

REQUEST FOR APPLICATIONS

***Patient-Based Discovery Research  
with Electronic Medical Records***

***Pre-Application Workshop: March 9, 2011  
Application Receipt Date: Noon, April 12, 2011***

**A. Background:** The purpose of this RFA is to invite patient-based research proposals that make substantial use of the PSHMC Electronic Medical Record (EMR) database that currently includes data on over 1 million unique patients. Although the primary applications of EMRs today are still in the realm of activities related to patient care, enormous opportunities are emerging to utilize EMRs to enable patient-based discovery research.

At this time, the PSHMC EMR database includes the following types of information:

- Patient Demographics;
- Electronic orders (medications, admitting diagnosis, procedures, consults, diets, diagnostic tests);
- Clinical Documentation (cancer staging, infection tracking, clinical trials, pain assessment, discharge documentation);
- Encounter/visit data (date, clinical service, location, admit/discharge data);
- Clinical Results (laboratory, radiology, EKGs, other diagnostic studies);
- Medications administered (therapeutic classes, dose, unit, administration routes, times);
- Billing data (diagnoses - ICD-9, procedures - CPT-4 , groupers - DRG); and
- Encounter/visit charges (service/procedure charges, room charges, supply charges.)

Most of these data are discrete or constrained to a controlled list of allowable values. Additional information concerning available data and their characteristics is available from Darrell Walter ([dwalter1@hmc.psu.edu](mailto:dwalter1@hmc.psu.edu)).

Some examples of the types of studies that would be responsive to this RFA include using the EMR to:

- Obtain data for longitudinal studies or data mining for hypothesis testing;
- Conduct comparative effectiveness research to assess treatment efficacy and safety in diverse populations;
- Gather phenotypic data to conduct genome-wide association studies;
- Identify patients at high risk for complications or disease development for preventive interventions;
- Develop statistical methods to address phenotypical heterogeneity;
- Determine the impact of environmental factors or lifestyle on susceptibility to disease and treatment outcome;
- Uncover novel etiologic pathways that may serve as targets for new therapies; and

- Develop protocols to ensure patient privacy and confidentiality.

These examples are provided only to illustrate some types of studies that would make substantial use of the EMR and are not intended to describe the entire universe of studies that would be responsive to this RFA.

## **B. Eligibility Criteria:**

1. **Applications submitted in response to this RFA must propose patient-based research that makes substantial use of PSHMC Electronic Medical Records;**

2. **The Principal Investigator (PI) of an application must have his or her primary academic appointment in the College of Medicine.** In addition to the basic science faculty, virtually all physicians employed by The Milton S. Hershey Medical Center have a primary academic appointment in the College of Medicine;

3. **If the PI is not an HMC licensed healthcare provider, then there must be a Co-Principal Investigator who is an HMC licensed healthcare provider** (e.g. physician, nurse, pharmacist, therapist, psychologist, etc);

4. All potential applicants are invited and encouraged to attend a **Pre-Application Workshop on March 9, 2011 from 12:15-1:15 pm in Room C2860.**

5. Investigators who are eligible for this program may submit one application in response to this RFA;

6. Applicants to this program may be eligible to apply for and receive other competitive institutional research support provided there is no scientific overlap between the projects.

## **C. Program Guidelines:**

1. Applications may request up to \$50,000 direct costs for up to 1 year to support new research projects at the Penn State College of Medicine/Milton S. Hershey Medical Center;

2. Grant funds may be used to support the salary and fringe benefits of the PI and/or Co-PI (collectively up to 5% effort, not to exceed a total of \$10,000) and research staff (in proportion to effort dedicated), biostatistical support, student stipends, supplies, equipment, publication costs, and expenses related to the use of human subjects;

3. Grant funds may **not** be requested to support the salaries of other faculty members, either fixed term, tenured or tenure track, or for travel to conferences; however, travel expenses directly related to the conduct of the research project are allowable;

4. If the PI and/or Co-PI propose to devote more than 5% effort to the project, other funding is required to support the additional salary and fringe benefits;

5. Other funding is required to support the contributions of any collaborators from other colleges/campuses;

6. Although IRB approval is not required to submit an application in response to this RFA, protocols must either be approved or determined to be exempt by the IRB before an award will be made;

7. PIs of funded awards must agree to either present their findings at a College of Medicine seminar or submit a final written report to Research Development at the conclusion of the award;

8. PIs of funded awards must also agree to serve on the College of Medicine Scientific Review Committee for a two year period, upon request.

**D. Institutional Priorities:** Priority will be given to the most highly meritorious proposals that make substantial use of PSHMC Electronic Medical Records to address important health issues and offer the potential for expanded research that will be competitive for extramural support;

**E. Review Process:** Applications will undergo an initial review for scientific and technical merit by the College of Medicine Scientific Review Committee (SRC) that will use the NIH review criteria and new scoring metric which may be accessed at :

(<http://www.pennstatehershey.org/web/researchdevelopment/home/internal/reviewcriteria>). Specifically, the SRC will evaluate the responsiveness of each application to this RFA and the significance, investigator(s), innovation, approach and environment and any additional criteria that are relevant to the application. The SRC will also identify changes in study design and methodology that would strengthen each proposal and these recommendations will be returned to the applicant with the reviewer's critique at the conclusion of the review process.

**F. Awards:** The recommendations of the Scientific Review Committee will be forwarded to the Vice Dean for Research and Graduate Studies who will select the applications to be funded. Contingent on the receipt of meritorious proposals, one or two awards will be made on or about June 1, 2011.

**G. Pre-Application Workshop:** All Investigators who intend to submit an application to this program are invited and strongly encouraged to participate in a Pre-Application Workshop on **Wednesday, March 9, 2011 from 12:15-1:15 pm in Room C2860**. At the workshop, the requirements of the RFA and Instructions to Applicants will be reviewed, the expectations of the Scientific Review Committee will be discussed, and there will be an open forum for discussion of related questions.

**H. Additional Information:** Any questions regarding this RFA should be referred to Research Development ([researchdevelopment@hmc.psu.edu](mailto:researchdevelopment@hmc.psu.edu); Phone x6949).

## Instructions for Applicants

# *Patient-Based Discovery Research with Electronic Medical Records*

### **APPLICATIONS MUST USE THE FOLLOWING FORMAT:**

- 1. Page Format** - All pages of the application should have 1” margins all around and use Arial, Helvetica, Palatino Linotype or Georgia typeface and a font size of 11 points or larger. Number all pages consecutively beginning with the Face Page.
- 2. Face Page** with a descriptive title of the project (not to exceed 81 characters); the name, degree, and department of the Principal Investigator/Co-Principal Investigator and any collaborating investigators; and the email and phone number of the PI and Co-PI.
- 3. Table of Contents:** Include a Table of Contents with page numbers for each section of the application.
- 4. Abstract:** Briefly summarize the objectives, methods, and health-relatedness of the proposed research project in terms that will be informative to other persons working in the same or related fields and insofar as possible, understandable to a scientifically or technically literate lay reader.
- 5. Specific Aims:** State concisely the goals of the proposed research and summarize the expected outcome(s), including the impact that the results of the proposed research will exert on the research field(s) involved, and list succinctly the specific objectives of the proposed research. Specific aims must be no more than 1 page on a separate sheet.
- 6. Research Strategy:** This section should describe the proposed research project and be organized as outlined below. Sections a-c should not exceed 5 pages single spaced including figures and tables. If the application has multiple Specific Aims, the Significance, Innovation and Approach for each Specific Aim may be addressed either individually or collectively.
  - a. Significance-** Explain the importance of the problem or critical barrier to progress in the field that the proposed project addresses, how the proposed project will improve scientific knowledge, technical capability, and/or clinical practice in one or more broad fields, and how the concepts, methods, technologies, treatments, services, or preventative interventions will be changed if the proposed aims are achieved.
  - b. Innovation-** Explain how the application challenges and seeks to shift current research or clinical practice paradigms. Describe any novel theoretical concepts, approaches or methodologies, instrumentation, or interventions to be developed or used, and any advantage over existing methodologies, instrumentation, or interventions. Explain any refinements, improvements, or new applications of theoretical concepts, approaches or methodologies, instrumentation, or interventions.
  - c. Approach-** Describe the overall strategy, methodology, and analyses to be used to accomplish the specific aims of the project, how the data will be collected, analyzed, and interpreted, and how the proposed research will make substantial use of the PSHMC EHR. Discuss potential problems,

alternative strategies, and benchmarks for success anticipated to achieve the aims. If the project is in the early stages of development, describe any strategy to establish feasibility, address the management of any high risk aspects of the proposed work, and describe precautions to mitigate any procedures, situations, or materials that may be hazardous to personnel.

- d. **Human Subjects** – Please clarify the status of your IRB application (in preparation, submitted and currently under review, determined to be exempt, or approved). In addition, please briefly address the following:
- (1) **Involvement, Characteristics and Design-** Describe the proposed involvement of human subjects and justify the characteristics of the subject population, including their anticipated number, age range, and health status if relevant. Describe and justify the sampling plan, the recruitment and retention strategies. and the criteria for inclusion or exclusion of any subpopulation. If relevant, explain the rationale for the involvement of special vulnerable populations, describe procedures for assignment to a study group, describe and justify the selection of an intervention’s dose, frequency, and administration, list any collaborating sites where human subjects research will be performed, and explain how data from each site will be obtained, managed, and protected.
  - (2) **Sources of Materials-** Describe the research material that will be obtained from living individuals in the form of specimens, records, or data. Indicate who will have access to individually identifiable private information about human subjects and provide information about how the specimens, records, and/or data will be collected, managed, and protected as well as whether material or data that include individually identifiable private information will be collected specifically for the proposed project.
  - (3) **Potential Risks-** Describe any potential risks to subjects (physical, psychological, financial, legal, or other), and assess their likelihood and seriousness to the human subjects. Where appropriate, describe alternative treatments and procedures, including the risks and potential benefits of the alternative treatments and procedures, to participants in the proposed research.

Although no specific page limitation applies to this section of the application, generally 1-2 pages should be adequate. If IRB approval has been obtained, provide the protocol number and date approved.

- e. **Literature Cited-** (no page limit)

**7. Research Project Budget and Justification**– Use the budget form on the Research Development Website: <http://www.pennstatehershey.org/web/researchdevelopment/home> Use June 1, 2011 as the requested start date of the award and calculate Direct Costs only. Also provide a brief justification for the requested budget items on a separate page.

**8. Biographical Sketch** of the PI. Use the new PHS 398 Biographical Sketch Format H: <http://www.pennstatehershey.org/web/researchdevelopment/home/forms> . Complete the educational block at the top of the format page, and complete sections A, B, C, and D as follows:

**A. Personal Statement.** Briefly describe why your experience and qualifications make you particularly well-suited for your role in this project.

**B. Positions and Honors.** List in chronological order previous positions, concluding with the present position. List any honors.

**C. List selected peer-reviewed publications** or manuscripts in press in chronological order. Do not include manuscripts submitted or in preparation.

**D. Research Support.** List all active and pending research projects. Provide project title, sponsor, project period, and funding awarded/requested. Indicate whether each project listed does/does not overlap with this application.

**9. Future Plans:** Assuming that this feasibility study is successful, describe anticipated plans to apply for external funding including the identity of the most probable sponsor and the expected receipt date for submitting the first such application.

**10. Attachments:** Attach the information requested below. **DO NOT INCLUDE ANY REPRINTS, MANUSCRIPTS, CDs, DVDs, OR OTHER ATTACHMENTS.**

**a. Departmental Commitments-** Attach a letter(s) from the Department Chair(s) to document the percent effort that the PI and Co-PI will commit to this project and describe any commitment of departmental resources that will contribute to the project.

**b. HMC IT Commitment-** Attach documentation from Darrell Walter to confirm that the EMR data needed for the proposed study will be available.

**c. Other Commitments-** If the research proposed requires the use of facilities or other resources that are under the purview of another investigator(s), include a letter from that individual to document the availability of those resources for use in the proposed research.

**A Proposal Internal Approval Form will be required at a later date if the application is selected for award.**

**Application Deadline:** On or before **Noon, April 12, 2011**, applicants should: a) submit four (4) hard copies of the application to Research Development, Room C1630; and b) submit an electronic Adobe version (.PDF) of the application in ONE file to the drop box at <https://rddropbox.hmc.psu.edu/documentdrop.php>. For **Document Title**, use the following – Last name of the PI EMR Date (e.g. JonesEMRApril2011). Please do not use any characters except for numbers and letters. You will need to use your **Penn State Access ID** to submit your application.

**Please direct any questions regarding these instructions to Research Development at [researchdevelopment@hmc.psu.edu](mailto:researchdevelopment@hmc.psu.edu) or 717-531-6949.**