

THE RESEARCH PROTOCOL: WHAT, WHY, WHO, HOW, AND SO WHAT

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THE RESEARCH PROTOCOL

WHAT?

WHY?

WHO?

HOW?

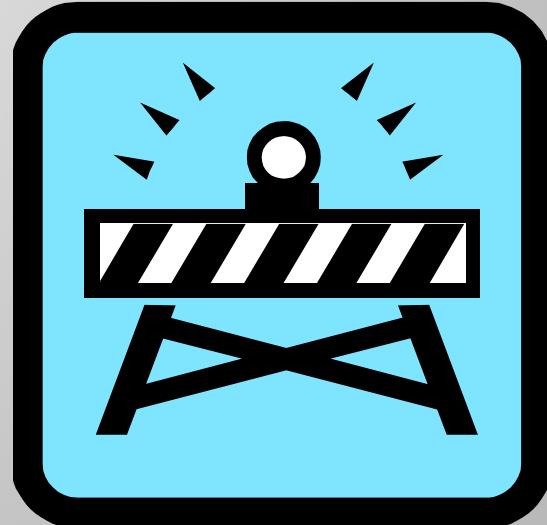
SO WHAT?

OBJECTIVE

To review the basic elements of the research protocol and identify where the essential questions what, why, who, how, and so what may be answered.

OBSTACLES

Good research ideas are sometimes hindered by poor communication of the written plan to carry out the research.



OBSTACLES

Protocol issues frequently cited by reviewers

- Inadequate justification of sample size
- Questionable feasibility
- Analysis plan missing or inappropriate for the design
- Insufficient background and rationale for the study
- Inadequate description of procedures
- Hypothesis statement or aims are vague/not clear

A WELL-WRITTEN PROTOCOL WILL:

- Avoid delays in approval
- Facilitate study implementation and conduct
- Reduce errors and protocol deviations

A PROPOSAL OF RESEARCH VS. A PROTOCOL FOR RESEARCH CONDUCT

PROPOSAL

- Presentation of an idea for research
- emphasis on rationale and innovation
- generally intended to solicit funding

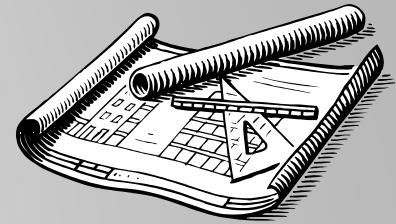
PROTOCOL

- Detailed plan of how a study is to be carried out
- emphasis on study procedures

THE RESEARCH PROTOCOL

- IRB Review
- Study implementation planning
- Guide for study conduct

THE RESEARCH PROTOCOL



Your research protocol is your blueprint for conducting the study and should allow assessment of:

1. Scientific merit
2. Safety of human subjects
3. Procedures for conducting the study

ESSENTIAL QUESTIONS TO BE ANSWERED BY THE PROTOCOL



WHAT
WHY
WHO
HOW
SO WHAT



WHAT?

- What is the research about?
- What question(s) is the research intended to answer?



WHY?

Reason or rationale for study



WHO?

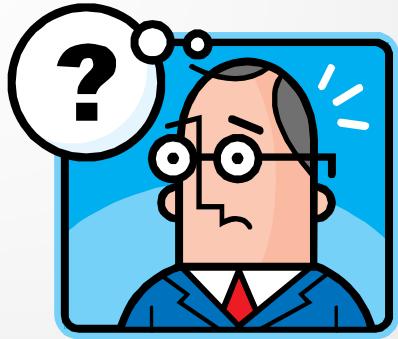
Who will be the subjects

- Target population
- Study population
- Inclusion/exclusion criteria



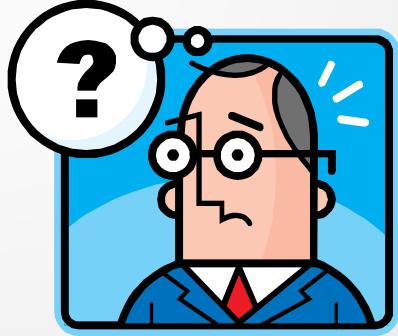
HOW?

- Study design
- Study procedures
- Sample size and/or power
- Data analysis



SO WHAT?

- Significance of findings
- Impact on practice
- Contribution to knowledge



SO WHAT?

“If a research project is not worth doing at all, it is not worth doing properly”

Protocol Section	Essential Questions
Specific Aims	WHAT: outcomes and predictors WHO: study population
Background	WHY: rationale SO WHAT: significance
Research Design and Methods	WHO: study population HOW: study procedures
Data Analysis	WHO: study population and how many HOW: analysis plan
Human Subjects Protection	WHO: subject recruitment and enrollment HOW: informed consent, confidentiality

STUDY TITLE

A descriptive study title can convey

- Research question or objective
- Research design
- Study population
- Outcome and predictor measures

The WHAT, WHO, and HOW of the research

STUDY TITLE

EXAMPLE (Industry)

A phase II, randomized, double-blind, placebo-controlled study to evaluate the safety and efficacy of drug X in patients with disease Y

WHAT

HOW

WHO

STUDY TITLE

HOW

EXAMPLE (non-industry)

A randomized, controlled trial to determine the impact of regular exercise on the blood glucose levels of elderly patients with type 2 diabetes

WHAT

WHO

SPECIFIC AIMS

The specific aims section clearly conveys WHAT the study is about, WHO the study population is, and outcome and predictor measures

SPECIFIC AIMS

- Clear statement of the research question
- Statement of hypothesis
- Study objectives listed as primary, secondary, exploratory

SPECIFIC AIMS

The research question drives the design, procedures, and analysis of the study.

The research question should be FINER

- Feasible
- Interesting
- Novel
- Ethical
- Relevant

SPECIFIC AIMS

Specific aims derive from the research questions

Aims should be SMART:

Specific: precise, avoid being vague

Measureable: quantifiable

Achievable: feasibility

Relevant: beneficial

Time-bound: achievable within study period

SPECIFIC AIMS

Study objectives/aims should be prioritized as:

- Primary
- Secondary
- Exploratory

BACKGROUND AND SIGNIFICANCE

- WHAT the study is about
- Review of the literature
- Identify short comings of previous studies
- Need for further research
- Make the case for WHY the proposed study should be done
- Implications of the findings (SO WHAT)

RESEARCH DESIGN AND METHODS

Description of strategies to be used to answer the research question and accomplish each specific aim.



STUDY DESIGN

HOW

A statement on the type of study indicates the methods to be used.

- Randomized, controlled trial
- Cross sectional survey
- Retrospective, case-control study
- Prospective, cohort study

STUDY POPULATION

WHO

- Description of study population
- Inclusion/exclusion criteria
- Sources of recruitment
- Feasibility of recruiting sample size
- Follow up and retention strategies

STUDY PROCEDURES

HOW

Detailed description on
how the study is to
be conducted.



STUDY PROCEDURES

- Recruitment, sources and methods
- Screening and enrollment
- Randomization plan
- Visit schedule with description of study activities/procedures
- Lab tests and methods
- Specimen preparation, handling, storage, shipping
- Clinical evaluations, i.e. physical exams, scans
- Data collection

STUDY PROCEDURES

Describe plans for data safety and monitoring

- Potential adverse events, detection and plan for reporting
- Safety monitoring plan, i.e. DSMB, and interim reviews

STATISTICAL CONSIDERATIONS

HOW MANY



Sample size determination based on:

- Expected effect
- Variability of the outcome measure
- Acceptable type I error rate
- Acceptable type II error rate

STATISTICAL CONSIDERATIONS

HOW MANY



Also consider:

- Non-response and losses to follow up
- Multiple comparisons and interim analyses
- Study design and method of analysis/test statistic

STATISTICAL CONSIDERATIONS

HOW MANY



Other justifications for sample size

- Time
- Availability of subjects
- Costs/budget

NOTE: Sample size should never be arbitrary

STATISTICAL CONSIDERATIONS

HOW

DATA ANALYSIS PLAN

How the data will be analyzed, including hypotheses to be tested, the test statistic to be applied, and level of statistical significance for:

- Primary outcome
- Secondary outcomes
- Exploratory outcomes

SUMMARY

A well designed, well written protocol should address the questions WHAT, WHY, WHO, HOW, and SO WHAT sufficiently to allow for determination of both scientific merit and safety of human subject.

SUMMARY

Poorly designed research is unethical