

What to Include in a Research Protocol

(See page 3 for *Preparing a Database / Chart Review Study*)

Label it: Include title, PI name & version date/version number

1. PURPOSE AND BACKGROUND

- _____ a. Brief references to literature and statements of the problem, purpose of the study, research question (and hypothesis if appropriate)
- _____ b. Relevance and importance of the problem stated
- _____ c. Justification for study involving humans
- _____ d. Specific aims of the research: state concisely and realistically what the research is intended to accomplish.
- _____ e. Background: briefly state the background of the study. Include a critical evaluation of existing knowledge, and specifically identify the gaps which the project is intended to fill.

2. STUDY DESIGN

- _____ a. Type of study design
- _____ b. Principle variables or outcome measures stated
- _____ c. If a treatment efficacy study, size of a clinically important difference stated; if there are multiple efficacy parameters, primary efficacy parameter stated

3. SUBJECTS

- _____ a. Subjects defined and subject sampling method described
- _____ b. Number, reason for choosing this sample size
- _____ c. Source of subject population (i.e., clinic, private practice, general population)
- _____ d. Criteria for inclusion and exclusion
- _____ e. How will subjects be identified for study inclusion? By review of medical records or hospital database, advertisement, previous research participation?
- _____ f. Will your method of identification and/or recruitment violate subjects' expectations of confidentiality regarding their medical records or history in ANY way?
 - If yes, how are you addressing the issue?
 - If no, how are you assuring this?

4. METHODS

- _____ a. Methods clearly described
- _____ b. Clearly describe procedures involving subjects
- _____ c. Special procedures (investigational drugs, radioisotopes, electrical equipment, etc.)
- _____ d. Frequency and duration of each procedure
- _____ e. Location of research procedures
- _____ f. Validity and reliability of measurement tools addressed
- _____ g. If subjects to be randomized, randomization procedure stated
- _____ h. Potential biases or problems identified and addressed

5. DATA ANALYSIS

- _____ a. If the study is designed to test a hypothesis, sample size derivation explained and appropriate power issues addressed
- _____ b. Specific statistical analysis methods stated and appropriate
- _____ c. Dependent and independent variables stated or variables to be analyzed stated

6. POTENTIAL BENEFITS

- _____ a. Benefits to the individual subjects and/or parent, if any.
- _____ b. Benefits to the population from which the subject is drawn
- _____ c. Benefits to science, society, humanity in general

7. POTENTIAL RISKS

- _____ a. Psychological, social, physical, economic, violations of normal expectations
- _____ b. Legal: How will findings of child abuse or reportable illegal behavior be addressed?

8. PRECAUTIONS TAKEN TO MINIMIZE RISKS

- _____ a. If confidentiality is an issue, specify how it will be managed, i.e., coding procedures; storage of and access to identifying data; when data will be destroyed. [Please note that management of risks does not change “risk” classification to “no risk”.]

9. COMPENSATION OF SUBJECTS

- _____ a. Will subjects be paid? If yes, how much and when.
- _____ b. Will there be any extra costs, such as extra lab tests or procedures, required by the research that would not normally be required for treatment?
- _____ c. Will the subject/parents insurance be billed for research related costs?

10. OTHER INVESTIGATORS

- _____ a. Will there be other investigators involved in the study, in addition to those you have listed on the application form?
If yes, how will you assure they are qualified and trained to participate as an investigator?

11. INSTRUMENTS (attach all questionnaires, test batteries, etc.)

- _____ a. How will this information be stored to assure limited access?
- _____ b. Will any subject identifiers be stored separately?

12. DATA AND SAFETY MONITORING PLAN

- _____ a. Type of Safety Information to be collected
- _____ b. Frequency of collection & review of safety data
- _____ c. Statistical tests to determine if harm is occurring
- _____ d. Conditions that trigger immediate suspension of research, if applicable

13. PROVIDING FOR PRIVACY, CONFIDENTIALITY, AND INFORMATION SECURITY

- _____ a. Describe the plan to protect the subject’s privacy and confidentiality of the data.
Procedures should be in compliance with all applicable VA and other Federal requirements.

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11. DATA AND SAFETY MONITORING PLAN (if applicable)

- _____ a. Discussion with the subject of potential study outcomes that may have an effect on the subject’s health or well-being
_____ b. A plan to notify individual subjects or their health care providers of findings that may affect the subjects’ health.

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