1. DEVELOPMENT OF NOVEL CLINICAL TRANSLATIONAL METHODOLOGIES, AND PILOT AND TRANSLATIONAL CLINICAL STUDIES

7) Informatics Needs

• Clinical trials management software (CTMS)

• Concrete development of Penn State KnowledgeNet (ability to mine the EMR and to develop clinical and translational research projects using it as a database)

• An effective communication and coordination environment

2. BIOMEDICAL INFORMATICS

7) Specific Informatics Needs:

a) Funding for retreats and conferences and other inter-campus meetings.

b) People: we need 3-5 FTE; these are people generally with master’s-trained computer scientists, possibly with some clinical and possibly with some bioinformatics experience.

c) Commitment; there needs to be dean-level commitment to move forward with acquisition systems, integration of those systems and informatics retreats.

d) Resources to support the evolution of our data warehouse (KnowledgeNet) to support analysis of our clinical and financial data.

e) Resources to conduct research and analysis of the national patient database.

f) Support to expand our informatics training activities (we have fledgling medical and pharmacy informatics programs; there is demand and opportunity – but no program – in nursing informatics; PSU Harrisburg has a medical informatics track for IT professionals). HMC leadership to create the HMC IT and Informatics Department. COM and PSU leadership to create a PSU Informatics Department within a few years.

g) Resources to implement a suite of clinical research data management products that will expand and enhance our clinical trials activities.

3. TRANSLATIONAL TECHNOLOGIES AND RESOURCES

7) Specific Informatics Needs:

This is addressed above in 3(E). The time frame is rather immediate, as we probably need to have the organization and staffing of a visible “Bioinformatics/Biostatistics Center” service in place before the CTSA application. Additional mundane (but non-trivial) informatics needs include the need for a common calendar/scheduling program that covers both campuses, one that integrates with existing PDAs and programs and can be used to optimally schedule meetings across the two campuses. Video Conferencing between the two campuses could be greatly aided by having a single contact point at UP for scheduling any video conference room (such as exists at Hershey).

4. RESEARCH DESIGN AND BIOSTATISTICS

7) Specific Informatics Needs:

The current informatics tools for data capture and data management in the GCRC are adequate, but probably will require expansion and enhancement with the evolution to a CTSA.
5.  **ETHICS AND REGULATORY KNOWLEDGE**

7) Specific Informatics Needs:

Create a unified web-based system to avoid duplicating forms for the IRB, clinical trials office, “blue sheets,” NIH etc. This would include auto-fill features for both departmental/institutional information and user-entered information that is needed in multiple data-fields (immediate)

- Utilize web-based educational tools for teaching (see Albany bioethics masters program)
- Use the internet to communicate important information to those involved in conduct of research (see http://www.uic.edu/depts/mcam/communique/)

6.  **PARTICIPANT ANT CLINICAL INTERACTIONS**

7) Specific Informatics Needs:

- We need IT help to support a more comprehensive inventory of clinical resources on both campuses. We assembled a “grid” containing an inventory of centers, facilities, expertise, and equipment that is available to researchers on both campuses. However, it is clear that we have only scratched the surface of what excellent clinical and translational research, is currently being done, albeit in silos, and further work is needed to fully capture all of these resources so that the best ones can be highlighted in our CTSA application. We suggest that an easy-to-use online form be posted on the web that will allow center directors and others who are knowledgeable about these resources to catalog centers/facilities/access to special populations and to indicate how their efforts support the larger goals of the CTSA. Ideally, this would be available for entries by the end of the summer of 2007. In order to get a comprehensive survey completed in time to write the grant, this step needs to be automated and easy.

- We need an easily identifiable, frequently updated website for community members who want to learn about PSU research projects. In its simplest form, this would be a list of studies that are in active recruitment with brief descriptions and contact information for individual projects. For example, the PSU diabetes center sends out a newsletter describing research projects involving diabetes. Community members who volunteer for research are often disappointed when they do not meet narrow inclusion criteria for a study---we need to capitalize on that interest by referring them immediately to other projects. Individual research teams would be encouraged to share this resource with anyone who calls to get information about a research study. We need technical help to set up the webpage and administrative help to update the study descriptions.

- We need a web interface in which community members can submit their name, contact information, and limited health information to a database of potential study volunteers. UPenn provides an excellent model for a HIPAA compliant, privacy-protected database where potential volunteers can identify themselves and provide health information that is searchable by researchers. Our UP campus has a database of families who are willing to be contacted for research projects. This could be a model for development of an easily accessible portal for individuals to identify themselves as willing to be contacted about research. The UP GCRC keeps paper records from subjects who say that they would like to be contacted for future research projects, but these records must be accessed manually.

- The GCRCs currently at HMC and UP do not have access to online scheduling. This is an urgent need. A custom designed scheduling tool developed for GCRCs (“Webcamp”) is available to us, however, it has never been implemented at either site. This would significantly reduce nursing involvement in scheduling and it would allow rapid response to participant scheduling needs by individual study staff. This would also facilitate the production of annual reports of usage, and allow us to study and document patterns of GCRC utilization.

- The clinical data warehouse project at HMC needs additional staff support so that the electronic medical records can be integrated with the other 17 systems at HMC which contain analyzable data, including lab test results, insurance and billing, etc. This effort has been started but it needs more staff
and more funds to complete this massive project before the CTSA is submitted.

7. COMMUNITY ENGAGEMENT

7) Specific Informatics Needs:

One of the important tenets of translational science is to bring new discoveries to bear on the general population. This will mean that the reach of the University into primary care practices and communities across the commonwealth of Pennsylvania needs to be developed and strengthened. The College of Medicine already has a primary care practice based research network (PBRN), but it is too small and localized to support the expanded needs of a CTSA. We propose that we grow the present PBRN. This network needs to be tied electronically. There already exists a tool to tie together community practices - the Electronic Primary Care Research Network (ePCRN). The ePCRN was developed under a grant from the NIH roadmap process. Among its capabilities are tying together practices, recruitment of potential research subjects, assistance with sample size determination, and enhanced conferencing capabilities based on internet-2. This allows virtual video conferencing from any PC and could be used for training/education of community physicians. A common standard for capturing information from medical record has been developed. This database can be searched in a secured fashion to determine the number of eligible subjects in the database. If a practice has an electronic health record, potential subjects for a research study can be flagged for the provider in their electronic health record.

8. RESEARCH EDUCATION AND TRAINING

6) Specific Informatics Needs

Database/Software for Evaluative Queries:
The most immediate need is for a database and set of software tools to improve a variety of critical data collection needs, including: a) assessment of current students; b) tracking of students once they leave PSU; c) faculty research expertise; d) faculty training record; e) program training record. Having such data in easily retrievable format would greatly enhance our ability to unify and improve clinical and translational efforts within education. While some of the information is available through existing PSU tools (FRED, ISIS), significant items are not available (e.g., post-PSU career tracking), and what is available is not in a unified, easily usable database. One more immediate solution would be to consider utilizing such as the BRET (Biomedical Research, Education, and Training) database at Vanderbilt University (either a direct purchase or a leased service provided by Vanderbilt). Examples of questions that should be possible to answer with the database include: What are the publication records of PSU graduates? How many courses are team-taught by professors from differing disciplines / professional backgrounds? How many publications reflect cross-campus collaborations? How do the professional positions of CTSA program graduates differ from those of traditional program graduates?

Improvement of FRED:
Expansion of FRED would further facilitate the ability of individuals within both medical and research fields to communicate, consult, and collaborate. For a strong CTSA application, a broadened inclusion of faculty from all campuses is necessary. A current search for any branch-campus (not UP or Hershey) faculty yields no results. Expanding the database to include clinicians, graduate students, post-docs, and residents would allow further cross-talk across medical and research disciplines. Better measures should be taken to implement updating of the database with incoming/leaving faculty and external URL changes. Extracting/exporting information into/from FRED from departmental databases/websites with similar research descriptions would ease update mechanisms. Distinguishing between keywords of current focus, expertise, and interest would assist students and postdocs searching for professors as potential mentors or simply for specific consultation. Additional useful fields would include species studied, courses/lectures taught, present/past members of the lab (for PIs), collaborators, meetings attended, and whether or not the individual is looking for post-docs, students, techs, etc. Providing a means to search for these new fields and other existing fields (e.g. research description, publication titles) would create a powerful tool. Linking the ANGEL and FRED database would provide a way to manage "course" and "lecture" fields and would also provide an opportune means of increased assessment capabilities.

Distance Technology
Expanding the use of distance technology between PSU campuses and clinical sites with would allow students and current practitioners (e.g. in rural clinics) to connect to experts in the field for consultation or CE purposes. Innovative videoconferencing applications such as Adobe Connect provide simultaneous point-to-point videoconferencing from a desktop. Current initiatives such as World Campus and UPHershey connections have already extended educational opportunities. Building upon this technology and expanding its usage may enhance this strength even more.