



Investigator-Initiated Studies (IIS) Program Proposal Template Form

On an attached document, please include the following (limit proposal to less than 10 pages):

1. BACKGROUND AND RATIONALE

Describe the disease or condition, current treatment, prior data on the test drug for this or related conditions, and why this study should be done (including, if appropriate, information on the choice of dose(s), dosing regimen, and duration of treatment).

2. OBJECTIVE

State the specific aim or hypothesis this study will answer.

3. SUBJECT SELECTION

If applicable to the study design and outcome, describe the inclusion criteria, including the age range, sex distribution, inpatient/outpatient status, diagnostic criteria, and other pertinent demographics of the subject population to be selected. Describe the exclusion criteria indicating any diseases, conditions, drug treatment, diets, or other criteria that are a basis for exclusion of a subject from enrollment. The number of subjects to be enrolled should be stated and justified (eg, power calculations).

4. METHODS

Describe in detail how the study will be performed. As a minimum, the following information should be included:

- a. A description of the design of the study, including the kind of control group to be used, if any, and a description of the methods to be used to minimize bias on the part of subjects, investigators, or analysts.
- b. The drug dose to be administered, including maximum dosage and the duration of an individual subject's exposure to the drug.
- c. A description of observations and measurements to be made to fulfill the objectives of the study.
- d. A description of clinical procedures and endpoints, laboratory tests, or other measures to be taken to monitor the effects of the drug in the subjects and to minimize risk.

5. INVESTIGATOR RESPONSIBILITIES

- a. Statements regarding obtaining Institutional Review Board (IRB) approval of the study and written informed consent from all subjects enrolled in the study should be included.
- b. A section describing the procedure for recording and reporting serious adverse events should be included in the proposal.
- c. At the completion of the study, the investigator must prepare a final report on the results of the study.

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6. DATA ANALYSIS

All endpoints need to be listed with the primary endpoint(s) explicitly indicated. If more than one primary endpoint is nominated and the study is not a proof-of-concept trial or otherwise exploratory in nature, the pattern of results that will support the alternate hypothesis needs to be stated. Where multiple primary endpoints are proposed to test a hypothesis, sample size calculations need to show that there is sufficient power to detect the proposed effect sizes on all endpoints, not just one. In sufficient detail, describe how you intend to analyze the data.

7. BUDGET

Provide a detailed budget, including a specific breakdown of overhead costs and resource funding when applicable.

8. TIMELINE

9. REFERENCES