

Guide to Writing a Research Protocol

The following outline is offered as guidance to assist you in drafting your protocol for submission to Schulman. Each of the topics must be addressed in the protocol. The protocol must include a signed cover page with a version date or a version number.

1. **Study Synopsis** – include an introduction and a discussion of the study design and whether the proposed research is retrospective or prospective; provide an overview of all study related procedures; discuss any procedures that are experimental; identify which of the procedures are considered standard of care and which procedures are included only for the purposes of the study; indicate those costs that will be incurred by the subject and what if any procedures/charges will be paid by the Sponsor
2. **Background** – include a discussion of previous relevant studies
3. **Objectives** – state the purpose of the currently proposed research study
4. **Subject Selection** – provide an explanation of how subjects will be selected; include a list of inclusion and exclusion criteria
5. **Study Procedures** – discuss expected duration of study participation; provide a detailed, visit-by-visit list of procedures; explain when and how subjects will be consented for the proposed research; indicate who will be available for consent discussion; indicate any additional informed consents that may be associated with the study related procedures (e.g., sub-study informed consents); describe the study treatment and explain how the study treatment will be administered (including dosages, if applicable)
6. **Risk/Safety Information** – describe the expected risks of study related procedures that are not considered standard of care; discuss how these risks are minimized by the study design
7. **Monitoring/Reporting of AE/SAE** – indicate who will monitor AEs and SAEs; how is an SAE and an AE defined in the proposed research; describe how safety events will be collected from the subjects; who will receive reports of collected safety events
8. **Study Oversight** – describe the conditions under which the study may be prematurely terminated and who will be responsible for making this determination; state that they study will be made available for monitoring, auditing, IRB review and regulatory inspection by providing direct access to study related source data
9. **Data Management** – brief discussion of any planned analysis of the study data
10. **IRB Review/Ethics/Informed Consent** – include a description of regulatory and ethical consideration related to the proposed research (*sample* language is provided below as guidance; please modify as appropriate for the protocol)

- **IRB Review/Ethics/Informed Consent**

The protocol, informed consent document and relevant supporting information must be submitted to the IRB for review and must be approved before the study is initiated. In addition, any subject recruitment materials must be approved by the IRB prior to being used. This study will be conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki and that are consistent with Good Clinical Practice and applicable regulatory requirements. The study must be conducted in accordance with the regulations of the United States Food and Drug Administration (FDA) as described in 21 CFR 50 and 56 [*add 312 for IND studies or 812 for device studies*], applicable laws and the IRB requirements.

The Sponsor must submit any change to the protocol to the IRB for review and approval before implementation. A protocol change intended to eliminate an apparent immediate hazard to subjects may be implemented immediately provided the FDA and the reviewing IRB are notified within 10 working days.

It is the responsibility of the investigator to provide each subject with full and adequate verbal and written information using the IRB approved informed consent document, including the objective and procedures of the study and the possible risks involved before inclusion in the study. Informed consent must be obtained prior to performing any study-related procedures, including screening and changes in medications including any washout of medications. A copy of the signed informed consent must be given to the study subject.

11. **Confidentiality** – at minimum, the protocol should clearly address, but not be limited to the following items as they relate to the confidentiality of study-related records:
 - a) A statement describing the extent, if any, to which the confidentiality of records identifying the subject will be maintained;
 - b) A statement that notes the United States Food and Drug Administration may inspect all records related to the study (For FDA regulated studies only);
 - c) A statement describing whether or not a monitor, auditor, IRB and/or other regulatory authorities will have access to study-related medical records;
 - d) A statement that study-related records identifying the subject will be kept confidential and, to the extent permitted by applicable laws and/or regulations will not be made publicly available;
 - e) A statement that if any results of the study are published, the subject's identity will remain confidential.
12. **Intended Use of the Data** – describe the expected end use of the data collected and how it relates to the purpose and objectives of the proposed research.