FOUNDATION FOR
Women & Girls+
with Blood Disorders
+ Includes people who have or had the ability to menstruate

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

Research Project Intent
The intent of this RFA is to fund cross-disciplinary basic, translational or clinical research that requires a collaboration between hematology and another subspecialty relevant to the Foundation's mission, (e.g., Ob/Gyn or other women's/girls' reproductive health specialty). We believe that this is an under-studied area that has many fruitful areas, exploration of which would benefit this population group. Ideally this subspecialty partnership would already be well-established with a demonstrable track record of academic productivity. If not already well-established, the proposal must document a new but substantive cross-disciplinary partnership. The proposal should clearly define the participation of each named collaborator's role on the proposed project; and demonstrate strong institutional commitment to this research effort from all collaborating services.

Ideally, institutional commitment would be represented by strong letters of support for the applicant and collaborators from representative Department or Division head and that guarantees the protected time required to perform the proposed study.

Research Applicant's and Research Mentor's Biosketch
The applicant and any significant mentors and collaborators should include an NIH biosketch.

Personal Statement
The applicant should include a personal statement that outlines his/her career development plan including future career goals, significance of the research area, and how the study, if funded, will advance the applicant's research and overall career goals.

Mentorship and Mentorship Justification
The proposal must clearly describe the following for each identified mentor: 1) prior mentorship experience; 2) academic focus and relevance to the applicant's proposed research; 3) pre-existing mentor-applicant relationship, if any; 4) role in the proposed project; and, 5) an appropriate plan for applicant/project supervision as well as progress evaluation, which includes details regarding the mentor-mentee meeting frequency and plans for scheduling these meetings (in person vs. tele-conference, etc.). If the mentor and the applicant are not at the same institution, include a clear description of the

supervisory and progress evaluation plans to illustrate commitment to the partnership's success.

Letters of Support

Letters of support from the Research Mentor and the collaborating specialist should be included (1-page, 12-point font/.5" margins).

Research Proposal Requirements

- Background and Importance: Provide a brief overview of the importance of the proposed research to both the field and to the Foundation's mission. The proposal should:
    - outline the rationale of the proposal and the foundation for the hypothesis(es) to be addressed;
    - establish the link between the proposed study and previous work done on the topic;
    - lay the groundwork for the proposed study; and
    - demonstrate why the proposed work is important and timely. A section describing potential limitations should include expected challenges and how these would be addressed, as well as study limitations may affect the generalizability of the results.

- Hypothesis and Specific Aim(s): Propose a clearly stated hypothesis as the basis for the specific aim(s) of either a definitive study or a pilot study that would further inform a future definitive study. The hypothesis and specific aim(s) should be clearly stated, concise, meaningful, and typically written in the present tense. A good hypothesis should be free of ambiguity, express the relationship between variables or concepts, and imply an empirical test that will test its accuracy.

- Study Design: Describe the specific steps to be taken to execute the research plan. Depending on the nature of the proposal, commonly included sections would be the procedures used to contact / enroll subjects, obtain informed consent, and collect and analyze the data generated. Describe laboratory methods, including the assays and why they are appropriate. If experimental laboratory studies are being performed, a description and justification of methods is required. If a widely used test is selected, a reference(s) suffices. For prospective clinical trials, specify how the intervention will be allocated and administered, baseline and post-intervention follow-up examination(s) and testing, etc.

- Subject Selection: Describe the study and control populations, and explicitly indicate the source of and sampling protocols for each. Clearly state inclusion/exclusion criteria.

  Statistical Justification: Provide appropriate statistical justification for the proposed experimental methods, analysis plan, and sample size calculations.

Indicate why the sample size is sufficient to inform the hypothesis, and include evidence there is appropriate expertise to conduct the analysis.

- Well-Defined Study Outcomes: Describe well-defined primary and secondary outcomes that can be objectively measured and assessed so that the results of the study can be interpreted. Briefly describe the particular measures, forms, and/or data collection tools that will be used to document outcome variables.

- Potential limitations and how they will be addressed

- Expected Study Timeline: Describe the time frame during which data will be collected (i.e., retrospective study; chart reviews), or intervention administered (i.e., prospective study; clinical trials) and which analyses will be prioritized.

- Budget Justification: Justify how the award will be spent. The proposal should also document how this award either sufficiently resources the proposed project, or sufficiently complements existing funding. Note: the grant will allow up to 10% indirect costs unless there is a waiver of indirect cost from the institution.

- IRB Approval: If required, IRB approval must have been submitted or already approved at the time of application. Since this is intended to be a one-year proposal, pre-exiting IRB submission is deemed critical to the successful completion of any proposal.

- References: Use the AMA citation method for all citations.