

Clinical and Translational Science Institute Genomics and Proteomics Core Laboratories Pilot Program

The University of Pittsburgh Clinical and Translational Science Institute (CTSI) is pleased to announce a new program to support pilot studies in the Genomics and Proteomics Core Laboratories (GPCL). The Genomics Core Laboratory was established in 1999 with support from the Office of the Senior Vice Chancellor for the Health Sciences (OSVC), and the Proteomics Core Laboratory was launched in 2001, again with support from the OSVC. At that time, the Proteomics Core was placed under a common administrative unit with the existing Genomics Core Laboratories in order to create administrative efficiencies; this unit was named the GPCL. A third component of the GPCL, the Bioinformatics Analysis Core (GPCL BAC) was added in 2007 to provide assistance to investigators with the interpretation of the enormous quantities of data generated by most genomics and proteomics experiments. The GPCL BAC was the first CTSI-supported core facility to be established. The entire GPCL was moved under the purview of the CTSI in 2008. The breadth of research capabilities found in the comprehensive CTSI GPCL is described at <http://www.genetics.pitt.edu/>.

Clinical and translational research results frequently lead to the conclusion that genomic or proteomic data should be an important component of the overall study that is underway. However, the need for such data is often not anticipated at the outset of a study, and the investigator may not have the experience necessary to generate such data. Further, preliminary genomics or proteomics results are often required to substantiate the value of new research directions when proposed in grant applications for external funding. The CTSI GPCL Pilot Program, (GPCLPP) is intended to provide translational and clinical investigators with the opportunity to

- Obtain experience in designing experiments using genomics or proteomics technology;
- Obtain experience in conducting experiments with genomics or proteomics technology previously not used by the investigator;
- Explore new research directions suggested by previously obtained research results; and
- Obtain preliminary data to support requests for external funding.

Awards in the GPCL pilot program will be made in the form of vouchers to the GPCL for services to be provided to award recipients for use on the project proposed in the GPCLPP application. The maximum amount to be awarded for any given project is \$15,000. An investigator may only receive one award under this program.

As part of the application process, the principal investigator must meet with either the Director of the GPCL, Paul Wood, or the Assistant Director of the GPCL, Janette Lamb, to determine whether the GPCL can provide the appropriate expertise and technology for the proposed research. This meeting will also be used to establish an appropriate budget for GPCL services (including for BAC services, as discussed below). The signature of either Mr. Wood or Dr. Lamb on the cover sheet of the application is required and certifies that he or she deems the study appropriate for GPCL services and feasible within the budget constraints. If, following this consultation, it is determined that the investigator will need assistance with interpretation of experimental results, the budget request should include funds to cover the costs of BAC data analysis. In such a case, the principal investigator must consult with James Lyons-Weiler,

Scientific Director of the BAC, to ensure that the study design will result in the highest quality data possible. Mr. Wood can be contacted by e-mail at pgw@pitt.edu; Dr. Lamb can be contacted by e-mail at jal18@pitt.edu; and Dr. Lyons-Weiler can be contacted by e-mail at jim@bioinformatics.pitt.edu.

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 GPCL pilot program. In general, instructors are not eligible to serve as principal investigators; an exception to this may be given if his or her department chair will certify in writing that the project for which GPCL pilot program support is requested is an independent research project, directed by the instructor. Research associates, fellows, and postdoctoral researchers are not eligible to serve as primary investigators, nor are investigators from other institutions. Applications from junior investigators are strongly encouraged.

Application Deadlines

Applications may be submitted at any time as long as the proposed project will be completed by June 30, 2010 (the end of Fiscal Year 2010) or will be conducted and completed between July 1, 2010 and June 30, 2011 (Fiscal Year 2011). Review of applications and funding decisions will be completed in no more than four weeks after receipt. If CTSI funds available for this program are committed at a level that would preclude further awards in Fiscal Year 2010, meritorious applications will receive awards in Fiscal Year 2011. Once funds are committed in Fiscal Year 2011 at a level that will preclude additional awards, this solicitation will be withdrawn.

Budget Information

The monies awarded will support direct costs only; no indirect costs will be provided. As noted above, funding will be in the form of a voucher issued to the GPCL for services to be performed for use on the project proposed in the GPCL pilot program application. The amount that may be requested will be determined through consultation with GPCL leadership and may not exceed \$15,000. If the project requires funds in excess of \$15,000, the budget must indicate the source of the additional funds.

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 GPCL 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 should 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 provides the name, degree, academic title, primary departmental affiliation, and contact information (telephone number, fax number, and e-mail address) of the principal investigator. 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.* Please note that 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.

As noted above, the principal investigator must meet with Paul Wood or Janette Lamb prior to submission of the application. A meeting with James Lyons-Weiler may also be required. Mr. Wood's or Dr. Lamb's signature must appear on the cover sheet to certify that the project is feasible and the budget is appropriate. If necessary, as discussed above, Dr. Lyons-Weiler's signature must also appear.

II. Research Plan

The research plan may be no more than three pages in length and should summarize the study goals and design with sufficient context to understand how the data will be used to support applications for external funding. If the project complements research that is funded by external sources, there must be a clear statement as to why funds to support the GPCL-based project were not included in the original application for that project; an additional page may be used for this statement. The plan should also address the feasibility of completing the study during one of the time frames specified above.

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

The budget should include a description of the GPCL services to be provided and the costs associated with those services, as determined by Mr. Wood or Dr. Lamb. Any ensuing award will be in the form of a voucher for services paid to the GPCL; any unexpended funds at the conclusion of the project will be returned to the CTSI. The budget should also include an explicit statement as to the percent effort to be expended by the principal investigator. This effort must be greater than zero. If the application does not require cost-shared investigator effort as described above, a description of the PI's role in the primary project must be included.

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. *Time to acquire necessary protocol approvals must be factored into the determination as to whether or not the project can be completed in Fiscal Year 2010 or completed in Fiscal Year 2011, as described above.*

Review Criteria

1. Is the research an integral and essential part of a broader research program?
2. For investigators with significant external funding to support the overall project, should the GPCL-based research component have been anticipated in the application for the external funding, or did the need for the GPCL-research component derive from recent results? If the former, there will be a negative impact on the review.
3. Does the proposed research address a clear hypothesis? If not, is generation of the data scientifically defensible?
4. If the project were successful, does the application address next steps, both for the overall project and for securing extramural funds based on the generated pilot data?
5. Does the research represent a novel approach to a clinical condition or outcome or to an important translational study?

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 Mr. Paul Wood, pgw@pitt.edu.

CTSI Reporting

The CTSI is funded through a Clinical and Translational Science Award from the National Center for Research Resources (NCR) 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 NCR. CTSI and/or Translational Technology Core or Pilot Core staff will contact recipients of the GPCL pilot awards to obtain the necessary information for the annual report to NCR. These contacts will direct award recipients to a unique CTSI portal where awardees will need to update and verify information regarding the GPCL pilot award. The web portal will contain information on interactions with CTSI, as well request information about any recent publications resulting from GPCL pilot awards. Investigators will receive an email from CTSI directing them to the CTSI Portal at the appropriate time.