

Title:

PI:

Note: Protocol headers/footers should include page numbers, protocol version number, date, protocol name or descriptive identifier, PI name, and Sponsor (if applicable)

ELEMENTS OF A CLINICAL RESEARCH PROTOCOL

Title Page: *The title page should include the elements listed below that are applicable to your study. Include name, department, address, phone and email contact information for each individual listed.*

Study Title:

Principal Investigator:

Sub-Investigator(s):

(Mentor/Advisor)

Medical Monitor:

Laboratory(ies):

Study location:

Sponsor:

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Table of Contents - *Required for FDA-regulated studies; recommended for all protocols.*

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I. Abbreviations/Definitions

Required for FDA-regulated studies; recommended for all protocols. Define all abbreviations, measurement units, and/or particular or peculiar terms used throughout the protocol.

II. Protocol Summary

Provides a brief synopsis of the study, generally no more than 1-2 pages (manuscript abstract format).

III. Background and Rationale

Establishes the significance of the topic to be researched and provides conceptual framework for addressing the hypothesis(es). Justifies proposed methods for intervention and assessment. Should include a statement placing the study in the context of the development or proposed use of the test article (if applicable).

Title:

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IV. Hypothesis and/or Specific Aims

Should clearly state the hypotheses to be tested and the objectives or specific aims.

V. Test Article

Required for FDA-regulated studies. Provides a brief description of the investigational product/device. If applicable, include information on formula/strength, route of administration, dosing schedule, and manufacturer/make/model (devices).

VI. Study Design and Procedures

Must provide details of clinical study design, including an in-depth narrative of the methodology to be employed. Flow charts or study calendars may be used to describe procedures and tests. Identify if any procedures are already being performed for diagnostic or treatment purposes.

VII. Study Population

This should include the study inclusion/exclusion criteria; expected number of subjects to be enrolled and age range of the subjects. If the study is a chart review only, the source of the data and data elements must be listed.

VIII. Risks and Benefits

This should provide the expected risks and benefits of the study procedures and the procedures taken to minimize those risks. Provisions to protect subject privacy and the confidentiality of the data should also be addressed.

IX. Efficacy Assessments

Provides a description of the outcome measures and endpoints to be used to evaluate efficacy of the experimental procedures.

X. Safety Assessments

Provides details for how adverse events, serious adverse events, and/or unanticipated adverse device effects will be captured and reported to the Sponsor and FDA. (See Suggested Language for Select Protocol Sections).

XI. Data Handling and Recordkeeping

Provides information on the method(s) for data collection and specifies data collection tools. Should also address confidentiality, de-identification of data, data storage, and security measures. (See Suggested Language for Select Protocol Sections).

XII. Statistical Plan

Provide details of planned data analyses and statistical considerations. In addition to proposed statistical analyses, when appropriate, this section should include a justification of the sample size and a statement regarding power based

Version #:

Date:

Page 2

Title:
PI:

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on one or more of the primary outcome measures.

XIII. Ethical Considerations

This should include a description of the informed consent process or justification for waiver as appropriate. (See Suggested Language for select Protocol Sections).

XIV. Quality Control and Quality Assurance

Required for FDA-regulated studies. Describe any quality assurance or quality control systems to be used. If such systems are not pertinent to your study, please indicate that as well.

XV. Study Registration and Publication

Provides information on the planned dissemination of data, including plans for publications, presentations, and website registration. (i.e. www.clinicaltrials.gov). (See Suggested Language for Select Protocol Sections).

XVI. References

List all references cited in the protocol and/or pertinent to the study.

XVII. Appendices

Supplemental documents such as data collection forms, surveys, questionnaires, advertisements, and flyers may be included as appendices to the protocol.

Recommended Resources for Protocol Development

For ALL Protocols

- UAMS Research Support Center Project Team Unit
 - o David Avery (daavery@uams.edu; 501-686-7093)
 - o John E. Seng, Ph.D. (jeseng@uams.edu; 501-686-5961)
- UAMS IRB Policy 10.3, [Protocol Content and IRB Submissions](#), January 24, 2011

For FDA-regulated Studies

- 21 CFR 312, Subpart B, 'Investigational new Drug Application (IND)' ([21CFR312.23](#))
- Guidance for Industry. E6 Good Clinical Practice: Consolidated Guideline, Section 6, pp. 38-42, ['Clinical Trial Protocol and Protocol Amendment\(s\)'](#)

Additional resources available on the RSC Website:

- Suggested Language for Select Protocol Sections
- Tips for Writing Human Subject Research Protocols