



**THE VASCULAR MEDICINE INSTITUTE (VMI)
ANNOUNCES
THE PILOT PROJECT PROGRAM IN HEMOSTASIS AND VASCULAR BIOLOGY
(Revised, December 2015)**

The VMI was established at the University of Pittsburgh in 2008 as a home for rigorous, cutting edge, basic and translational research in hemostasis, red blood cell biophysics, transfusion medicine, cardiovascular biology, mitochondrial biology and nitrite-nitric oxide and reactive oxygen species biochemistry in order to expand understanding of the control of blood flow to organ systems; with the ultimate goal of developing novel therapies for diseases such as pulmonary hypertension, sickle cell vasculopathy, atherosclerosis, hypertension, and heart disease.

Program Summary

The VMI Pilot Project Program in Hemostasis and Vascular Biology (P3HVB) is intended to attract investigators new to the general areas of hemostasis and vascular biology by seeding innovative and translational research projects that have the potential to open new avenues for critical research in the general areas of :

- Transfusion medicine
- Transfusion-related lung injury (TRALI)
- Hemostasis and platelet biology, especially as focused on the integration of the roles of red cells, platelets, and hemostatic factors
- Hemophilia
- Small pilot clinical trials in above areas or vascular biology

The program will support grants of \$25,000-\$50,000 for one year duration. On an annual basis, approximately \$250,000 will be available for new awards. Applications for new projects may request up to \$25,000. If a previously awarded project is successful in demonstrating that the area of research is important and innovative, the investigator may apply for competitive renewals of up to \$50,000 in additional funds.

There will be an annual submission date of March 15. If that date falls on a weekend, the submission date will be the Monday immediately following that weekend.

Budget information

The monies awarded will support direct costs only; no indirect support will be provided. Funding may not be used for travel or computer equipment. *The monies awarded may not be used for salary support for the principal investigator nor, in the case of a mentored investigator, for a research mentor. Note, however, that effort is required of the principal investigators, must be reflected on the budget page, and must be counted when determining the investigator's total effort to ensure that he/she does not exceed 100% effort when all activities are considered.*

In planning budgets, please note that requests for no-cost extensions (carryovers) will need to be justified in detail. Approval will be contingent upon demonstration of significant progress in the conduct of the project and on evaluation of the reasons for the delay in its completion. If an award is to be made, no monies can be expended until any necessary regulatory protocols (IRB, IACUC, rDNA, CORID, hSCRO) are approved. The start date for the project will be dependent on such approval.

Eligibility

University of Pittsburgh faculty members at the levels of assistant/research assistant professor, associate/research associate professor, and professor/research professor are eligible to apply as principal investigators. Instructors, fellows, and postdoctoral researchers may also apply as principal investigators if they can demonstrate a track record of research success, if there is a research mentoring plan from a qualified faculty member at the rank of associate professor (not research track) or higher, and if there is a commitment from the faculty member in whose laboratory the instructor/fellow/postdoctoral researcher works that all necessary laboratory resources will be available for the proposed project. See below for relevant instructions.

For any given research group, only one award may be active at a given time. That is, if there are several research faculty members working under the umbrella and mentorship of a given faculty member, only one award may be active for the entire group, independent of whether the principal investigator on the P3HVB award is the senior investigator or any of the research faculty members.

Projects that focus on translational integrative vascular biology with an emphasis on the role of red cells, platelets, and hemostatic factors will be of high priority, although other areas of research will be considered. Such a priority is consistent with the interests of the Institute for Transfusion Medicine and the Hemophilia Center of Western Pennsylvania, both of which have provided the current funding to support this program. Should other funding sources become available for the P3HVB, the relative priority on the role of red cells, platelets, and hemostatic factors will be commensurate with the relative levels of funding from and priorities of the other sources. Independent of the source of funding, translational research will be of the highest priority. Thus, it will be incumbent on an applicant to convince reviewers that the results of a laboratory-based program have the potential to be translated into clinical utility.

The application must include the following items:

I. Cover sheet

The first page of the application must be a cover sheet that gives the name, degree, academic title, primary departmental affiliation, and contact information (telephone number, fax number, and e-mail address) of the principal investigator if he/she is of a professorial rank. If the principal investigator is an instructor, fellow, or postdoctoral researcher, this information must be provided for both the applicant and the research mentor for the project. If the research mentor is someone other than the faculty member in whose laboratory the applicant has a primary appointment, this information must also be provided for that faculty member. The signature of each individual named on this cover sheet must also appear.

The signature of the relevant departmental/divisional administrator must also appear to acknowledge that effort is required of the principal investigator and that this effort must be counted when determining the investigator's total effort to ensure that he/she does not exceed 100% effort when all activities are considered.

II. Letter(s) of support

If the principal investigator is an instructor, fellow, or postdoctoral researcher, a letter of support from the research mentor must be included that documents the relevant mentoring plan. If the research mentor is someone other than the faculty member in whose laboratory the applicant has a primary appointment, there must also be a letter from the faculty member with primary responsibility for the applicant that documents that all necessary resources for conducting the project are available to the applicant. Demonstration of an appropriate mentoring plan and of the availability of necessary resources will be some of the criteria used in evaluating the application.

III. Research Plan

The research plan may not exceed five single-sided pages; please note general instructions, below. It should include:

- Discussion of the significance/importance of the problem; the novelty of the concept and strategy; the likelihood that, if successful, the project will provide sufficient preliminary data to enable a competitive application to an external funding source.
- Description of the research to be performed including how the research and the data to be gathered will connect to the question being posed. If an already approved IACUC or IRB protocol will be required for the proposed work, that protocol should be included for review of its contents. The included protocol will not count against the page limits for the research plan. Whether an approved protocol is included or not, sufficient information must be provided to convince the reviewers that the proposed methodology is appropriate to the problem.
- Evidence that the investigator (or, where relevant, his/her research mentor) has a significant track record in conducting the type of research (techniques/methodology) proposed.
- If the application is a competitive renewal of a project that received an initial \$25,000, one-year award from the P3HVB or that received a renewal award of \$50,000, it is incumbent on the applicant to demonstrate that additional funding (of up to \$50,000) is warranted. One additional single-sided page (for a total of six pages for the research plan) may be included to document results from the previous year of funding and to indicate why these results warrant further support from the P3HVB. It is the investigator's responsibility to convince the reviewers that the progress made in the previous year of funding was significant enough to warrant an extension of the project. If the request is for a second (or subsequent) renewal, the investigator should make a compelling case that the project is not yet ready for support from an external funding source (such as the NIH).

Note: Investigators who have established and successful track records in scientific areas outside the scope of this solicitation are encouraged to consider expanding their efforts into hemostasis and vascular biology and to submit applications for this pilot program. Where possible, such applications should draw connections between the applicability of the investigator's technical expertise to that needed for the proposed study.

The bibliography must not exceed one single-sided page; this is not included in the page limit for the research plan.

Please note that if any one of the page limits is exceeded in a given application, or if any required information is missing, that application may be administratively withdrawn from consideration, without review.

IV. Biographical Sketches and Support Pages

The NIH-format biographical sketch (see page I-90 of the SF424 Application Guide, updated November 25, 2015, <http://grants.nih.gov/grants/funding/424/index.htm>) and the NIH-format Other Support document (see page III-8 of the

Supplemental Grant Application Instructions) must be included for the principal investigator and any named mentor. The personal statement in each biographical sketch should be appropriate for the research proposed in the P3HVB application. If a further update to the SF 424 Application Guide is extant at the time of application submission, the biographical sketch and other support information should conform to the "Instructions for a Biographical Sketch" and the section on "Other Support Information" in the updated Guide.

V. Budget and Budget Justification

The NIH-format budget page (PHS 398 Form 4; Rev. 08/12 Approved Through 8/31/2015), <http://grants.nih.gov/grants/funding/phs398/phs398.html>, should be used. Later revisions are also acceptable. An additional page should be included for the budget justification; all pieces of equipment must be explicitly justified as critical to the performance of the proposed research. Even though no P3HVB funds may be used for salary for the principal investigator, his or her *effort* on the proposed study must be reflected on the budget page (principal investigator *salary* should not be provided).

General Instructions, Format, and Guidelines

The application must be clear, readily legible, and conform to the following three requirements: 1) The font must be Arial, Helvetica, Palatino Linotype, or Georgia 11-point or larger; 2) Margins, in all directions, must be at least ½ inch; and 3) Text in figures, charts, tables, figure legends, and footnotes may be smaller in size but must be readily legible. If these are not legible, there may be a negative impact on the evaluation of the application.

IACUC, IRB, IBC, hSCRO, and CORID

If IACUC, IRB, IBC, hSCRO, or CORID protocol approvals are required in order to conduct the research, the relevant approvals must be obtained before money will be released to support the project.

Review Criteria

The primary review criteria are:

- The scientific feasibility and scientific merit of the project
- The potential to lead to more comprehensive studies
- That the project is novel and innovative
- The degree to which the project is translational
- As noted above, the degree to which the project explores the role of red cells, platelets and hemostatic factors
- That the letter(s) of support for instructors, fellows, or postdoctoral researchers demonstrate (s) adequate commitment to the applicant and to the project.

Applications will undergo peer review by non-conflicted investigators from the University of Pittsburgh or UPMC. Recommendations made as a result of the peer review process will be forwarded to the internal advisory board of the VMI for final selection of grants to be awarded. Successful applicants will be expected to present their findings, both in written form and through presentation, to the VMI.

Applications are to be submitted electronically, as a single pdf file, to Ms. Dorothy Voith, M.S., M.B.A., Administrative Director, VMI, voithdm@upmc.edu, with a cc to Kirsten Schwoegl, Administrator, VMI, schwoegl@upmc.edu by 5:00 pm on the receipt date identified above. No exceptions will be made to the receipt date. Within one week of the receipt date, each applicant should receive an e-mail message from Ms. Voith notifying him/her that his/her application has been received. If an applicant does not receive such notification, he/she should contact Ms. Voith.

Questions about the program should be directed to Mark Gladwin, M.D., Director, VMI, gladwinmt@upmc.edu.

Please note that any applicable revisions to the solicitation will be posted at least two months before any given submission deadline.