



FWGBD Research Grant 2023

*Promoting XXcellence in Women's Health:
Optimal Management of Women and Girls with Blood Disorders*

Special Award Focus Area: Bleeding Disorders Affecting Women and Girls
Award Target: Junior Faculty or Fellows

Introduction

Menstruation, pregnancy, childbirth, and menopause present unique challenges in women and girls with blood disorders. Undiagnosed, untreated blood disorders in women have profound medical consequences at every life stage. Delay and/or failure in diagnosing and appropriately managing blood disorders in women and girls are major public health problems, resulting in significant morbidity, substantially reduced quality of life, many days lost from work and school, unnecessary invasive procedures, and high healthcare costs.

The experience, training, and dedication of three internationally recognized physicians in women's blood disorders, Dr. Andra James in obstetrics and gynecology, and Drs. Barbara Konkle and Roshni Kulkarni in adult and pediatric hematology, is what led to the recognition that a foundation focused on education and awareness in these areas was clearly needed. Their discussions and efforts culminated in the Foundation for Women & Girls with Blood Disorders (FWGBD). In 2010, the FWGBD, a non-profit 501(c)3 organization, was founded to serve as a single-site, single-source of information and education for physicians and healthcare providers.

FWGBD's Mission is to ensure that *all women and girls with blood disorders are correctly diagnosed and optimally managed at every life stage* by:

- Raising awareness and educating healthcare providers including, but not limited to, pediatricians, adolescent medicine providers, family practice providers, internists, hospitalists, obstetricians & gynecologists, pediatric and adult hematologists/oncologists, geriatricians, nurse practitioners, physician assistants, nurses and social workers
- Translating and disseminating information and the results of research to these healthcare providers
- Providing support for and encouraging research in this area

The Foundation is dedicated to achieving the correct diagnosis and optimal management of blood disorders and accompanying reproductive problems in women and girls with bleeding disorders—von Willebrand disease (VWD), symptomatic carrier states for hemophilia A and B, other rare clotting factor deficiencies, inherited and acquired platelet disorders including immune thrombocytopenic purpura (ITP); the thrombophilias; sickle cell disease (SCD) and sickle cell trait (SCT); and all congenital and acquired anemias.

FWGBD has been gained recognition and momentum by securing support to be a key resource for providing education, guidance and expertise to physicians and other healthcare providers in the care of women and girls with blood disorders. FWGBD's Board and Medical Advisory Committee members (<http://www.fwgbd.org/about>) are leaders in clinical care for research focusing upon women with blood disorders.



The FWGBD Special Research Award Focus Area: Bleeding Disorders

The overarching purpose of the award is two-fold: to support a research project in bleeding disorders and their impact on women and girls. The project is to be one proposed by junior faculty or fellows who are pursuing careers in the following disciplines: Adult or Pediatric Hematology; a Women's Reproductive Health speciality such as Obstetrics/Gynecology, Adolescent Medicine, Pediatric/Adolescent Gynecology, or another subspecialty for which a major focus is the care of women and girls with bleeding disorders; and 2) to foster and sustain widespread interest in translating research into clinical care that will ultimately improve the lives of affected women and girls.

Research projects that will be accepted for consideration include ***hypothesis-generating and/or pilot projects in any of the following areas:***

Basic research – projects that answer fundamental biologic questions or clinically-related, laboratory-based questions.

Clinical and/or implementation research – projects that explore new treatments, medications, biomarkers and/ or diagnostic techniques or the implementation of clinical research outcomes in relevant clinical practice settings.

Translational research – projects that bridge the gap between basic and clinical science to refine and advance the application of an idea or discovery to improve healthcare delivery and/or patient outcomes.

The objectives of the 2023 ***FWGBD Promoting XXcellence in Women's Health Award*** are:

- Create and sustain the interest/knowledge on the part of the next-generation of healthcare providers, i.e., the physician-researcher workforce working in blood disorders affecting women/girls, **with a focus, in the special awards, on Bleeding Disorders**
- Foster collaboration among two core disciplines for women and girls with blood disorders (WGBD)—Adult or Pediatric (including Adolescent) Hematology and Obstetrics/Gynecology; a Women's Reproductive Health specialty such as Adolescent Medicine or Pediatric/Adolescent Gynecology; or another subspecialty relevant to the Foundation's mission that involves the care of women and girls with bleeding disorders
- Provide opportunity for junior faculty or fellows to conduct research in this important area



Proposed Timeline*

Applications are due	September 15, 2023
Notification of awards	December 1, 2023
First grant award payment	February 1, 2024
Progress report due	August 1, 2024
Final project report due	February 29, 2025
Final grant award payment (contingent on report)	March 13, 2025

*Depends on final signing of contracts

Eligibility

Eligible applicants must:

- Submit a complete application (see criteria below)
- Be an MD or DO who is junior faculty who qualifies as an early-stage investigator (see below), or a current fellow, in Adult or Pediatric Hematology; Obstetrics/Gynecology; a Women's Reproductive Health speciality such as Adolescent Medicine or Pediatric/Adolescent Gynecology; or another specialty that involves the care of women and girls with bleeding disorders
 - Junior faculty is defined as:
 - Must hold a US academic position
 - Must be within seven-years of completing training in Pediatric or Adult Hematology or Women's Reproductive Health speciality
 - Must be within seven years of completing training* for a career that will have a substantial component of, or overlap with, the disciplines of hematology and/or women's reproductive health as of January 1, 2023

* Exceptions to the seven-year requirement may be made for applicants who provide a justifiable explanation for being more than seven years out of fellowship, such as taking time off for family-related matters or for changing career path in medicine. Applicants who seek an exemption from the seven-year requirement should email an explanation as well as a letter of confirmation from the mentor to kfunkhouser@fwgbd.org so that a determination may be made as to eligibility before the application is prepared.

- Identify and confirm an experienced primary research mentor who is mid-career or senior faculty with a research track record in obtaining research funding at the applicant's home institution



- Demonstrate active, working collaboration with a peer in the related discipline— Women’s Reproductive Health specialty for the Hematology applicant, or Hematology for the Women’s Reproductive Health specialty (or related career) applicant
- Have an approved or pending IRB approval at the time of grant submission
- Have not been a prior FWGBD RFA recipient

Collaboration Requirement

Cross-disciplinary basic, translational, or clinical research that requires a collaboration between Adult or Pediatric Hematology and Obstetrics/Gynecology; a Women’s Reproductive Health specialty such as Adolescent Medicine or Pediatric/Adolescent Gynecology; or another subspecialty relevant to the Foundation’s mission that involves the care of women and girls with bleeding disorders is **REQUIRED**. Ideally it would pre-exist the application.

Available Funding

This award is intended as a supplemental non-salary research support grant, for a one-year period. **Two awards** will be granted; each **award total is \$35,000**. Up to 10% of the grant award may be used toward indirect costs. A no-cost extension for up to two years total for expending the full one-year amount will be considered based upon request from the investigator if sufficient justification can be made that a second year is necessary to complete the research project and ultimately benefit the health outcomes for women/girls with bleeding disorders.

With justification, the funding can be used toward:

- Statistical support
- Database development
- Technician support
- Laboratory supplies

Other non-salary items related to the research project will be considered upon request by the investigator and are subject to approval by the FWGBD Award Review Committee. Final approval may be contingent upon response to comments from the FWGBD award review committee following initial review.

Responsibilities and Conditions

1. **Grant Agreement:** Upon acceptance of the research grant, the awardee, and FWGBD will sign a formal Grant Agreement prepared by FWGBD’s legal counsel.



2. **Acknowledgment:** Every publication, thesis, or presentation reporting the results and/or analyses of the research award shall explicitly acknowledge the support of the Foundation for Women & Girls with Blood Disorders, as outlined in the signed Grant Agreement. Awardees agree to provide FWGBD with a copy of any publication, abstract, or presentation reporting the results and/or analyses of the award project.
3. **Rights and Welfare of Human Subjects:** The recipient is responsible for protecting the rights and welfare of human subjects in any clinical research activities involving the FWGBD awardee.
4. **Progress Report:** Awardees are required to submit a Six-Month Progress Report (of 1-3 pages) and a Financial Report indicating the grant funds have been applied to the specified objectives of the Award. The deadline for submission of this report will be listed in the awardee's Grant Agreement. Upon receipt and approval of the Progress Report by the FWGBD Research Award Review Committee, FWGBD will issue the final check representing full payment of the award to the recipient.
5. **Final Report:** Awardees are required to submit a Final Narrative and Financial Report on the 12-month anniversary of the awarding of the Grant as described in the Grant Agreement and by the date listed therein.

Proposal Preparation and Submission

Candidates must submit completed applications no later than 11:59 PM (EDT) on Friday, September 15, 2023, in one PDF document to: kfunkhouser@fwgbd.org

Completed applications must include the following:

1. Award Application Form - available at fwgbd.org/fwgbd-research-RFA
2. Candidate's Biosketch - Standard NIH format
3. Personal Statement in which the applicant 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 career development (e.g., publication plan, how the pilot data generated from the proposed study will support overall career goals including future intended career development award applications (2-page limit in 11-point Arial font/.5-inch margins).
4. Research Mentor's Biosketch - Standard NIH format
5. Research Mentors' Letter(s) of Support (1 page, 12-point font/.5" margins)
6. Research Mentorship and Mentorship Justification
The proposal must clearly describe the following for each identified mentor:
 - I. location within home institution*



- II. prior mentorship experience
- III. academic focus and relevance to the applicant's proposed research
- IV. pre-existing mentor-applicant relationship if any
- V. track record of mentor in obtaining research funding
- VI. Mentor's role in the proposed project, and
- VII. 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.).

***NOTE:** Permission to have a primary mentor at another institution must be requested in advance by emailing an explanation as well as a letter of confirmation from the mentor to kfunkhouser@fwgbd.org so that a determination may be made as to eligibility before the application is prepared. A clear description of the supervisory and progress evaluation plans to illustrate commitment to the partnership's success must be included.

7. Letter of Support from collaborating specialist—Women's Reproductive Health Specialist or Hematologist or other
 8. If applicable, letter from a collaborating data organization or biorepository certifying that the data/specimens required by this proposal are available to the investigator
 9. Research Proposal: (4-page limit in 11-point Arial font, excluding references)
 - a. Background/Importance including significance for W/G with bleeding disorders
 - b. Hypothesis / Specific Aim(s)
 - c. Study Design, including sample size estimation and subject selection
 - d. Statistical Justification
 - e. Well-Defined Study Outcomes
 - f. Potential limitations and how they will be addressed
 - g. Expected Timeline (through completion date of the project)
 - h. Budget Justification
 - i. References
 9. Budget (in Excel spreadsheet)
 10. IRB Status (for human subjects) and/or IACUC Status (for animal studies)
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Criteria for Assessing Applications

- Significance of the proposed research project to bleeding disorders in women and girls
- Interest of the applicant in bleeding disorders in women/girls as a core area of her/his career including background training
- The quality and feasibility of the research plan
- The quality, experience, level of involvement, and time given by the mentor and the institution to research mentorship for the candidate, as well as an adequate research environment and the potential for training in basic, translational, or clinical research
- Clear delineation of the roles of the Mentor and the Awardee/Mentee
- The availability of cross-disciplinary collaboration, and the quality and level of this collaboration between Hematology; a women's reproductive health specialty such as Obstetrics/Gynecology, Adolescent Medicine, or Pediatric/Adolescent Gynecology; or another specialty that involves the care of women and girls with bleeding disorders
- The commitment and percent (%) effort of the applicant within the context of career development and trajectory

To reiterate, **a research proposal must be** cross-disciplinary basic, translational, or clinical research requiring a collaboration between Adult or Pediatric Hematology and Obstetrics/Gynecology; a women's reproductive health specialty such as Adolescent Medicine or Pediatric/Adolescent Gynecology; or another subspecialty relevant to the Foundation's mission that involves the care of women and girls with bleeding disorders. This is **REQUIRED**.

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