

THE CLINICAL and TRANSLATIONAL SCIENCE INSTITUTE (CTSI) and the SMALL MOLECULE BIOMARKER CORE (SMBC) ANNOUNCE THE SMALL MOLECULE BIOMARKER PILOT PROGRAM

The Small Molecule Biomarker Core (SMBC) was founded through a partnership between the University of Pittsburgh Clinical and Translational Science Institute (CTSI) and the School of Pharmacy's Department of Pharmaceutical Sciences. The SMBC has both personnel with the relevant expertise and the equipment necessary for the discovery and quantitative measurement of small molecular weight biomolecules (mass to charge ratio less than 2000) including, but not limited to, estradiol, arachidonic acid metabolites (cytochrome P450, cyclooxygenase, and lipoxygenase pathways), Vitamin D analogues, and nicotine/cotinine. The SMBC provides interpretation of the obtained data on a collaborative basis. The addition of new assays is ongoing at the SMBC.

The SMBC will provide quantitative analysis of small molecules for clinical and translational research studies. The services include complete sample processing, although an investigator may choose to process his or her own samples and still take advantage of the services offered by the SMBC. The facility utilizes a UPLC/MS/MS in addition to other state-of-the-art instrumentation. The highly sensitive and specific techniques employed allow an investigator to obtain accurate measurements of multiple biomarkers in a given sample, maximizing the ability to link basic science with clinical outcomes.

More information about the SMBC may be found at www.biomarkers.pitt.edu.

Program Summary

The Small Molecule Biomarker pilot program is intended to support projects that will generate the preliminary data necessary to strengthen applications for extramural funding from federal or not-for-profit sources. Pilot projects will not be supported that are aimed at generating preliminary data to support applications to industry or for-profit entities. In particular, pilot funds may be used to generate preliminary data on biomarkers for which there are established experimental protocols. If a study requires the measurement of biomarkers for which there is currently no established experimental protocol, the investigator must work with the director of the SMBC (Dr. Samuel Poloyac) to determine the feasibility of developing the assay and producing data for the proposed project. Pilot funds may be requested for such a study if the assay development is determined to be feasible. The application need not address funding for the development of the assays since funds are available to the SMBC for assay development from sources outside of the scope of this pilot program. Dr. Poloyac's signature on the face page of an application is required to indicate his agreement that a study where assay development is included is feasible. Pilot program funds may be used only for the purchase of services from the SMBC.

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 primary investigators to the SMBC pilot program. Instructors, research associates, fellows, and postdoctoral researchers are not eligible to serve as primary investigators, nor are investigators from other institutions.

Application Deadlines

Applications may be submitted at any time so long as funds may be reasonably expected to be expended by June 30, 2010. Review of applications and funding decisions will be completed in no more than three weeks after receipt. If funds available for this program are committed at a level that would preclude further awards, this solicitation will be withdrawn.

Budget Information

The monies awarded will support direct costs only; no indirect costs will be allowed. Funding will be provided in the form of a voucher for purchase of services from the SMBC for the project outlined in the application. Budget limitations for applications to this pilot program are not specified because the

nature and scope of the proposed research will vary from application to application. The proposed budget must reflect the actual costs of the proposed project. It is anticipated that awards will range from \$3,000 to \$10,000. Projects exceeding \$10,000 must either have a provision for covering the balance of the costs beyond \$10,000 or must request and justify a waiver for exceeding the maximum award.

Principal Investigator Effort

If the application is to support a new, unfunded project, investigator effort is required at a level appropriate to the actual level of effort expected to be expended on the SMBC pilot program project. This effort will not be supported by the pilot program award and must be cost shared by the investigator's department.

If the application is to supplement a current federal or non-profit agency funded project, additional investigator effort is not required. A copy of the Notice of Award for the currently funded project must be provided with the application for verification.

Application Components: *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. Please see the appendix to this document for an example of an appropriate cover sheet. The principal investigator and his or her respective department chair or appropriate responsibility center director (*e.g.*, division chief or institute director) who can authorize cost sharing (if applicable) against an Entity-02 or -04 institutional account must sign the cover sheet. These signatures certify acceptance of principal investigator's cost shared effort and no indirect cost. The appropriate institutional account numbers against which the effort will be charged must also be provided. *If the project is funded, cost shared effort must be reflected on the SPAR document and copies of the relevant SPAR must be provided to the CTSI administration upon request.* The applicant may dispense with the signature of the department chair or appropriate responsibility center director in instances, as noted above, where the application is to supplement a current federal or non-profit agency funded project.

The principal investigator(s) must meet with Dr. Samuel Poloyac, Director of the SMBC, and Dr. Beth Minnigh, core supervisor, as a first step in the pilot application preparation process to determine the appropriate methodology to be used and to assess the feasibility of the project. Dr. Poloyac's signature attesting to the feasibility of the proposed study including new assay development, if applicable, is required before the application can be accepted. Dr. Minnigh may be contacted at (412) 648-9854 or by e-mail at mam212@pitt.edu. She will arrange appropriate discussions with Dr. Poloyac.

II. Research Plan

The research plan should be no more than two pages summarizing the study goals and design with sufficient context to understand how the data will be used to support applications for external funding. The plan should also address the feasibility of completing the study before June 30, 2010.

III. Biographical Sketches and Support Pages

The NIH-format biographical sketch and NIH-format Other Support document (revised November, 2007, <http://grants.nih.gov/grants/funding/phs398/phs398.html>) must be included for the principal investigator.

IV. Budget and Budget Justification

The budget may be a line item description of how many samples will be analyzed for each analyte with the associated cost. This budget description must correlate to the research plan in a clear way. If the total budget for the proposed project is greater than the amount requested, it should be clearly noted and the source of the additional funds identified. The project cost related to SMBC services should be determined in meeting with Drs. Poloyac and Minnigh. The budget should also include an explicit

statement as to the level of effort to be expended by the principal investigator. This level of effort must be greater than zero. If the application does not require cost-shared investigator effort as described above (see Principal Investigator's Effort), then a description of the principal investigator's role in the project must be stated.

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; 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 in black ink and readily legible. If these are not legible, there may be a negative impact on the evaluation of the application.

IACUC, IRB, IBC, ESCRO, and CORID

If IACUC, IRB, IBC, ESCRO, 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. Approved protocols need not be submitted as part of the application. Please note that should an award be made, the services of the CTSI Regulatory Core (<http://www.ctsi.pitt.edu/common/resCoresRegul.shtml>) should be used to facilitate the preparation of required protocol applications.

Review Criteria

1. Does the research have clear hypotheses for measurement of biomarkers to assess clinical conditions or predict outcomes?
2. Does the research have a clear, defined plan for securing extramural funds based on the generated pilot data?
3. Does the research represent a novel approach to a clinical condition or outcome?

Submission

Applications are to be submitted electronically in pdf format to Ms. Melissa Penkrot at mam266@pitt.edu. Applicants will receive confirmation of receipt of the application within one week of submission. If confirmation is not received within one week, please contact Ms. Penkrot at (412) 648-8984 or by email. Questions about the program should be directed to Dr. Beth Minnigh at mam212@pitt.edu.

CTSI Reporting

The CTSI is funded through a Clinical and Translational Science Award from the National Center for Research Resources (NCRR) of the National Institutes of Health. Recipients of such awards are required to report any use of CTSI services by investigators in an annual progress report to NCRR. CTSI and/or Translational Technology Core staff will contact recipients of the SMBC pilot program awards to obtain the necessary information for the annual report to NCRR. These contacts will direct award recipients to a unique CTSI portal where awardees will need to update and verify information regarding the SMBC award. The web portal will request information about interactions with CTSI, as well request information about any recent publications resulting from SMBC pilot awards. Investigators will receive an email from CTSI directing them to the CTSI Portal at the appropriate time.

APPENDIX: CTSI/SMBC Pilot Program Application Cover Sheet

Please note that all information requested below is required.

Project Title

Principal investigator

Name and Degree

Academic Title

Primary Departmental Affiliation

Address

Telephone Number

Fax Number

E-mail address

Department Chair's Signature*

Institutional Account Number

or

Funded Project Number

(Please provide a copy of the notice of award)

This signature certifies acceptance of primary investigator cost shared effort and no indirect cost or certifies that the primary investigator already has a funded project that does not require effort for this application.

* Department chair or appropriate Responsibility Center Director (e.g., division chief or institute director) who can authorize cost sharing against an Entity-02 or -04 institutional account

Samuel Poloyac, Ph.D.

This signature certifies that the project has been reviewed for feasibility.