Request for Applications for the CTSA-ACARD Internal Small Grant Program

One of the goals of the Clinical and Translational Science Award (CTSA) -- shared by the University of Pennsylvania (Penn) and its partner institutions, the Children’s Hospital of Philadelphia (CHOP), the Wistar Institute (WI), and the University of the Sciences in Philadelphia (USP) -- is to apply pharmacoepidemiologic approaches to improving the effectiveness and safety of drugs and other therapeutics. The CTSA is administered by the Institute for Translational Medicine and Therapeutics (ITMAT). The ACARD (Automated Claims and Medical Record Databases) Core is housed in the Center for Clinical Epidemiology and Biostatistics (CCEB).

To foster epidemiologic research using large databases, the ACARD Core provides access to a resource whereby CTSA investigators can perform epidemiological studies of large population databases (Medicaid, GPRD, and THIN) available at Penn. The ACARD Core also provides access to the needed hardware and software in an environment supported by expert faculty supervision. Resources are provided for the conduct of pilot studies with each data resource. Assistance is provided to meet with investigators, to apply for data-use agreements where necessary, to assist applicants in writing research proposals to ensure that the study is informed by in-depth understanding of the strengths and weaknesses of each data resource, and to assist with data management, data analysis, and manuscript preparation.

Ultimately, the goal of the CTSA-ACARD is to encourage investigators with diverse training to conduct studies focused on translational therapeutics and pharmacoepidemiology, and to facilitate these research efforts by making available to them existing large databases that can provide answers more quickly, and at a lower cost, than studies involving de novo collection of data. To this end, the CTSA-ACARD is prepared to provide administrative guidance, technical advice, funding, and access to currently available data resources for qualified applicants.

Accordingly, this RFA provides for five levels of involvement:

1. **Access to the ACARD databases** - ACARD will provide free access to the GPRD, THIN, and Medicaid databases for investigators who are skilled in data management and can perform translational therapeutics and pharmacoepidemiology studies on their own.

2. **Feasibility studies for GPRD or THIN** – ACARD will provide up to one free feasibility study per investigator per year. The feasibility studies will provide frequency counts of patients with one outcome variable and one predictor variable of interest to the investigator. Additional feasibility studies will be supported depending on availability of ACARD funding and the perceived merit of the request.

3. **Feasibility studies for Medicaid/Medicare** – ACARD can support feasibility studies for investigators interested in using Medicaid/Medicare data for research. Because the cost of conducting such feasibility studies in Medicaid/Medicare data can be variable, such requests will be reviewed on a case-by-case basis to determine what can be provided without additional charge to the investigator under the current budget.

4. **Exporting data files from GPRD or THIN to a PC environment** – ACARD intends to fund small grants to export analytic data files from the full GPRD or THIN databases (residing on a server) for use on a PC. This funding is for researchers who have pilot-tested their variable creation, cohort selection criteria, and statistical code using the 10% sample data residing on a dedicated PC (known as ‘Victoria’). These grants are for $1000 each, all of which must be used for the cost of the Biostatistical Analysis Center (BAC) to export the data from the full GPRD or THIN databases for further analysis by the investigators. The BAC will implement the SQL,
SAS, and/or STATA code provided by the applicant to create the study data files. The BAC will not be responsible for determining the integrity of the code. If selected for funding, the funds will be directly transferred from ACARD to BAC.

5. Performance of pilot studies in GPRD, THIN, and Medicaid to support grant applications - ACARD intends to fund the conduct of pilot studies in support of future grant applications. Such studies might be used to determine the feasibility of a proposed hypothesis and/or research design. For example, an investigator may need to demonstrate for a funding agency the number of eligible subjects with a minimum period of follow-up and who are above a certain age. Such feasibility studies require programming costs beyond that described in funding levels #2 and #3 above. Applicants requesting this level of support will work with ACARD and BAC staff to assess their needs and design preliminary studies that fit within the funding resources of the CTSA. Selection of studies for this level of funding will be based on the perceived merit of the future grant application and the feasibility of the requested preliminary studies.

ELIGIBILITY
- All faculty, fellows, and residents from Penn, CHOP, WI, and USP are eligible to submit applications. Applications by a fellow or resident must be endorsed by a faculty member who takes scientific responsibility for the study.
- Applications should address research questions that are amenable to study in the large automated databases available in the CCEB.
- Manuscripts and presentations resulting from this support should credit the Penn CTSA accordingly.

SELECTION CRITERIA
- Applications to be funded by the CTSA will be reviewed by a panel of reviewers and scored similarly to the methods used by NIH review panels. Preference will be given to those applications that are likely to either have immediate clinical, scientific, or public health impact, or are likely to lead to additional research funding.

APPLICATION PROCEDURES:
- There are no application deadlines. Applications will be accepted on an ongoing basis.
- An initial letter of intent is required and should include a maximum of a 2-page (12 point Arial font, single space) description of the project. After pre-screening of these letters of intent, the applicant will be notified whether or not a full application can be submitted.
- Applications should include a cover letter, an Abstract, budget justification, and a maximum of a 5-page description of the project, using single space, 12-point Arial font and a minimum of 1 inch margins. Proposals for research projects should be formatted as follows: Specific Aims, Background, Study Design (including Source Population, Analysis, and Sample Size), Limitations, and Implications.
- Applicants requesting support for dissemination of research findings should provide a budget justification and an abstract of the study results.
- Submit all letters of intent and applications to James Lewis (lewisjd@mail.med.upenn.edu).
- Please address any questions to Rita Schinnar (ritas@mail.med.upenn.edu).