Below are examples of objectives you may wish to achieve; feel free to add your own individual goals. Having defined your goals, then list specific actions you will take to achieve them.

Examples of Objectives for a Mentoring Partnership:

- Support, encouragement & sharing of experience in implementation of Mentee and/or Mentor goals (e.g. writing paper).
- Professional support and career guidance as appropriate (e.g. preparing promotion documentation).
- Opportunities for educational, research or clinical collaborations.
- Additional objectives:
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Specific Objectives and Actions to Achieve the Objectives:

Mentee	Mentor
1	1
2.	2.

Year One	Year Two
Complete Research-Related Trainings	Obtain All Required CORIHS Research Project Approvals
Identify Potential Research Project Options and Mentor(s) to Consider	Begin Your New Research Project
Attend Potential Mentor Team Meetings and Finalize Mentor Choice	Present Preliminary Research Project Findings at Meeting
Develop Research Project Proposal with Mentor Team	Complete Research Project and Submit Manuscript to Peer-Review
Submit for Publication a Case Study/Series, Systematic Review or Book Chapter Review	Write and Submit Grant Proposal

Resources – Research Leaders

- **Dean's Office**
  - Dr. Lina Obeid – Vice Dean for Research
  - Office of Scientific Affairs
  - https://www.osa.sunysb.edu/
- **Departmental Web Sties**
  - Vice Chairs for Research
  - Division Chiefs
  - Senior Faculty
- **Other Key Resources**
  - Dr. Margaret McNurlan
  - x4-8095 or Margaret.McNurlan@stonybrook.edu

Thanks!


What you do today can improve all your tomorrows.
Ralph Marston