

Specifications for Fulfilling the Grant Requirements to the Foundation of Women's and Girls Blood Disorders

I. <u>Developing the Research Project</u>

- 1. This particular application requires collaboration between two subspecialties: hematology and obstetrics-gynecology (or a women's reproductive health specialist). Ideally this collaboration would already have been established and would have been demonstrated to be effective. At the very least the collaboration would need to be demonstrated by having a strong letter from the collaborating service that would clearly define what the collaborator would do and how they would do it.
- 2. The institution ideally would be represented by the department head or the division head being supportive as indicated by the fact that they would provide enough time for the applicant to proceed with their study and to carry it out. A letter in support would be useful.

II. <u>Developing the Research Proposal</u>

- 1. Feasibility; it must be a project that seems as if it could be completed in the time allotted in the current circumstances of the applicant.
- 2. The proposal needs to address a specific question. The proposal needs to be able to resolve at least a part of the question and/or establish the basis as a hypothesisgenerating study to lead to a more definitive study of the question.
- 3. It needs to have appropriate statistical considerations depending on size.
- 4. It needs to have well-defined outcomes that can be clearly measured and assessed so that the results of the protocol will be interpretable.
- 5. The budget requires a justification that explains how the money will be spent. Note that the grant would allow up to 10% indirect costs unless there is a waiver of indirect cost from the institution.

III. Securing IRB Approval

1. IRB approval must have been submitted or already approved (given). Since it is intended to be a one-year proposal, if an IRB has not already been submitted, the chance that the grant can happen would seem very small in the space of one year.

Outline of The Research Proposal

I. Scientific Question / Hypothesis / Specific Aims/Objectives

a. The problem statement/ scientific question describes the problem posed by the proposed study and specifies it in the form of Research Hypotheses. The research hypotheses should be very specific in presenting what aspects of the research topic you will be studying, and how. The hypotheses should be optimally clear, concise, meaningful, and typically written in the present tense. One recommended statement of the criteria for a good hypothesis is that is: a) be free of ambiguity, b) express the relationship between two variables or concepts, and c) imply an empirical test. Avoid having more than one hypothesis embedded in a single, complex statement. A conceptual model represents a visual depiction of the relationship between all the variables in your study. It is a good place to start when planning your research project, and also helps in developing your hypotheses.

II. Background/Need

a. This section consists of an overview of the research question and some indication of the study' worth and the contribution it is apt to make to the field of study. It should include rationale for the research project. Use references to establish the link between the prosed study and the previous work done on the topic, lay the groundwork for the proposed study, and demonstrate why this important and timely. The literature review is not just a complication of facts, but a coherent argument that leads to the description of the proposed study.

III. Methods/Study Design, including sample size estimation

1. Study Duration

Describe the time frame during for which data will be collected (i.e., retrospective study; chart reviews), or intervention administered (i.e., prospective study; clinical trials).

2. Subject Selection

Of particular importance in this section are:

- a. the sampling procedure to be used random, stratified, convenience
- b. the source of the subjects
- c. the criteria for selection clearly state inclusion/exclusion
- d. the rationale for determining sample size use power test to determine sample size for significance; realistic estimates of crossovers, dropouts must be used in calculating sample size

3. Instrumentation or Measures

This section <u>lists all the variables (intervention as well as outcome variables)</u> you would be examining in your study, and describes what particular measures, or forms, or data collection sheets you will be using to measure the variables.

4. Procedures

This section provides a detailed description of the exact steps to be taken to conduct your research. This includes the procedure used to contact subjects, obtaining Informed Consent, and collecting the data. For prospective clinical trials, specify the way the intervention will be allocated (randomization, single blind, double blind), baseline examination, administer intervention, post-intervention examination, etc. You need to specify the termination policy for your study.

IV. Anticipated Results, including measurable and validated outcomes

In this section, present your findings as clearly as possible. The Results section contains tables, figures, transcript summaries, and a description of what is noteworthy and important about these. Begin with a description of the sample. Simple demographics can be presented in tabular form. Follow with presenting your findings in terms of the research questions/hypotheses tested.

V. Potential limitations and how to address them

This section typically contains:

- an overview of significant findings
- a consideration of the finding in light of previous research
- a careful examination of findings that fail to support your hypotheses
- limitations of the study that may affect the generalizability of the results
- recommendations for further research
- implications of study for professional practice
- VI. Expected Timeline (through completion date of the project)
- VII. Significance for women and girls with blood disorders

VIII. References

You must cite all studies referred to in the proposal, using the AMA citation method.