

UNIVERSITY OF PITTSBURGH
CLINICAL AND TRANSLATIONAL SCIENCE AWARD
PROPOSAL

CTSI Community PARTners
(Partnering to Assist Research and Translation) Program

SUBMITTED MARCH, 2006

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Transforming Health Practice:**CTSI Community PARTners (Partnering to Assist Research and Translation) Program**

The absence of functional collaboration among the research, practitioner, and lay communities contributes to the inefficiency of the research enterprise with respect to enhancing the health of the population. Failure to proactively enlist community involvement in clinical research agendas results in difficulty meeting recruitment goals, which, in turn, delays timely completion of clinical trials. In addition, there is ample evidence that new research findings are slow to enter the practice environment. Multiple reasons have been postulated, and they tend to center upon the limited and isolated relationships between the communities of interest and the academic research enterprise. This absence of ongoing meaningful relationships contributes to a lack of trust and confidence between the community and researchers, independent of the pursuit of the goal of enhancing the health of the population, and incomplete communication, if not miscommunication, about research and research findings.

The University of Pittsburgh Clinical and Translational Sciences Institute (CTSI) has as one of its primary functions the development of a sustainable institutional program to engage the community in clinical and translational research. The CTSI broadly defines the community as comprising the 1) lay community, 2) health provider community, and 3) community of research investigators. To that end, the Community PARTners (Partnering to Assist Research and Translation) Program will be established to support the engagement of these communities in collaborative relationships that will facilitate trust and ongoing communication. The broad objective of this program is to foster ongoing communication and build informed communities that collaborate in the generation of research hypotheses, conduct of research studies, and translation of research findings into practice.

The **specific aims** of the Community PARTners Program are to:

- 1. Develop a “research informed lay community” that actively participates in (a) clinical research studies, (b) translation of research discoveries to individuals and populations, and (c) the development of clinical and translational research agendas;**
- 2. Develop a “research informed multidisciplinary health professional community” that actively participates in (a) evidence-based practice that fosters the translation of research findings, (b) study participant recruitment and (c) conduct of clinical research as well as the development of clinical and translational research agendas; and**
- 3. Develop “community-informed researchers” who foster the performance of clinical and translational research by (a) educating, (b) communicating with, and (c) partnering with lay and multidisciplinary health professional communities.**

The CTSI postulates that the development of research-informed lay and health provider communities and community informed research investigators will facilitate: 1) the recruitment of subjects into clinical research studies; 2) the translation of research discoveries to individuals, communities and populations; and 3) the development of research agendas that are relevant to residents of western Pennsylvania. Furthermore, the CTSI hypothesizes that this fundamental principle of community engagement will increase the standard of health care and promote translation of research discoveries in the region by promoting the practice of evidence-based health care in the community.

BACKGROUND

The “golden years” of clinical research that occurred between the end of World War II and the early 1960s focused on patient-oriented clinical research.¹ The interrelationship between clinical care and research during these years resulted from continuous interactions among physicians, scientists, and patient-subjects and a two-way movement between the clinical and laboratory settings.¹ This stemmed from the close proximity of basic science laboratories, clinical wards, and physiologically based research units, which, in turn, led to a social organization of and an academic home for clinical research.

During the last three decades, the focus of clinical research has transformed from the study of the sick¹ to more comprehensive studies and trials in human subjects.² Clinical research has also become an integral component of the broader applied discipline of translational science. Translational science includes two segments: 1) application of discoveries generated during research in the laboratory and in preclinical studies to the development of trials and studies in humans and 2) enhancing the adoption of best practices that are identified by clinical research in the community.³ Therefore, the ultimate goal of clinical research and translational science is to improve health as well as prevent and treat disease among individuals, communities, and populations. Thus, recruitment of subjects takes place among inpatients, outpatients, healthy and at risk populations as well as disease-affected individuals. Broadening of the definition of clinical research has been associated with the rapid expansion of the research enterprise and a demolition of the historical academic home for clinical research.

Yet barriers exist for both the conduct of clinical research and its translation into practice. Investigations of barriers to clinical research indicate that patients are hesitant to participate in research studies due to study demands (e.g., appointments, procedures), travel, costs, preconceived preferences for a particular treatment, concerns about the uncertainty of treatments, and concerns related to the consent and regulatory processes.⁴ Community barriers include skepticism about equality in partnerships, historical inequality in access to resources, competing demands on time and resources, and knowledge and skills in the research process among community members.⁵ These barriers are particularly relevant to minority, underserved, uninsured, poor, and rural communities, all of which have lower participation rates in clinical research.⁶ Additional barriers include ineffective communication between patient and provider, community infrastructure, lack of outreach, and the lack of understanding about the value of research in improving health.⁶ Additionally, these populations are more inclined to distrust academic medical centers as a result of historical and existing inequities in healthcare, health disparities, under representation of minorities in health professions, and history of mistreatment in clinical research studies (e.g., Tuskegee experiment). In general, trust in the health care system is low at this point in time, and the public does not distinguish between clinical research and the health care system.⁷

The delay or avoidance of adoption of research findings in practice also constitutes a significant problem. It is estimated that there is a 10-20 year lag in incorporating research findings into routine clinical practice.⁸ Moreover, it has been reported that only about 60% of patients receive recommended care for chronic conditions.⁹ Multiple factors influence the slow pace of adoption of research findings.¹⁰ These include the perceived benefit of the findings, how well they fit with current needs and practices, the level of complexity, whether the findings can be tried/tested with a small sample of patients, and whether the implementation can be observed.³ Others include concern about the adequacy of resources, the similarity or difference in the situation of practice, and the necessity to strive for those goals (e.g., accessibility, credibility and expectations).¹¹

Development of relevant partnerships is fundamental to addressing these barriers. Engagement of the lay community can help to dispel the problems with trust, access, and knowledge and will allow investigators to address community concerns regarding resources, time, and priorities. A complementary approach to recruitment of subjects from the community employs the development of partnerships between academic health centers and community-based professionals.¹² This entails not only informal partnerships but education of the practitioners about research design and the value of research.¹³ The development of both community and health professional networks to promote clinical research and its translation have common fundamental elements.⁵ Academic health centers must provide the community (lay and health provider) with a/an: 1) trusting bi-directional relationship; 2) education as to the benefits and risks of research studies; 3) sustainable benefits (e.g., services, resources, access to state-of-the-art health care); 4) knowledge about research ethics and protection of human subjects; 5) education about the value and benefits of research and its findings; and 6) infrastructure to support the performance of research in community settings. It must also provide investigators with the skills and knowledge to communicate with diverse communities. Each of these elements requires long-term university educational, financial, and logistical (e.g., information technology) commitments to the lay and health provider communities.

Current State

The University of Pittsburgh is fortunate to be home to many novel and successful community engagement initiatives and resources. The intent of the CTSI is not to eliminate or replace them, but to leverage their

strengths in the establishment of a centralized, coordinated engagement program that will eliminate barriers between schools, disciplines, institutions, and communities. This section describes the following: 1) the community surrounding the University of Pittsburgh; 2) selected research centers and existing programs at the University of Pittsburgh and the UPMC that serve as examples of best practices in community engagement; and 3) limitations of the current state that impede community involvement in clinical and translational research. The Design and Methods section describes how these resources will be transformed into a program that will expand the capacity of the CTSI to engage the lay, health professional, and research communities in collaborative partnerships that will advance the discipline of clinical and translational research.

The Surrounding Community

The University of Pittsburgh is centrally located in Pittsburgh, a neighborhood-centric urban community. The community of interest encompasses a diverse array of persons and organizations. County statistics reveal that Pittsburgh contains a well-educated, aging population residing in small households. Disability rates (14%) are higher than average.¹⁴ The population of approximately 1,209,484 (county), is 52% female and 17.3% over 65 years of age, compared with a national average of 12%.¹⁵ Over 17% are persons of color, with nearly 1/3 of the city itself. The community is well educated, with 90% having a high school degree and 31% having a college degree or greater. Approximately 11% of the population is below the poverty level. Nearby, and within the healthcare catchment area are several small rural counties where the proportion of elderly is higher, as is the proportion who are disabled, and education levels are lower.

Selected Research Centers and Existing Programs

Graduate School of Public Health (GSPH) Among the community engagement programs housed in the GSPH, is the Center for Minority Health (CMH), a lead entity within the schools of the health sciences to coordinate the academic, research, and service activities of faculty and students who deal with issues relevant to minority health and health disparities. In this capacity, the center's evidence-based interventions are closely tied to the National Initiative to Eliminate Racial and Ethnic Disparities in Health and the nation's health promotion and disease prevention agenda established in *Healthy People 2010*.¹⁶ The center's community health promotion and prevention work is channeled through the EXPORT Health Community Outreach and Information Dissemination Core. The CMH also works closely with research investigators to help build their capacity to increase the participation of underrepresented populations in research. The CMH will continue to be a resource to the research community and will be called upon to offer consultation on reaching the minority populations in the area.

School of Dental Medicine (SODM) The Center for Oral Health Research in Appalachia (COHRA) is a collaborative effort between the University of Pittsburgh's Center for Rural Health Practice and the SODM. Viewed from an ethnography perspective, Appalachia constitutes a unique American culture, often referred to as the "forgotten minority." It has been long recognized that children and adults in Appalachia, have significant oral health disparities compared with the general U.S. population. Oral health problems develop early in life among Appalachians, resulting in a trajectory of poor oral health over the life course. The overarching mission of COHRA is, through enhanced understanding of the nature of the person-environment interaction, to inform and implement effective community-based prevention programs aimed at the reduction of oral health disparities. To accomplish this mission, COHRA has been organized around a unifying theme that can be summarized as a multifactorial, developmental characterization of person-environment interactions in children that result, over their life course, to the development of oral disease liability. Mindful of the need for culturally appropriate and targeted intervention at the community level, COHRA is strongly linked to the Appalachian community through organizations such as the University of Pittsburgh's Center for Rural Health Practice and the West Virginia Rural Health Education Partnership. COHRA will serve as a template for the engagement of rural communities in CTSI activities.

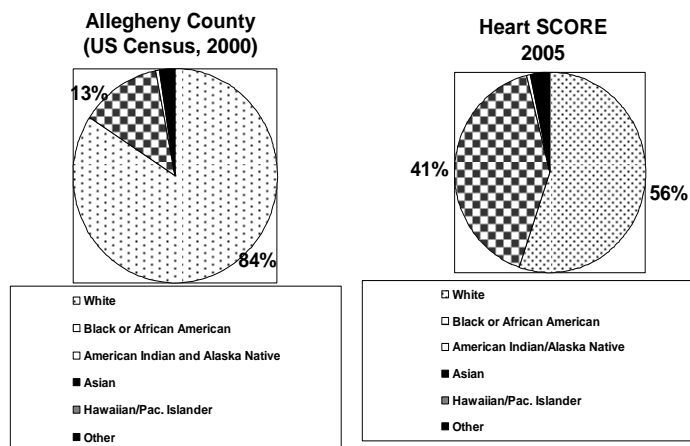
School of Health and Rehabilitation Sciences (SHRS) Operated under the auspices of the SHRS, the University of Pittsburgh Rehabilitation Engineering Research Center (RERC) on Telerehabilitation serves people with disabilities by researching and developing methods, systems, and technology that support remote delivery of rehabilitation and home health services for people who have limited local access to comprehensive medical rehabilitation in outpatient or community-based services. Research and development activities are in the areas of telerehabilitation infrastructure and architecture; telerehabilitation clinical assessment modeling;

teleassessment for the promotion of communication function in children with disabilities; remote wheeled mobility assessment; behavioral monitoring and job coaching in vocational rehabilitation; and remote accessibility assessment of the built environment. Education and training initiatives are integrated into the research and development processes in order to develop expertise among consumers and providers. The RERC will serve as a consulting resource for investigations that utilize telehealth technologies in the collection of data or delivery on interventions with distant or isolated populations.

School of Medicine (SOM) Heart Strategies Concentrating On Risk Evaluation (Heart SCORE) is a large scale community based participatory research program that was developed by Steven Reis, MD (CTSI Principal Investigator) to address Healthy People 2010's Goal of Eliminating Health Disparities.¹⁶ The objectives of this Commonwealth of Pennsylvania funded study are to: 1) improve CVD risk stratification among African Americans in western Pennsylvania; 2) identify CVD disparities based on race and socioeconomic status; 3) evaluate biological mechanisms for population differences in cardiovascular risk; and 4) implement and evaluate a multidisciplinary community-based intervention program to decrease CVD risk in high-risk populations. Heart SCORE was designed as a prospective cohort study seeking to enroll 2,000 residents of western Pennsylvania with equal representation of Caucasian and African American subjects. Nested within this cohort study is an intervention study that evaluates a multidisciplinary culturally sensitive community-based behavioral modification intervention to reduce CVD risk. Ongoing recruitment is occurring in partnership with several community partners including the Urban League of Pittsburgh, Metro-Urban Institute Office of Applied Religion (MUI-OAR) of the Pittsburgh Theological Seminary, Center for Healthy Hearts and Souls, the Jewish Health Care Foundation, a network of more than 30 local churches and community organizations, and community-based physicians and health professionals.

As a result of the trust that has been established within this investigator-initiated university-community partnership, Heart SCORE has recruited a cohort of nearly 1900 study participants with a distribution of minority participants that is more than threefold that of Allegheny County (see Figure 1). This study has not only demonstrated the success of a community-based participatory research program in Pittsburgh led by the CTSI principal investigator, but has also provided data that will reduce race-related disparities in CVD (manuscripts in preparation and submitted). From a service perspective, Heart SCORE's recruitment program has provided educational and health screening benefits to more than 2000 individuals who live in underserved communities surrounding the University of Pittsburgh. Heart SCORE will serve as a model of community participatory research in establishing community-research partnerships.

Figure 1. Heart SCORE Recruitment Data (n=1881).



School of Nursing (SON) The SON initiated an extensive program in evidence based practice (EBP), which provides the foundation for the education of nurses at a variety of levels (BS, MS, PhD). Three levels of education are included. First is the foundational education in EBP, which includes basic statistical skills, critical evaluation of the research literature, strategies for accessing the literature, and identifying and using patient preferences and values in designing care. The second level focuses on the development of expertise in EBP and redesigning practice. This includes more advanced skills in interpretation of statistical analysis, evaluating and comparing bodies of evidence for utility in practice, and designing and evaluating evidence-based protocols within the practice setting. The third level prepares the student for contributing to the science underlying practice. In addition to developing a greater understanding of design and analysis methods, this enhances skills in activities such as performing meta-analyses, evaluating evidence and practice to determine the next important questions, and conducting research. To support this initiative, faculty within the SON have

developed a number of "tool kits." Criteria and guided forms have been developed to review literature from various design perspectives, such as randomized clinical trials, observational studies, and qualitative studies. Identification of sources of information about more common cultural, ethnic, religious, and other personal characteristics have been identified to support learning about the value and preference issues that need to be considered in planning care. A third tool kit includes information on conducting literature searches, with case study examples that incorporate patient characteristics (e.g., cultural and religious practices) and clinical findings (e.g., co-morbid conditions).

The ability to educate students is important for the future of health care and for clinical research and translation. However, it is also important to promote the use of research findings among current practitioners. Given the long delay in adoption of research findings in practice, 10 to 20 years in health care,⁹ passive approaches are likely to be unsuccessful. Therefore, another element of this initiative is to examine the barriers to adoption of EBP principles in current clinical practice and to determine models of successful adoption. Therefore, several activities are underway. A survey to examine institutional and individual readiness for EBP supported care management is being undertaken in five rural hospitals. Preliminary data suggest that the education of the nurses in practice did not include research principals in many cases and that the perception was that the use of research did not apply outside of academic health centers. Following a more inductive approach to foster adoption of EBP principles in practice, nurses from one hospital have begun the process of interviewing patients post-discharge to determine the level of understanding and adherence to discharge instructions. At the time of this writing 92 patients have been interviewed. A facilitated review of the data collected will discover problems with post-discharge adherence (estimated to be about 50% based upon the current literature on adherence). A facilitated examination of a review paper on adherence interventions will identify improvements that can be made in discharge instruction, followed by a second post-discharge assessment of patients. If this strategy is successful, the process will be disseminated to other settings. If not, alternative strategies will be evaluated. Within the academic health center, faculty from the SON sit on a committee to develop evidence based protocols for care delivery. Concurrent with this initiative is the development and conduct of a continuing education series for practicing nurses at various levels, including advanced practice nurses and nurse educators. The SON is experienced in distance education throughout Western Pennsylvania, and this educational technology will be utilized to enhance the EBP program and to reaching a broader audience. This initiative will serve as the paradigm for a CTSI-based initiative to educate and promote adoption of research (i.e., EBP) among practicing clinicians from multiple disciplines.

School of Pharmacy (SOP) The SOP and the Rite Aid Corporation have partnered to develop four centers of excellence for medication therapy management and advanced pharmacy practice in Rite Aid pharmacies in the Pittsburgh area. Each Rite Aid Center provides this service in support of four to eight additional stores bringing the total number of Rite Aid stores where patients are served to 28 stores in the Pittsburgh Area. The Rite Aid Centers of Excellence all employ software developed by the SOP to capture information about the patient and outcomes in addition to the information normally captured about medications dispensed. This network will be expanded to eight regions nationally from fall of 2006 to spring of 2007. The Rite Aid Centers of Excellence provide a unique method for enrolling community-dwelling patients into clinical studies or patient registries.

Non-Health Science Schools The Center for Rural Health Practice at the University of Pittsburgh Bradford regional campus provides clinical researchers with access to rural communities and health providers as well as identifies and articulates research health issues that are relevant to rural America. The center is located in northern Appalachia and serves a six-county region in northwestern Pennsylvania. Its service area is characterized by disparities in socioeconomic status, health status, and access to care. Within this region, the center has been instrumental in the development of a regional healthcare network, the *Kinzua Regional Health Alliance*. The *Alliance* is comprised of the five non-UPMC affiliated hospitals serving this region and additional health providers such as home health agencies, nursing care facilities, paramedics, dentists, and other health personnel. Using this network, the center has conducted studies addressing the financial vulnerability of rural home health agencies and built an integrated community health database for health planning purposes. Other efforts include a study of rural health workforce shortages, hosting a research study site for the University of Pittsburgh's School of Dental Medicine's NIH-funded Center for Oral Health Research in Appalachia, conducting an employer-based health promotion initiative, and the development of rural terrorism preparedness trainings and resources. This healthcare alliance will work synergistically with the

CTSI to identify facilities and participants for clinical trials and develop research programs that identify and reduce rural health disparities. The center also has access to ITV facilities that can be used to provide targeted training and education to rural health providers and support telehealth biomedical applications such as those that are being initiated by the School of Health and Rehabilitation Sciences. The interactive nature also allows for feedback from rural providers that can aid in the development of clinical research that is relevant to the rural population.

Centers for Research The University of Pittsburgh is fortunate to have numerous NIH supported centers of excellence addressing a variety of research programs. These programs provide a consolidated source of interdisciplinary investigators who are addressing clinical problems of relevance in the community, and most have educational programs in place for junior investigators. Table B.1 of this proposal contains selected examples of NIH supported centers that will provide dissemination sites for programs developed by the Community PARTners Program, such as cultural sensitivity training, community communication, and other initiatives. The PARTners Program will, in turn, serve as a resource for the dissemination of center activities within the research communities and health professions communities.

UPMC The UPMC is the dominant health system in western Pennsylvania, having 45% of the market Share in Allegheny Count and 25.3% of the market share in its 29 county service area. The UPMC consists of 19 hospitals and 350 outpatient offices and specialized outpatient sites. Its institutions account for 3 million outpatient visits, 150,000 inpatient admissions, 350,000 emergency room visits, and one million home health care visits each year. (Additional details on the UPMC are in the CTSI Overview section and Tables B.2 and B3 of this proposal.) The UPMC has targeted specific initiatives within their regional institutions. For example, the UPMC has designated Braddock Hospital as its flagship hospital for leadership in working to eliminate health disparities within the region. This hospital was chosen based on its tradition of service to low income, minority communities located within its service area. The St. Margaret's Hospital, a suburban general hospital, has been designated as a center for Information Technology. Horizon Hospital, a rural community hospital, is participating in the nursing evidence-based practice initiative. Other areas of emphasis, including community and industry initiatives, exist throughout the system.

Limitations of the Current State

The research enterprise at the University of Pittsburgh has an extensive long-term track record of the performance of clinical and translational research in the community. For example, the successful development of the polio vaccine by Dr. Jonas Salk and colleagues at the University of Pittsburgh in 1955 required the translation of the Salk team's basic science discovery by the performance of clinical studies in communities surrounding the university. This program formed the foundation for translation of the development of a vaccine that eradicated polio to national and international community practice. Numerous other examples exist. For example, studies on cardiopulmonary resuscitation have led to guidelines for the management of cardiac arrest. The Graduate School of Public Health has contributed to numerous large-scale multicenter trials that have informed health policy (e.g., the MRFIT and WHI studies). The School of Nursing has carried out studies on patient adherence in research and practice that have also informed the research agenda. The Schools of Health and Rehabilitation Science have contributed a bioengineering and rehabilitation perspective to mobility enhancements for the disabled. Despite these and numerous other examples of successful translation of basic research to the communities in Pittsburgh, university investigators continue to encounter barriers to clinical and translational research that are similar to those that are faced by most urban academic researchers across the United States. The clinical and translational research effort is further hampered by lack of a coordinated effort to engage the community in research activities as each investigator typically addresses these barriers independently.

The culture and neighborhoods surrounding the university limit the exposure of investigators to adjacent communities. These communities have diverse populations who are primarily socio-economically disadvantaged. Over 200 years of history has bred a long-term sense of distrust. In the recent past, however, the university has developed aggressive outreach programs to improve its relationship with and solicit guidance from surrounding neighborhoods.

Numerous barriers have been identified by representatives of the community and by multidisciplinary health practitioners within the community. Practitioners have expressed concerns about the burden placed on an

already busy staff and practitioners, both in terms of participation in research initiatives as well as in investment in adopting findings beyond those recommended in accepted guidelines. Value associated with specific initiatives is not always perceived. Often the findings of the research itself are seen as not applicable to the practice setting, often due to the complex clinical pictures that patients present while studies often address a single dimension without attention to other conditions that may be presented by the research subject. Concerns exist about the diversion of patient care from the practice center. In addition, the conduct and utilization of research historically has not been a strong component of practitioner education. "Research tracks" in educational programs across the health sciences have separated the typical practicing clinician from the basic or clinical investigator. At times when efforts are made to disseminate research findings to practice, a uni-directional, linear approach is taken, ignoring the experience, setting, and knowledge of the practitioner in adapting findings to the unique setting. Furthermore, although the patient's experience of health care is multidisciplinary, elicitation of participation and dissemination of research findings is often within disciplines.

The University of Pittsburgh and UPMC have developed model programs to address these barriers. While these programs have had substantial impact on individuals, their overall community impact have been limited as a result of narrow scope (e.g., focus on specific disease entities or disciplines) as well as limited and cyclical resources. The impact and sustainability of these programs can be optimized by organizing them in the CTSI academic home using a multidisciplinary collaborative approach that has been supported by institutional, foundation, and federal funds. Therefore, a major objective of the Community PARTners Program will be to address the barriers to efficient clinical and translational research as a coordinated, collaborative activity.

CORE DESIGN and METHODS

The development of an institutional program of community engagement in the CTSI is critical to sustaining the clinical and translational research enterprise at the University of Pittsburgh. The CTSI will transform the practice of fragmented and decentralized community engagement at the University of Pittsburgh to a coordinated institutional approach. This will allow resources to be pooled, committed investigators to be formally trained in cultural sensitivity and appropriate approaches to community engagement, and the community to have a "point person" to contact in their development of health-related programs. Accordingly, the Community PARTners Program will: 1) develop an institutional framework that will result in an effective, sustainable community engagement program; 2) identify and centrally organize existing decentralized "best practices" community engagement resources at the University of Pittsburgh and UPMC; 3) integrate existing programs into the new CTSI Community PARTner Program; 4) organize existing and newly developed community, health provider, and research investigator networks; and 5) address barriers to effective community engagement as they arise. This section will describe the administrative and operational foundation of the PARTners Program and then address the proposed activities for the three target communities.

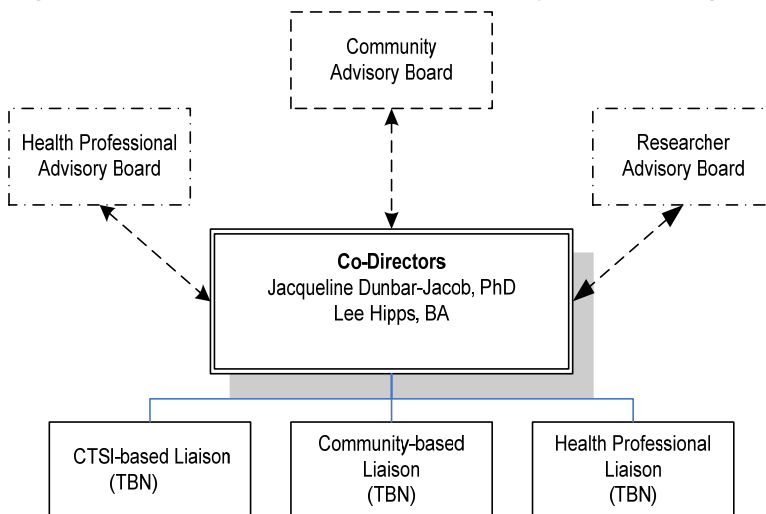
Administrative and Operational Foundation

The Community PARTners Program will utilize an innovative administrative and operational foundation wherein there is representation from each of the communities of interest (Figure 2).

Directors The Community PARTners Program will be co-directed by a member of the CTSI (with experience as a health care provider and a researcher) and a member of the lay community. Shared leadership will foster a true sense of partnership and enhance the ability of the Community PARTners Program to meet its objectives.

Jacqueline Dunbar-Jacob, PhD, RN, FAAN, has been involved in numerous community and clinical research activities. She

Figure 2. Administrative structure of Community PARTners Program.



is active within the community through participation in health improvement and workforce initiatives at local foundations as well as through workforce initiatives at the state level. She is currently a board member of three local organizations, including the UPMC Shadyside-Presbyterian Hospital, and is a participant in the UPMC vice-presidents for patient care services monthly meeting. She chairs the national advisory board of the Institute for Healthcare Communication, a national continuing education organization that delivers training in patient-provider communication. She is active in interdisciplinary professional organizations, including past-president of the Society of Behavioral Medicine and the Academy of Behavioral Medicine Research, which address the interplay of behavior and medical conditions, and past board member of the Society for Clinical Trials. She currently serves on two NIH advisory boards (DSMB of the Diabetes Prevention Trial, NIDDK) and chairs the Scientific Advisory Board of the roadmap measurement initiative, Patient Reported Outcomes Measurement System (PROMIS). She has served on three other NIH advisory boards: 1) the advisory board of the Hypertension Prevention Trial (NHLBI), 2) the DSMB of the Optic Neuritis Treatment Trial (NEI), and 3) the National Institute for Nursing Research advisory board as well as on numerous NIH working groups. She served as deputy director of the behavioral science group of the Lipid Research Clinical Program and behavioral science advisory during the design and feasibility phase of the Diabetes Control and Complications Trial. Her own research, which is clinical in nature and NIH funded, has actively engaged community practices in the recruitment of subjects for over 15 years. She is principal investigator for the NIH supported Center for Research in Chronic Disorders which focuses principally on adherence (patient, provider, investigator) and quality of life. She is currently project leader of the adherence and retention core of the Pepper Center. In addition, she leads the School of Nursing, including the EBP initiative, which was funded by the Robert Wood Johnson Foundation as an executive nurse fellow leadership project. She has secondary appointments in two of the health science schools.

Lee Hipps, BA, Executive Vice President, Urban League of Pittsburgh is a highly respected community leader with extensive experience in organizational management, strategic management, program development, and customer service. Mr. Hipps served as Director of Support Services for Magee-Womens Hospital, for nine years, during which time he gained expertise and skill in meeting the complex and often competing needs of health care institutions, health care providers, and community members. Mr. Hipps currently serves as the Executive Vice President and Chief Operating Officer of the Urban League of Pittsburgh, an organization that has played a central role as an advocate and direct service provider in basic human services in Pittsburgh since 1918. In addition to having an integral role in the logistical implementation of CTSI Community PARTner Programs, the Urban League will serve as a link between the CTSI and other community organizations. During his tenure at the Urban League, Mr. Hipps co-developed successful community-based participatory research programs with Dr. Reis, CTSI PI.

Community PARTners Program Liaisons Success of the PARTners Program relies heavily on the communication, interaction, and integration and use of resources across the three communities of interest. To that end, the Community PARTners Program will institute an operational foundation consisting of three types of liaisons, each with a focus on a specific community of interest: the **CTSI-based Community Liaison**, the **CTSI-based Health Professional Liaison**, and the **Community-based Liaison**. Each liaison will be responsible for interacting with his/her counterparts, the program co-directors, and the advisory boards to ensure the needs of their constituencies are addressed.

The **CTSI-based Community Liaison** will be an integral part of the CTSI-based Research Facilitator program (see the CTSI Overview section of this proposal) and will interact directly with researchers, university schools and departments, and UPMC to identify investigator needs that are relevant to promote community-based participatory research, clinical research in the community, and the translation of research to practice. A major role of the CTSI-based Community Liaison will be to establish and maintain a centralized repository of resources related to community engagement. This will be done by identifying existing community engagement programs as well as formal and continuing education courses related to community engagement, and evaluating their applicability for inclusion in the program repository. This liaison will also meet individually with investigators who are referred to them via the CTSI Research Facilitators to assess the investigators' needs and connect them with relevant resources. The CTSI-based liaison will be expected to work closely with the Health Professional and Community-based counterparts to facilitate requests brought forth by these liaisons by identifying and mobilizing resources within the university and UPMC environments. The CTSI-based Liaison

will be responsible for identifying gaps in education, services, and resources and collaborating with the program directors and other CTSI cores in the development of methods to bridge those gaps.

The **Health Professional Liaison** will be a registered nurse with clinical research and education experience who will serve as an advocate for members of the multidisciplinary health professional community. This individual will be responsible for cultivating relationships with community-based health professionals and identifying and addressing their needs for educational programs related evidence-based practice and clinical research. A major responsibility of this liaison will be to coordinate the pilot Evidence-Based Practice (EBP) initiative that is outlined later in this section.

The **Community-based Liaison** will serve as an advocate for the lay community. This liaison will be a registered nurse who operates from the PARTners Continuity Clinic that is described later in this section. This individual will be responsible for performing selected health screenings and making referrals as well as identifying needs and requests for education, services, or resources brought forth by the lay community. This liaison will work with other CTSI-based liaison counterparts to identify resources and orchestrate these programs.

Advisory Boards To ensure that the Community PARTners Program addresses issues of relevance to the target communities, three advisory boards will be formed to provide guidance on program activities.

The **Community Advisory Board (CAB)** will be established during year one. Members will be well-respected individuals from the community, and efforts will be made to ensure representation reflective of the demographics of the surrounding community. During the first six months, the CAB will meet monthly to develop a mission statement, establish goals, define roles and responsibilities of members, and establish mechanisms to evaluate and prioritize needs and requests related to the lay community. Subsequently, the CAB will meet semiannually to provide guidance with respect to the program activities and services that target the lay community. It will be responsible for programmatic direction, the development of programs, and interpretation, and response to program evaluations. The CAB will also provide advice about interactions with community-based organizations and foundations, and public programs that should be cultivated as program partners. It will be responsible for advising the PARTners Program as to specific operational issues relevant to the lay community. These issues include, but are not limited to, those related to seeking and responding to input from the community, the development of appropriate community-based programs (e.g., educational, services, research), funding priorities for community-based participatory research, and initiating and sustaining relationships between the CTSI and local community, foundation, organization, and governmental groups. In addition, the CAB will provide an annual evaluation of the activities of the Community PARTners Program.

A **Multidisciplinary Health Professional Advisory Board (MAB)** will also be established during project year one. Membership will consist of multidisciplinary professionals from the surrounding practice community. During the first six months, the MAB will meet monthly to establish goals, define roles and responsibilities of members, and establish mechanisms to evaluate and prioritize needs and requests related to the health professional community. In subsequent years, the MAB will meet semi annually to provide input on barriers to clinical and translational research from the health provider perspective as well as to propose possible solutions. This group will also provide guidance on mechanisms to facilitate evidence-based practice and will provide specific feedback of the EBP pilot with regard to the progression of activities, specific process activities, and translational questions to be addressed. They will provide an annual evaluation of the progress and success of the EBP diffusion initiative. They will also contribute input to the identification of health professional needs with respect to participation in clinical research.

A **Researcher Advisory Board (RAB)** consisting of investigators, coordinators, research associates, and students will be established during year. Efforts will be made to ensure representation across disciplines and specialties. This board will also meet monthly during the first six months to establish goals, define roles and responsibilities of members, and establish mechanisms to evaluate and prioritize needs and requests related to the researcher community. The RAB will then meet semi-annually to provide feedback on program activities and provide guidance for the modification to or addition of new program services.

Engagement of the Lay Community

The lay community consists of the general public, patients undergoing care, members of occupational and business/professional groups, as well as foundations and organizations. Efforts directed toward the lay community will include each of these groups. The intent of the Community PARTners Program is to fully engage the community in an expanding and valued contribution to health and to enlist the community in development and utilization of clinical research. To this end, efforts will focus on educating the lay community, involving the lay community in the mentoring of investigators, promoting participation in clinical and translational research, and encouraging this community to play a role in the development of community-based research agendas.

Educating the Lay Community.

The Community PARTners Program will draw upon existing resources to develop a comprehensive lay community educational program that is responsive to the needs of specific targeted communities and simultaneously provides general and specific information about clinical and translational research. New educational material will be developed when there is a documented need that cannot be met by existing resources. The CAB will guide the development of the educational campaign, which will serve to build a trusting relationship with the community by providing health-related services (e.g., health screenings, referrals for the uninsured) and responding to community needs for educational, research, and health screening services. This philosophy is consistent with recent trends in clinical research and increased public scrutiny that have underscored the importance of incorporating public education and outreach into the clinical research enterprise. The campaign will educate individuals about health-related issues that are relevant to them and their community, the impact of clinical and translational research on their lives, the value of research and the promotion of health and wellness. Several methods will be used, including culturally-sensitive seminars, health and wellness screenings, individual counseling by community-based health professionals (e.g., pharmacists, nurses, paramedics), interactive web-based resources, a community research registry, culturally-sensitive educational literature, advertising campaigns, public service announcements, community-based initiatives in partnership with public health organizations, schools, churches, service organizations, and foundations. University-based programs will be leveraged whenever possible. For example, the School of Medicine offers a "Mini-Medical School" for lay audiences that has been received favorably by the this community. Therefore, education pertaining to clinical and translational research will be incorporated into the Mini-Medical School curriculum. Dissemination methods for other programs will be guided by the characteristics and needs of the target population. The PARTners Program will also work closely with the CTSI Center for Clinical and Translational Informatics to provide web-based mechanisms of dissemination. A Community Outreach Speakers Bureau (COSB) will be established as a mechanism to educate and engage the public via the provision of services (e.g., health screenings and speakers) for public functions upon the request of community organizations. The project will be a collaborative effort of the CTSI and the UPMC Office of Grants, Contracts, and Intellectual Property and is compatible with the mission statements of the University of Pittsburgh and UPMC. Health promotion will be the primary objective of this outreach program, with promotion of participation in clinical research being a secondary objective. The COSB will include speakers from a variety of disciplines and specialties, and community organizations will define the topics for outreach activities.

Mentoring Investigators and Trainees.

To promote lay community involvement in the mentoring of investigators and trainees, the PARTners Program will identify community organizations with an interest in serving as resources and service learning sites for investigators and trainees with an interest in community-based research. The Community PARTners Program will facilitate linkages for the investigators or trainees to work alongside these community members to develop a more in-depth awareness of specific communities. Benefits of this approach include enhanced relationships between investigators and service sites, greater understanding of community norms, increased responsiveness to community needs, stronger ties between the community and academia. This initiative will be evaluated from the perspective of the community organization and the mentee.

Promoting Participation in Clinical and Translational Research.

The Community PARTners Program will engage the public and promote participation in clinical and translational research by providing services that are tailored to needs of the population in an accessible, community-based setting. A Community Continuity Screening Program will be established in collaboration

with the CTSI Participant and Clinical Interactions Resources (PCIR) Core and the Urban League of Pittsburgh. This program will be housed in the new regional office of the Urban League, which will be located in a low income, primarily minority district within the city of Pittsburgh. This community home for the PARTners Program will facilitate access of the community to the university, and vice versa for the purposes of health screenings, health education, and participation in the clinical and translational research process. The Community Continuity Screening Program will be staffed by the Community-based Liaison, as described above. This concept has been endorsed by other community organizations (such as the Pittsburgh Theological Seminary) which have agreed to provide community homes for additional sites if evaluation results support expansion of the program.

The PARTners Program will also collaborate with the CTSI Novel Clinical and Translational Methodologies Core and the institutional public outreach campaign in the promotion of the system-wide registry of studies seeking subjects. Information about the registry will be disseminated at all educational and screening events facilitated by the PARTners Program. In addition, printed information on the registry (including the web address) will be distributed to all community partners, local libraries, and practice sites within the area. This information will include a registration form so that individuals not in the registry may join or sign up to receive a newsletter regarding studies that are being conducted at the University of Pittsburgh and affiliated institutions.

Setting Community-based Research Priorities.

Often the involvement of the lay communities is unidirectional. Communities are expected to value research, participate in studies as subjects, and advocate for research efforts while the ideas, the designs, the findings belong to the investigators. The intent of the Community PARTners Program is to expand upon this traditional approach to bring the lay community more fully into the research endeavor. The CAB will be utilized as a mechanism to involve the public in setting research priorities of interest to the community and contributing expertise to the research enterprise. Investigators planning to conduct studies within specific populations will be able to consult with the CAB. When appropriate, members of the CAB will facilitate the identification of subgroups that represent specific components of the community (e.g., elderly, parents, school teachers, unemployed, African American, Hispanic, Asian, Caucasian, Jewish, Muslim, disabled) to ascertain the health priorities of each that could help focus research efforts or facilitate recruitment. This will allow the CTSI to refer appropriate studies to the populations of interest as well as design communication for recruitment of populations that may have a lesser interest in specific questions. This approach will also enable us to identify how the community prefers to be approached, what the benefits to participation in studies would be and what sorts of incentives to participation could be ethically offered.

Engagement of the Health Professional Community

The health professional community is also made up of multiple subgroups, among them being physicians, nurses, pharmacists, dentists, physical therapists, occupational therapists, rehabilitation specialists, public health workers, and social workers. It also includes interdisciplinary groups within specialties; for example, psychiatry, endocrinology, cardiology, geriatrics, and pediatrics. Furthermore, the health professional community can be organized by setting in which care is delivered, such as acute care, long term care, home care, community settings, business settings, and public health. Just as different community groups are likely to have distinct cultures, values, and preferences, so too the various health care subgroups will have variations in culture, values, and preferences when it comes to clinical research. Efforts will be made to ensure representatives from each of these settings in program activities. The goal of this program component to develop a "research-informed multidisciplinary health professional community" that actively participates in (a) evidence-based practice that fosters the translation of research findings, (b) studies of participant recruitment, and (c) the conduct of clinical research. Several activities will be undertaken to accomplish those goals. To achieve this goal, the Community PARTners Program will focus on educating this community, involving the lay community in the mentoring of investigators, promoting participation in clinical and translational research, and encouraging this community to play a role in the development of community-based research agendas.

Educating the Health Professional Community.

In collaboration with the CTSI Center for Clinical and Translational Informatics, the Community PARTners Program will develop or adapt existing educational material and programs to a format that facilitates access by a geographically dispersed audience. Examples are web-based information, video conferencing and distance

learning seminars for more outlying practices, and web casts. In addition, processes from the evidence-based practice pilot (described below) that have produced positive and satisfying outcomes will be translated to online educational programs for the health professional community to use for both new learning and for refreshment. These processes will serve to educate the community professionals, develop research partnerships, increase the value of clinical research to practice, and support the identification of strategies to translate research into practice.

Mentoring Investigators and Trainees.

The Community PARTners Program will involve multidisciplinary health professionals in the mentoring process by identifying community practitioners and practices with an interest in serving as a resource or service learning site. Interested investigators will be matched with community practitioners in the setting in which their research is likely to take place to develop an understanding of the contributions and modifications that a setting may contribute to the procedures for carrying out clinical or translational research. Experiences would last from one day of shadowing a clinician or a patient to a week of integrating into the setting. It is anticipated that this sort of optional experience would serve to strengthen collaborations as well as offer an intensive informative exposure between clinician and investigator. To ensure a meaningful and constructive experience, this initiative will be evaluated from the perspective of the health professional and mentee.

Setting Research Priorities.

In an effort to engage the health professional community in setting research, priorities, the Multidisciplinary Health Professional Advisory Board will be charged with identifying research priorities and barriers to engagement in research. When appropriate, this advisory board will facilitate the identification of subgroups representing specific disciplines or settings. This will permit the PARTners Program to develop setting and discipline specific communication and to advise investigators on preferred practices in designing recruitment protocols and procedures for the conduct of research. It will also permit the matching of providers and investigators with similar research interests.

Researcher Community

Partnerships do not exist without adequate representation of all parties in the clinical and translational research arena. Therefore investigators and other members of the research team become critical elements in the development of partnerships to foster the expansion, efficiency, and utilization of clinical research. To that end the Community PARTners Program will undertake several initiatives for researchers. As previously noted, opportunities will be available for investigators to spend some brief periods of time in the lay and health professions communities for mentored learning experiences that are designed to foster an understanding of those communities. Other activities to be undertaken include education and the provision of service referrals.

Educating the Researcher Community.

The PARTners Program will provide education to the research community by linking community members with existing programs. In addition, two new initiatives will be developed: a certificate program in Community Communication Skills and a Seminar Series on community based research.

The Community Communication Skills will be a formal certificate program that offered to investigators and trainees from the Schools of the Health Sciences to develop a "community and communication informed" investigator community. Development of this training program will be guided by input from the diverse elements of the three advisory boards. Curriculum will address communication skills, cultural and community sensitivity, and mechanisms to partner with lay and health provider communities. Continuing medical education credits and continuing education units will be available. Completion of this certificate program will be a prerequisite to investigator participation in the Community Outreach Speakers Bureau.

The Seminar Series will be offered in collaboration with the Research Education, training, and Career Development Core. Presentations will address issues such as community and population based research methods, evidence-based practice, intercultural communication, and ethical issues in community-based research. Continuing medical education credits and continuing education units will be available. Series lectures will be available via web-casts to ensure access by a geographically dispersed audience.

Service Referrals for Researchers.

As previously described in the Administrative and Operational Foundation section, a centralized repository of university-based resources for community engagement will be established under the auspices of the Community PARTners Program. The CTSI-based Liaison will serve as a conduit to match investigator needs and requests with available resources. Requests might include assistance with public speaking, application of behavioral interventions, minority recruitment, use of technology in recruiting and following research subjects, promoting adherence and retention in clinical research, working in rural communities, partnering with community service/business providers, population research methodologies, and other relevant areas. This expertise exists throughout the Schools of the Health Sciences. Rather than existing solely within a school, department, or division, the PARTners Program will coordinate efforts to make such expertise available to all investigators within the CTSI.

Pilot Project

The Community PARTners Program will conduct a pilot project in evidence-based practice (EBP). This pilot will be based on the methods successfully employed by the School of Nursing's evidence based practice initiatives. A pilot **evidence based practice initiative** will be instituted in the first year of the PARTners Program. Practices within the set of community practices of the UPMC will be selected and an assessment of readiness and questions of interest will be conducted. This assessment will include a description of the practice, including the providers and the patient population seen, the resources within the practice to access the research literature, the experience and perceived skills of the health professionals and staff with research and EBP, the perception of barriers and benefits, as well as the perceived value of adopting EBP. Included will be a sociogram to determine the providers of influence within the community. EBP will be defined in two ways, the adoption of professional guidelines based upon research consensus, and the standard definition, that is, the individualization of care through the utilization of research findings, patient preferences, and practice capabilities. For the adoption of EBP, however, we will be utilizing the latter definition. Not only is this definition consistent with the concept of evidence based practice and the IOM guidelines for Health Professions Education¹⁷ it is likely to address provider concerns that standard guidelines do not "fit" with individual patients. Survey results will be used to 1) identify a practice in which to initiate an EBP model; 2) identify barriers to research utilization among community providers that can be useful in planning translational research initiatives; and, 3) disseminate information on the barriers to and resources available for EBP in the practice community arena.

During the second year, the survey results will be used to identify and invite one or two practices invited to participate in a pilot program to implement EBP within multidisciplinary community practice. Practices will be selected which have an interdisciplinary model of care either through multidisciplinary professionals within the practice or through close collaboration in care with other discipline practices. The initial practice will be within the urban setting. Consistent with models of diffusion,^{3,11,18,19} practice(s) will also be selected on the basis of their interest in adopting the model, their level of peer influence based upon the sociogram, and the availability of practice resources to move forward with the initiative. If the model is successful, as measured by the utilization of practices, satisfaction with the practices and the PARTners Program support for the project, and dissemination of the project to peers by the providers, practices with differing characteristics will be involved in the project, while outcomes outcome in the context of practice characteristics are consistently monitored. Reports on the outcomes of this model of diffusion will be disseminated, and the extent of participation in research studies following the EBP initiation will be monitored to determine whether the utilization of research may stimulate practitioners to partner in research efforts with investigators from the academic setting. As an incentive to the practices, support for dissemination activities (e.g. poster and/or slide presentations, collation of findings, tips and review of presentation skills) will be provided to the providers, with the expectation that individual providers would present to their local professional organizations and, potentially, to their national counterparts. The number of dissemination activities that are undertaken by the targeted group will be tracked and summarized annually.

The specific plan for implementation of the EBP model follows. A member of the Community PARTners staff will meet with the interdisciplinary practice partners initially on a weekly basis for one hour in the practice site at the close of office hours. Continuing education credits will be offered for these meetings. The staff will both educate and model the EBP process. Initially the practice partners will be guided to a clinical question of relevance to the majority of the practitioners and the identification of the domains of literature that may have

relevance. The practice will be asked to appoint one staff person who will develop expertise in literature searching. It is expected that this person would perform literature searches for EBP as well as serve as a resource to others in the practice. During the week the staff member will be provided with literature searching strategies as an overtime activity paid for by Community PARTners. Such education and support is available through expert librarians in the Health Sciences Library. A “tool kit” for searching and integrating the findings of the search, including evidence to answer the clinical question and patient characteristics, is available within the School of Nursing and will be available for use by the EBP project. Training activities will include a mentored search to bring evidence to the question that was raised by the practice partners.

The second meeting will consist of a review and discussion of the published evidence in the context of the characteristics of the patients in the practice. Discussions will focus on the quality of the evidence, the utility of the findings for patient subgroups, and proposed adaptations for use in the practice setting. Through this process the group will be mentored through the critical review of the literature and the generalizability of findings. Additionally, they will be guided through the process of adaptation to practice characteristics while remaining consistent with the findings reported in the literature. This discussion will continue with a third meeting, which will focus on the design of an implementation strategy. Attention will be given to the identification of targeted patients, training needs, if any, within the practice, identification of who within the practice is the most logical “interventionist”, and a plan for implementation. Thus, there will be three weekly meetings at the outset of the EBP dissemination activity. At the patient care implementation phase within the practice, Community PARTners staff will be available for consultation to the interventionist(s) over a one-month period of time. At the end of that implementation month, the assigned staff will meet with the practice group to identify successes, problems, and satisfaction with the EBP model within that practice. Problems will be addressed at subsequent meetings. Successes will be supported by monthly discussions with the practice for a period of six months, during which it is expected that new questions will be addressed, after which support will be gradually withdrawn and applied to a replication with appropriate modifications to a second practice partnership. Successful professionals/staff from the first site will be used to partner with the Community PARTners Program, with travel and time reimbursed, in the development of the second site. This model of peer dissemination will be evaluated and, if successful, will form the model for promotion of EBP within subsequent practice partnerships. By the third practice site, investigators will be invited to join in the educational effort both to bring their expertise to the program as well as to learn research translation strategies within the practice community. It is the intent to follow these initial programs with the development an application for funding to examine best practices for translation to practice, using an EBP model.

Evaluation

Formative, process, and outcome evaluations of the Community PARTner Program activities will be conducted (see CTSI Evaluation and Tracking Plan). Development of program initiatives will be guided by a formative evaluation. Process and outcomes will be tracked and measured by collecting objective data. In addition, program participants will be surveyed to collect satisfaction data. Evaluation results will be reviewed by the program’s advisory boards and CTSI administration on a semi-annual and annual basis, respectively.

Timeline

During the first six months of the program, efforts will be directed to start up activities. The first activity will be the formation of the advisory boards. Once these groups are in place, initial meetings will take place to review goals, outcomes to monitor, and processes planned. Establishment of a centralized repository of community engagement resources will also occur during the initial six months of the program. During the second six months, programs will be developed and necessary materials prepared.

The first offering of each of the Community PARTners Program initiatives will take place in the second year, beginning with the establishment of the lay community initiatives, followed by the EBP and health professional initiatives, and lastly the investigator initiatives. This will ensure that adequate attention can be paid to each initiative, with a view to integration across the program activities and the other cores of the CTSI. This sequence should ensure that adequate lay and health professions support is available before the investigators are brought into the partnership.

The third year will be focused upon repetition of programs along with evaluation, allowing for adjustments to be made with full community input before entering the fourth year. During the fourth year we will implement

adjusted programs, again with evaluation and input from the various community boards. It is anticipated that preparation of the renewal application will utilize these experiences to drive and expand future activities.

Transformational Elements

There are several transformational elements within the Community PARTners Program. First is an administrative and operational structure with representation from all stakeholders. This innovative structure will permit ongoing interaction with a multidirectional flow of communication among the critical elements in the community. The structure reinforces the value of each element of the broader community in a successful clinical and translational research enterprise. Second, the structure and activities address a neglected component of research education and dissemination by ensuring communities of laypersons, health practitioners, and investigators who have a better understanding of and ability to communicate with each other. Third is a structure that supports the diffusion and utilization of research through EBP and public communications initiatives. Fourth, the patient's experience of care delivery from multiple disciplines will be represented in the development and dissemination of critical knowledge and skills. Finally, a coordinated, centralized structure that is not dependent on funding cycles will enhance sustainability of the program. We believe that the infrastructure proposed for the Community PARTners Core will raise the value of clinical research, speed the dissemination of such research, and promote the partnerships so necessary for a successful clinical and translational research program in the interests of patient welfare.

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