



FOUNDATION FOR
Women & Girls
with Blood Disorders

FWGBD Research Grant

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

**2020 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 medical consequences at every life stage. Delay and/or failure in diagnosing and treating blood disorders in women and girls are major public health problems, resulting in significant morbidity, reduced quality of life, days lost from work and school, unnecessary invasive procedures and high healthcare costs.

It took the experience and training of three internationally recognized physicians in women's blood disorders, Drs. Andra James, obstetrics and gynecology, Barbara Konkle and Roshni Kulkarni, hematology, to realize the need for a foundation focused on education and awareness. Their discussions culminated in the Foundation for Women & Girls with Blood Disorders (FWGBD). In 2010, the FWGBD, a non-profit 501(c)3 organization, was launched 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, internal medicine physicians, obstetricians & gynecologists, hematologists/oncologists, geriatricians, nurse practitioners, physician assistants, nurses and social workers
- Translating and disseminating information and research to these healthcare providers
- Providing support and encouraging research in this area

The Foundation is dedicated to achieving the correct diagnosis and optimal treatment of blood disorders and accompanying reproductive problems in women and girls with bleeding disorders—von Willebrand disease (VWD), other factor deficiencies, platelet disorders, immune thrombocytopenic purpura (ITP); and the thrombophilias; sickle cell disease (SCD) and sickle cell trait (SCT); and all anemias.

FWGBD has been effectively gaining recognition and momentum as 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 and research in the area of women and blood disorders.



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The FWGBD Research Award

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

Research projects that will be accepted for consideration include ***hypothesis-generating projects***:

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 2020 ***FWGBD Promoting XXcellence in Women's Health Awards*** are:

- Create and sustain interest/knowledge 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 2020 special awards, on Bleeding Disorders.**
- Foster collaboration between two core disciplines for WGBD—the Obstetrician/Gynecologist (or Women's Reproductive Health specialist, such as Adolescent Medicine Provider, Pediatric/Adolescent Gynecologist, etc.) and the Hematologist
- Provide an opportunity for junior faculty or fellows to conduct research in this important area

Timeline

Applications are due	October 30, 2020
Notification of awards	January 4, 2021
First grant award payment	January 30, 2021



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Progress report due	June 1, 2021
Project final report due	December 30, 2021
Final grant award payment (contingent on report)	January 16, 2022

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 speciality that involves the care of women and girls with bleeding disorders
 - If a junior faculty:
 - Must hold a faculty position in a US academic institution
 - Must be within seven-years of completing training in Pediatric or Adult Hematology or Obstetrics/Gynecology (or Women's Reproductive Health speciality)
 - Within seven years of completing training for a career that will have a substantial component of, or overlap with, the disciplines of hemostasis and/or obstetrics/gynecology (or Women's Reproductive Health speciality) as of January 1, 2021

Exceptions to the seven-year requirement may be made for applicants who provide a legitimate explanation for being more than seven years out of fellowship, such as taking time off for family-related matters or for moving to another area of medicine. Applicants who believe they may be exempt from the seven year requirement should email an explanation to kfunkhouser@fwgbd.org so that a determination may be made as to eligibility before time is spent preparing the application.

- Have an experienced research mentor who is mid-career or senior faculty with a research track record at the applicant's home institution
- Demonstrate active, working collaboration with a peer in the related discipline—Obstetrics/Gynecology (or Women's Reproductive Health speciality) for the Hematology applicant and Hematology for the Obstetrics/Gynecology, Women's Reproductive Health speciality, or Related Career) applicant
- Have an approved or a pending IRB approval at the time of grant submission
- Have not been a prior FWGBD RFA recipient



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Available Funding

This award is intended as a supplemental non-salary research support grant, for a one-year period; the award total is \$35,000. Two awards will be granted, each at \$35,000. A portion of the funding can be used toward support for a statistician and/or technician. Up to 10% of the grant award may be used toward indirect costs. A no-cost extension to two years 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.

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.

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 2-3 pages) and a Financial Report indicating the grant funds have been applied to the specified objectives of the Award. The exact 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.



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Proposal Preparation and Submission

Candidates must submit completed applications no later than 11:59 PM (EDT) on October 30, 2020, 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. Research Mentor's Biosketch - Standard NIH format
4. Research Mentor's Letter of Support/Statement* (1-page max, 12-point font/.5" margins)
5. Letter of Support from collaborating specialist—Ob/Gyn or Hematologist
6. Personal Statement** of applicant outlining career development plan including future career goals, significance of this research area in Mentee's career development, and the specific impact of the Award on the Mentee's Career plan (2-page limit in 11-point Arial font/.5-inch margins)
7. Research Proposal: (2-page limit in 11-point Arial font, excluding references)
 - i. Scientific Question / Hypothesis / Specific Aims/Objectives
 - ii. Background/Need
 - iii. Methods/Study Design, including sample size estimation
 - iv. Anticipated Results, including measurable and validated outcomes
 - v. Potential limitations and how they will be addressed
 - vi. Expected Timeline (through completion date of the project)
 - vii. Significance for W/G with bleeding disorders
 - viii. References
8. Budget (in Excel spreadsheet)
9. Budget justification
10. IRB Status (for human subjects) and/or IACUC Status (for animal studies)

* The Mentor Statement should provide a clear delineation of his/her role in the Project and affirm the Mentee has protected time to complete the research.

** The Mentee Statement should provide a clear delineation of his/her role in the Project.



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Criteria for Assessing Applications

- The proposed research project's significance to bleeding disorders in women and girls
- The interest of the applicant in blood disorders in women/girls as a core area of her/his career in Hematology, OB/GYN, Women's Reproductive Health Specialty, such as Adolescent Medicine, Pediatric/Adolescent Gynecology, etc., or a related career with sustained overlapping focus on bleeding disorders in women and girls
- The quality and feasibility of the research project
- The quality, experience and 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 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
- The commitment and percent (%) effort of the applicant within the context of career development

To reiterate, interdisciplinary research proposals involving collaboration between a women's reproductive health physician and a hematologist are preferred.

The awarding of two research grants is made possible in part through the support of Takeda.