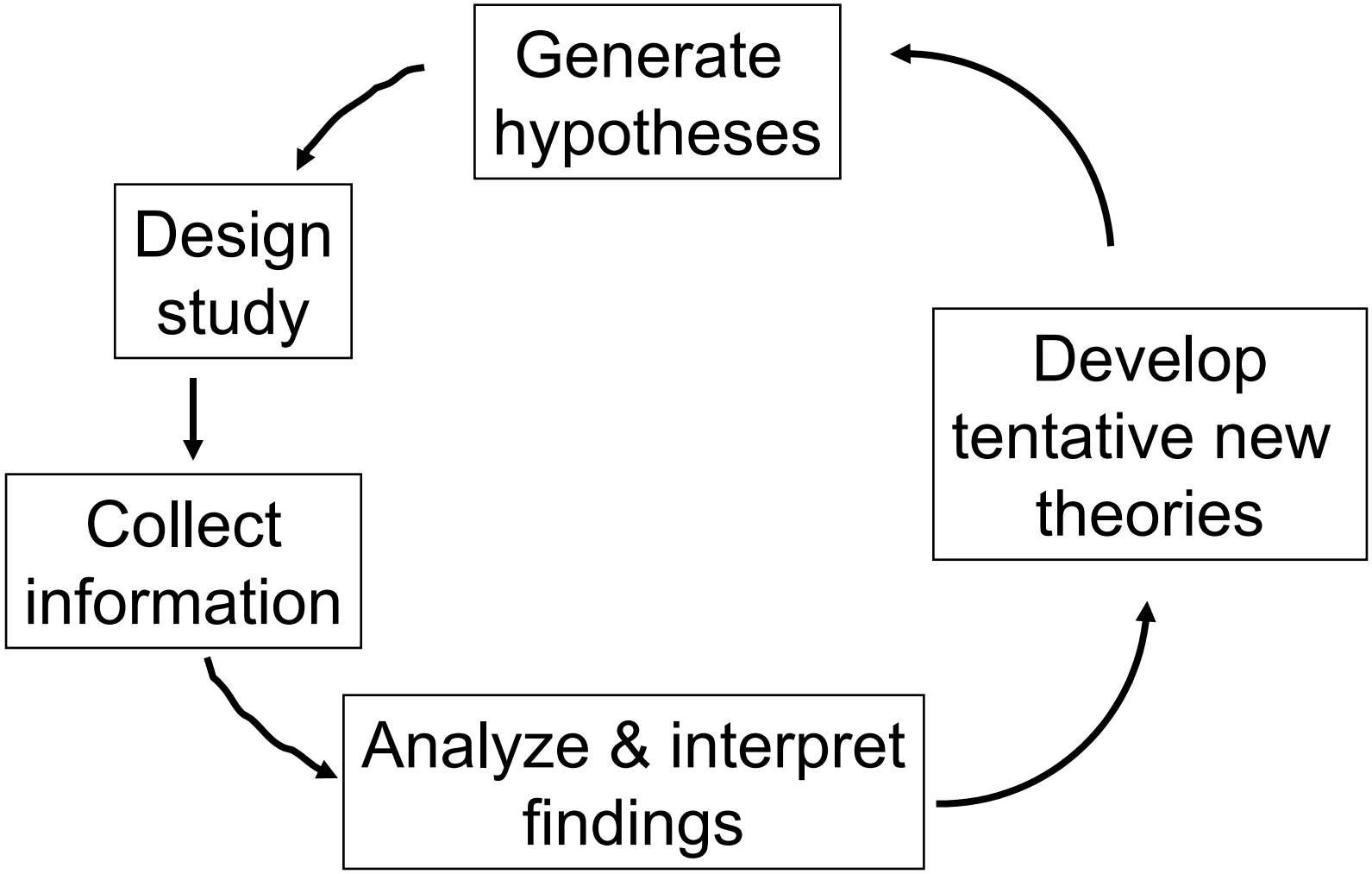
Survival Skills for Researchers

Study Design

Typical Process in Research



Purpose

- What is main purpose of research?
  - Ask questions and find answers!
- Have you ever conducted a study and not been able to reach conclusions about the results?
- Did you plan...

Goals of Study Design

- To formulate research question, choose specimens, plan measurements, plan analysis
- Maximize ability to infer from findings in study to truth in world

Drawing Conclusions

- Internal validity: Validity of conclusions drawn within study as based on actual findings

Generalizing

- External validity: Validity of inferences drawn from study to world outside study (also called *Generalization)*

Consideration of validity in design

- Maximizing validity should be considered in all parts of study design, implementation, and analysis
- Be a skeptic; look for and minimize sources of error

Steps in Study Design

- Formulate research question
- Identify subjects/specimens and plan technique for obtaining them
- Identify variables and plan measurements
- Formulate testable hypothesis and plan statistical approach

Formulating the Research Question

Research question is formulation of uncertainty about science or engineering that you wish to explore or resolve

- Find research topic of interest
- Narrow topic to research question
  - Important; results should be beneficial to science/engineering
  - New
  - Workable (not every problem is researchable)

Research Question

- State unresolved issue in terms of
  - Properties of interest
  - Specimens of interest
- Put the research question in writing

Observation/Experiment

- Observational study: Investigator observes uncontrolled events, measures variables without altering them
- Experimental study: Investigator controls an intervention or imposes a treatment

Selecting Subjects or Specimens

- Define broad, target set of interest and decide on experimental units
- Goal: To be able to extend findings in specific study specimens to associations in a population; to find a representative test group

Choosing Study Subjects: Basic Concepts

- Population: Complete set of subjects or measurements with specified set of characteristics
- Sample: Subset of population
- Subject or experimental unit: Object upon which measurements are made

Identifying Variables and Planning Measurements

- Define phenomena of interest, identify actual variables, and plan measurements of those variables
- Goals: To pick variables that represent phenomena of interest and to measure those variables with accuracy and precision

Basic Concepts: Independent and Dependent Variables

- Independent variables: Either controlled by investigator in experiment or chosen as predicting variable in observational study
  - Other names: Factors, predictor variables, explanatory variables
- Dependent variables: Measured as outcome
  - Other names: Outcome variables, response variables

Accuracy

- Accuracy: Degree of agreement between result of measurement and true value of the quantity measured
- Use measurement that actually measures what it is supposed to represent

Precision

- Precision: Degree of agreement of repeated measurements using same protocol
- Insure that measurement would have about same value each time it is measured

Strategies to Increase Accuracy & Precision

Plan to:

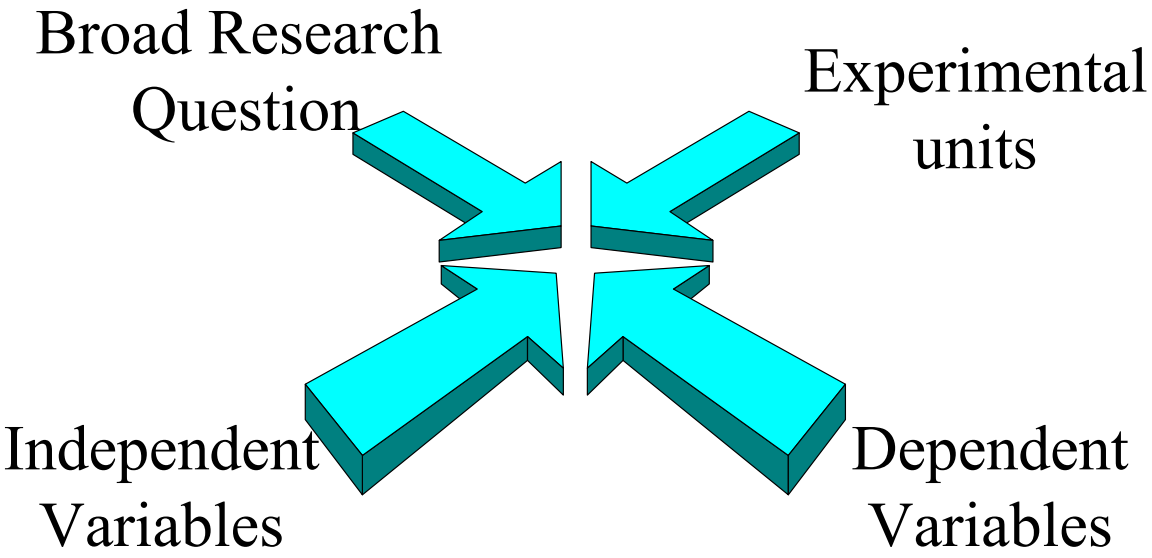
- Use standard operating procedures
- Train observers
- Calibrate instruments
- Automate measurements
- Use objective measures when possible
- Blind observer and subject

Formulating Hypothesis

- Hypothesis: Tentative statement that can be tested or investigated. Often involves explanation of phenomenon and states idea about cause and effect explicitly
- Goals:
  - Immediate: To establish strategy for analysis
  - Long-term: To be able to draw conclusions at end of study that actually answer research question

Research Hypothesis

- Formulate practical version of research question - *research hypothesis*
- Base it on research question, intended experimental units, and variables of study



Statistical Hypotheses

- Proof by contradiction
- Set up null and alternate hypotheses
  - Null: There is NO association
  - Alternate: There IS an association
- Show support for research hypothesis by rejecting null hypothesis

Choosing Analytical Approach

- In studies of associations between variables, statistical approach is determined primarily by type and scale of variables
- Decision trees can be used to aid in choosing statistical technique during design phase
- Note that final method may change after implementation -- violation of assumptions

References

Hulley SB and Cummings SR: Designing Clinical Research, Williams & Wilkins, 1988