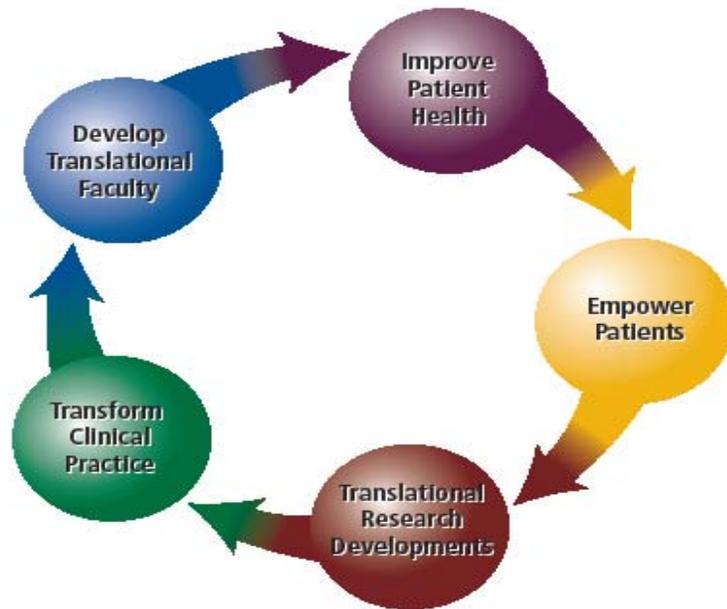


NIH Clinical and Translational Service Award Submission

Rush Translational Sciences Consortium

Executive Summary

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I. Overall Integrated Approach

Rush University Medical Center (Rush) is an integrated academic medical center (AMC) that arose out of the Rush Medical College. The Rush Translational Sciences Consortium (RTSC) was constituted in June, 2006 to serve as the home of translational research for Rush and its research partners. We have extended the borders of Rush to collaborate with a range of other institutions that are committed to developing tools or resources to share the mission to improve outcomes through healthcare research. Our major partners in this process include Cook County Bureau of Health Services with their flagship hospital Cook County Hospital and the faculty of the Pritzker Institute for Imaging at the Illinois Institute of Technology. In this summary, we review the broad directions of our grant submission using a structure that addresses the requirements of the NIH.

The mission of the RTSC is to facilitate scientific productivity to benefit public outcomes. This entails encouraging physicians, scientists and health care professionals to select careers in biomedical research, then nurturing their career development by creating an environment supportive of research activities and encouraging patients and human volunteers to participate in scientific studies. A central aspect of this process is ensuring the integration of “best practices” for research as well as for management processes to provide an optimal translational environment in bringing innovation from the bench to the bedside and then as appropriate out into the community.

Our specific aims are as follows:

1. Develop novel and clinical translational methodologies so that we have internal mechanisms to encourage innovation as well as external assessment mechanisms to insure adoption of relevant national best research practices;
2. Select pilot and collaborative translational and clinical studies that enable a sustainable venue for evaluating bi-directional efforts to advance strategic RTSC initiatives across the spectrum of bench to bedside to community;
3. Provide biomedical informatics that are organized as a cohesive array of enterprise-deployed information systems that enable accessible and efficient support for translational research activities within the RTSC by employing best practices allowing connectivity to other institutions participating in the Clinical Translational Sciences Award (CTSA) process;
4. Design biostatistics and clinical research ethics so that RTSC quantitative services are organized to facilitate innovative translational research with ongoing input to ensure that the principles of human research are respected;
5. Provide regulatory knowledge and support through the joint availability of an integrated, web-based research administration information system (Rush Research Portal) with ready access to knowledgeable research administrative professional to streamlines regulatory compliance while facilitating the conduct of efficient research;
6. Organize participant and clinical interaction resources to facilitate efficient and timely translational research with provisions for equitable resource distribution and reasonable cost recovery;
7. Foster community engagement that allows for sustained interactions with partners to discuss, devise and execute meaningful research that advances public health objectives relevant to our diverse stakeholders;
8. Provide translational technologies and resources that are available as services within the RTSC, organized to ensure the sustainability of these resources by a fair and transparent administrative cost recovery system and include a technology reconnaissance process to ensure that when important new research tools emerge, they are made available to RTSC investigators;
9. Foster research education, training and career development processes that are provided in an integrated, comprehensive fashion to support the development of the next generation of leaders in

a new academic discipline that sustains the environment for rapid and continuous science-based public health innovation;

10. Develop and track evaluation provisions to allow for continuous process improvements through comprehensive self evaluation and ensure the optimally productive use of resources available to the RTSC;
11. Provide a point of contact for the diverse partners capable of contributing to the NIH Road Map vision of translational research progress.

We have submitted a new application to NIH RFA RM 07-002, which outlines the many ways in which the RTSC, in conjunction with our partners, have created a nurturing academic home for translational research. This second Rush CTSA application also addresses the criticism regarding insufficient information about the research environment and addresses other constructive comments. We have thoroughly refined our plans and with considerable institutional support, significantly developed our translational infrastructure. The scope and depth of the NIH CTSA initiative helped to frame a more comprehensive vision of campus transformation and profoundly stimulated the leadership and faculty of Rush. The distillation of the in-depth exploration of campus strengths, weaknesses, opportunities and threats led to a broad strategic plan for the evolution of Rush and has provided the framework for our current submission.

The structure developed by the Rush research faculty to address the requirements for CTSA is the RTSC. The RTSC is aligned with the CTSA goal to implement well organized postgraduate training and career development programs that empower career success for translational researchers. The RTSC shares the NIH CTSA vision to integrate clinical and translational science across multiple departments, institutes and hospitals and other organizations; to identify and support faculty to conduct multi-disciplinary research in a more efficient and effective fashion, and to develop integrated translational curriculum to organically link basic, clinical and community investigators. The RTSC brings together research and administrative leaders from across the campuses to ensure that the ongoing and evolving needs of the research community are thoughtfully and creatively addressed. To successfully support this goal requires a more robust organizational structure to overcome administrative burdens and provide ready access to trial design, approval and regulatory support.

The RTSC is poised to respond to NIH's challenge of accelerating and strengthening translational research, training and IT processes; as well as to address the complex and burdensome regulatory requirements that are retarding research processes; to transform local, regional and national environments for translational science; and to assist AMCs in creating an "academic home" for the new discipline of translational research.

Rush has a legacy of community-based leadership. The Institute for Healthy Aging with collaborators has attracted over \$115 million of NIH support to study the health of selected Chicago neighborhoods over the last 16 years. There are over 10,000 people enrolled in one of the most comprehensive NIH epidemiological studies of the aging process. Investigators for the Institute for Healthy Aging and the Rush Alzheimer's Disease Center have an innovative collaboration with the Broad Institute (a consortium between Harvard and MIT for genomic studies) to define the genetic basis of Alzheimer's. This is a vibrant example of how Rush investigators are contributing to significant progress in biomedical research.

A. Institutional Support for Translational Research

After a two-year, multi-stage process of Institutional strategic planning, the executive leadership of Rush has made participation in the CTSA process a core goal of this Institution.

The research investments for the next five years are outlined in a strategic institutional plan which calls for alignment of Rush's teaching mission, its clinical care mission and its research mission to enhance our prospects of success in the RTSC evolving as a center of excellence in translational research. Since the last CTSA application, the most notable new investment is the commitment to grow the translational research faculty. Dedicated funds to systematically recruit new faculty are delineated along with the resources to prepare the requisite research space. This process began last year and those new faculty members are already having a positive impact on the research environment.

Rush Medical Center historically has been organized along traditional organizational structure based on academic disciplines. In contrast, however, Rush has also formed several highly successful cross-disciplinary programs (e.g., Rush Alzheimer's Disease Center, Rush Institute for Healthy Aging, Rush Arthritis and Orthopedics Institute). All of these programs have well-funded, peer-reviewed translational clinical and translational science research programs that cross departmental boundaries. In developing the RTSC to encourage innovation as suggested by the NIH, we have adopted the best practices of the Center/Institutes listed above in areas of governance, shared resources, appointments and bioinformatics. To further address NIH's mandate for greater collaboration, through the RTSC, we are proposing to leverage the extraordinarily successful operation of Rush Centers involved in developing large cohorts of epidemiological subjects. These cohorts would be a resource for wider collaboration not only with investigators inside of Rush but especially for outside collaborations with other CTSA-supported institutions.

Leadership of Rush has committed to providing an environment that enable the next generation of medical innovation. This involves building a new hospital that supports the delivery of team-driven health care and flexible systems to accommodate rapidly evolving patient care technology. Singular among the many upgrades to the campus is a commitment started in 2005 which will over the next six years to implement new patient care information systems at a cost of over \$100 million dollars (EPIC). The bulk of that expense is required to complete the installation of a comprehensive, unified electronic medical record across both the hospital and outpatient environment. Other specialized information systems to allow for clinical images distribution and storage, research management and for hospital finance will also be upgraded during this timeframe with a commitment for organic integration of these systems with EPIC. This aggregated information system will be the central nervous system of enabling an AMC to act in an agile, coordinated way in meeting the challenges of 21st century medicine.

A number of structural refinements are needed in the Rush research process to accomplish our vision of translational research. We recognize that core services for laboratory and clinical research must be organized and delivered in a more effective fashion. As a solution to this problem, we implemented a strategy proposed in our initial application to provide informational resources for PI access through the RTSC website. There are other elements of the RTSC which bring value to the NIH community of CTSA institutions. Among those are: leveraging Rush's strengths in community-based research and integrating the RTSC training and educational process. The current RTSC governance structure was developed with considerable input of the leaders of the Institute for Healthy Aging and Rush Alzheimer's Disease Center to build on their successful research management models.

B. Rush Translational Sciences Consortium Structure

The leadership of the RTSC includes a number of nationally prominent researchers with a legacy of research innovation. This governance of RTSC will include a director and Principal Investigator, an executive committee, and external advisory committee, a scientific leadership council, and various task groups. The directors and co-directors are as follows:

Principal Investigator James L. Mulshine, MD, Co-Principal Investigator Joshua J. Jacobs, MD, Co-Principal Investigator Martha Claire Morris, ScD, Co-Principal Investigator Paul M. Carvey, PhD, Co-Principal Investigator Robert A. Weinstein, MD, and Senior Research Administrator Thomas E. Wilson, MBA. These six professionals form the core leadership of the RTSC. The group has met weekly for the last two years to discuss RTSC directions. The RTSC works closely with its three partners, Rush, Cook County Hospital and IIT (Illinois Institute of Technology) having monthly executive committee meetings to monitor progress. The RTSC also acts as a translational catalyst for a broad array of partners, including Gads Hill and Dominican University. The RTSC is creating new mechanisms to partner with a number of institutions that bring unique translational research opportunities to the RTSC. These include the University Health System Consortium (collaboration in a new Center for Safety, Quality and Outcomes Research, the National Council of University Research Administrators (a new Masters in Research Management program) and with the Optical Society of America (OSA) (an evaluation project of new image processing tools to enhance the electronic publishing experience).

C. Communications Objectives

The overall communications strategy for RTSC balances traditional print communications (brochures, newsletters and direct mail) with Web communications and emerging technologies (podcasts, vodcasts, electronic newsletters and multimedia tools). Our plans draw on an infrastructure that includes a multifunctional marketing and public relations team, a successful government relations program, and a renowned research faculty with an excellent track record of scholarly publication. By pinpointing specific audiences such as outside investigators, prospective students, prospective faculty, community, local and national media, legislators, philanthropic audiences and community practitioners, we hope to recruit and retain the most qualified faculty. In addition, a goal of the RTSC is to enable two-way communication to bring matters of public interest to researchers' attention, and to use broadcast and print media to increase public, legislative, philanthropic and community awareness of translational research at Rush.

i. Publication Track Record

Rush has published more than 400 original journal articles, reviews and meeting abstracts since January 2005. Rush faculty typically publish their results in peer-reviewed journals and there has been abundant coverage of these contributions in the national and regional press.

II. Program Functions

A. Development of Novel Clinical and Translational Methods

Program Director: Rick Sumner, PhD

The intent of the RTSC is to facilitate rapid development of effective bench to bedside to community based studies in all parts of Rush, including the Medical College, Graduate College, College of Nursing and College of Health Sciences, as well as affiliate partners Cook County Hospital and IIT. To ensure the development and delivery of novel translational methodologies, we propose four specific aims: to disseminate information on existing translational technologies/methodologies to

basic, clinical and behavioral investigators; to institute translational methodology developmental grants to enhance translational research capability at Rush University; to provide opportunities for investigators to spend “mini” sabbaticals at other CTSA awarded institutions to learn novel methods relevant to growing translational research programs at Rush; and to provide a forum for RTSC investigators to define their future needs in the area of novel clinical and translational methods.

The integrated efforts of existing basic science investigators who study such important clinical questions as Alzheimer’s disease (AD), orthopedics, cancer, heart disease and HIV permits the rapid implementation of novel translational technology necessary to advance clinical medicine. Rush has a strong track record in developing highly novel clinical and translational methods across this broad range of major diseases.

i. Methods Development

There is a clear need for good communication among translational researchers so that the availability of novel technologies is readily communicated. We utilize various methods to communicate including the Annual Research Forum, hands-on training for specific technologies in individual labs, an electronic newsletter developed for the RTSC and web sites allowing investigators to obtain basic information, directing them to a specific investigator for further information.

Developments in imaging are profoundly influencing translational research across a wide array of preclinical and clinical medicine. As imaging evolves from a representational display tool to a more functional, quantitative tool, it is critical that more members of the translational research team understand the strengths, weaknesses, and proper interpretation of these analytical imaging tools. Investigators from Kitware, the OSA and the RTSC are currently collaborating to accelerate the validated use of high resolution imaging in medical applications such as cancer drug delivery. Kitware has developed new interactive visualization methods for authoring and publishing scientific documents. These tools will allow the research community to interact with the data from publications that provide links to image databases and advanced visualization tools. To insure the best productivity with such an investment, it is important to educate the potential user community as to how to effectively utilize such a powerful resource. The RTSC is leading an important evaluation process of this exciting new resource.

B. Pilot and Collaborative Translational and Clinical Studies

Program Director: Joshua J. Jacobs, MD

A major emphasis in the CTSA is to rejuvenate and prioritize the development of clinician-scientists and translational researchers in AMCs. Rush for many years has provided such support through small competitive grants from the University Committee on Research and the Rush/John Stroger Jr. Hospital of Cook County Collaborative and Research Program.

When submitting the initial first round CTSA application, the leadership of Rush set aside an additional \$500,000 per year (as matching funds for this CTSA proposal) as a new category of translational pilot projects for exceptionally promising translational research teams and programs. The processes and procedures developed and subsequently refined to distribute these pilot funds serve as the basis for the program proposed in the CTSA application.

The specific aims of the pilot program are: to support high quality, interdisciplinary translational studies at Rush that will serve as a focus for sustainable research programs at RTSC; to identify promising early-career, health care researchers and provide support for their transition to scientific independence in translational research; and to build translational disease-focused research teams that cover the spectrum of disciplines from basic research to community interventions.

A six-member committee of the Scientific Leadership Council (SLC) of the RTSC is responsible for allocating research funds for promising pilot projects. This committee, the Pilot Project Evaluation Team (PPET) will insure that the project is aligned with ongoing research and addresses an important clinical problem that will advance scientific knowledge or clinical practice in terms of new technologies, treatments, preventions or interventions.

The Pilot and Collaborative Translational and Clinical Studies program is now its second year and will be expanded upon successful receipt of the CTSA. The pilot program has made a substantial impact at Rush. The newly established selection and oversight process for the program as administered by the SLC has extended throughout the university to other extant funding mechanisms. The explicit focus on training, accountability, translational plans and productivity has positively impacted the research culture at Rush, promising to provide substantial returns on these strategic investments.

i. RTSC Funded Translational Projects Year #1

Project #1: Development of a Targeted Multiplex Proteomics Tool to Assess Women's Reproductive Health

The overall goal of this work is to develop a multiplex tool to objectively evaluate women's reproductive health based on the hypothesis that vaginal mucosal immunity, vaginal flora and sexually transmitted infections each influence the other. The delineation of these relationships will provide the clinician with a useful tool to assess women's reproductive health. Specific aims are to: 1) determine the utility of existing cytokine beads arrays (CBA) for detecting cytokines in female genital tract secretions; 2) develop CBA-type modules that detect innate and adaptive immune mediators; 3) develop CBA-type modules that detect common causes of vaginitis and healthy genital tract flora; 4) determine the patterns of immune mediators associated with specific pathogens and healthy flora. Preliminary data from this effort has already led to new NIH grant applications.

Project #2: Circulating Inflammatory Markers and Medical Temporal Lobe Integrity

By the year 2050, as many as 16 million people could have Alzheimer's disease (AD). Research that identifies risk factors for developing AD and that translates into biological and behavioral therapies that arrest progression of the disease is critically needed. If findings from this study confirm the hypothesis that there is a relationship between elevated serum levels of pro-inflammatory cytokines, reduced cognitive function and reduced integrity of the medial temporal lobe gray matter and associated white matter structures and pathways, they could effectively translate into knowledge that will have a direct impact on: 1) development and monitoring of anti-inflammatory medications and anti-amyloid vaccines; 2) the development of pharmacological treatments targeted to specific neural systems, and; 3) the identification of behavioral risk factors for inflammation that could lead to behavioral interventions at the community level.

Significant progress has been made in addressing the Aims of this project.

Project #3: Predictors of Osteolysis and Aseptic Loosening of Total Joint Replacement

Total joint arthroplasty is considered a safe, efficacious and cost-effective intervention for the management of end-stage osteoarthritis of the hip and knee. However, up to 10% of patients have premature loosening of the implant before 10 years, causing pain, disability and need for revision surgery. Revision surgery greatly increases the debility not only to the patient but also increases the economic burden associated with the management of individuals with osteoarthritis.

The translational plan is to implement a bioreactivity testing protocol for those orthopedic patients that meet the following clinical criteria: history of metal allergy; an orthopedic implant with pain from no known cause; or an orthopedic implant with no pain but identifiable bone loss. Successful development of this work will facilitate the establishment of Rush as a National Center of Excellence in orthopedic biomarker testing.

Project #4: Early Pathogenesis of Cardiovascular Disease in Women

Progression through the menopausal transition is associated with an increase in visceral fat. Since visceral fat may have adverse metabolic consequences for cardiovascular disease, the aim is to identify connections between the menopause-related development of visceral fat and the beginnings of subclinical cardiovascular disease in women.

The translational plan is to develop a program project which is directed toward the link between visceral fat and vascular disease. It features collaborations among the Rush Department of Radiology, Section of Cardiology, Department of Immunology, and Department of Preventive Medicine, and with the Section of Endocrinology at the University of Illinois and the IIT. IIT has also provided funding support for this effort and accrual goals of this trial have been met.

Project #5: Epidemiologic Study of Dietary Fats and Metals, Inflammation and Cognition

Previous studies suggest that fats and metals are related to dementia. One potential biologic mechanism is inflammation, and dietary fat has been shown to affect inflammation. In this pilot, we examine the feasibility of studying these relations in an ongoing study of incident Alzheimer's disease and neuropathology. The translational plan is to obtain NIH funding to expand data collection to the entire study cohort and to follow the participants over time for incident disease. Studying how dietary intake of fats and metals affects brain functioning and tissue in humans is unprecedented and is an excellent example of translational science.

C. Biomedical Informatics

Program Director: Denis A. Evans, MD

The bioinformatics functions of the RTSC build on a solid informatics infrastructure at Rush University and Rush to provide investigators with the informatics resources they require. Emphasis is placed on the aspects of good informatics practice and on the resources that are of the greatest value to investigators conducting translational research.

Rush research programs in some areas have achieved national prominence and excellent scientific productivity. Informatics resources in these areas are generally well developed and strongly functioning. A problem that must be confronted is that this informatics expertise is not well distributed to translational investigators throughout the RTSC system.

As part of a re-organization of research administration in 2005, the Rush Research Portal (RRP) was developed to serve as a web-based mechanism for investigators to access research administration functions. The establishment of the RRP was a conscious effort to respond to the needs of current translational researchers dealing with the increased demands on time from growing research complexity and demands on time from growing pressures for greater and more detailed regulation and oversight of research. The RTSC had purchased the web-base research administrative management system from Click Commerce and is collaborating with them to further develop capabilities to address additional research administrative challenges. Soon the RRP will allow for electronic development, submission, reviews and management of all clinical protocols, grants (including to NIH) and research contracts allowing RTSC investigators to manage a large part of

their research management needs through one unified web site, the Rush Research Portal. This will include provisions for managing research billing services for clinical trials services supported by Center for Medicaid and Medicare Services. By March of 2008, the RTSC will have the most advanced deployment of this software application in the country – that is the integration into a single review system for IRB, grants and contracts, and CMS billing functions.

D. Design, Biostatistics and Clinical Research Ethics

Program Director: Denis A. Evans, MD

The RTSC design and biostatistics requirements can be placed in three broad categories: those necessary for the optimal conduct of clinical trials; those for the optimal conduct of longitudinal observational studies; and those for the diverse requirements of the RTSC translational research and activities that do not fall into either category. Our goal is to integrate knowledge of clinical research ethics into all aspects of RTSC. To do this we plan to transform existing resources into an optimal means of supporting the interdisciplinary translational approaches proposed by the RTSC. The following Specific Aims are proposed:

- 1) Provide design and biostatistics support for the activities of the RTSC with design and analysis of clinical trials, longitudinal observational studies, and all other RTSC studies and activities
- 2) Prioritize the allocation of Rush design and biostatistics resources within the above areas to achieve the goals of the RTSC and the CTSA program overall
- 3) Achieve integration of knowledge of research ethics with all aspects of the RTSC
- 4) In collaboration with the research education, training and career development activities of the RTSC; provide instruction in research ethics for all trainees.

The very strong ethnic diversity of Chicago facilitates the strongly developing trend at Rush to conduct trials among diverse subjects. Rush has established an Office of Research Integrity (ORI) and Regulatory Affairs and has integrated this office's activities with those of the RCTA office. Coordination with the ORI emphasizing novel education and with the Rush Research Portal providing computerization of investigator interactions with the IRB is especially valuable to clinical research.

E. Regulatory Knowledge and Support Core

Program Director: Gunnar B.J. Andersson, MD

The Regulatory Knowledge and Support Core (RKSC) is crucial to Rush's emphasis on translational research and support of the research community. The goal of the RKSC will be to develop and incorporate best practices in research management through an effective, integrated and sustainable campus-wide program.

Specific aims of the RKSC are to: Create a comprehensive, unified integrity and knowledge core infrastructure, provide convenient and practical education to advance the training of translational researchers, integrate RKSC research administrative systems with the Rush electronic medical record system, and enable the ORI to address the research advocacy role by creating a research ombudsperson on behalf of human subjects.

The mission of the Office of Research Integrity (ORI) is to ensure respect for the conduct of human subjects' research according to current ethical standards, regulatory obligations and institutional policies and to maintain a culture where integrity pervades all aspects of the research process. During FY07, ORI focused on basic regulatory knowledge and problem solving in its training programs.

These programs exceeded minimum requirements by: 1) training research personnel to comply with federal and state laws and regulations as well as institutional policies; 2) monitoring progress in training efforts; 3) and assessing regulatory adherence. A successful training effort will encourage the Rush research community to value the contributions of human subjects, act responsibly, comply with federal and state laws and regulations as well as Institutional policies. To respect the contribution of individuals agreeing to participate in research studies, the ORI works to impart a professional code of ethics for investigators. ORI identifies and evaluate areas for improving research practices and education.

F. Participant and Clinical Interaction Resources

Program Director: Philip G. Janicak, MD

A core aspect of the RTSC culture is the belief that the problems of improving delivery of urban health care is fundamental to improving national outcomes for many major chronic diseases. With key administrative recruitment of national leaders in research integrity and administration, we are able to conduct research conforming to the highest standards of safety and quality. Dr. Denis Evans, an outstanding clinical/community-based investigator is the Director for Tracking and Evaluation Core, giving him an opportunity to monitor the resource allocation to ensure that the needs to advance large and small research investigations are properly addressed. Specific aims are to: promote greater participation in clinical and translational science by research scientists, clinicians and participants; coordinate and build upon existing research support systems of the RTSC; to increase the number of high-quality, cost-effective research studies in clinical and translational science; provide research support to increase the number of high-quality, cost-effective studies in clinical and translational science in community clinics of socio-economically disadvantaged minorities; and to provide a tracking system for high-quality translational science implementation and of dissemination of best practices in the community for improved health outcomes. The RTSC has a number of successful models of efficient implementation of high-quality clinical and translational research and will work to disseminate these program approaches more broadly throughout the RTSC.

G. Community Engagement and Research

Program Director: Martha Clare Morris, ScD

The RTSC provides health services to over 5 million residents of the Chicago metropolitan area and is the largest single provider to these ethnic minorities and socio-economically disadvantaged individuals. It is also unrivaled among Chicago AMCs in the conduct of large-scale, community-based studies. The overall aim of this application is to increase the magnitude and capacity of community (public, providers, and researchers) engagement in clinical translational research and best practices. Specific aims are to: increase understanding of public health needs; community needs; concerns and barriers to participating in translational research; and the capacity to address these needs, expand and coordinate outreach activities to the vast network of community partnerships, increase community knowledge of and participation in multidisciplinary, translational research and best practices, and train communities in the principles of community-based participatory research.

Due to the population of Chicago – significant racial and ethnic minorities with low socioeconomic status – the RTSC is uniquely positioned to address issues of health disparities. Rush has long conducted large, longitudinal, community-based epidemiologic studies. These investigators are recognized world leaders in their fields, with NIH funding over the last 5 years of more than \$84 million. More than 16,000 Chicago residents have participated in these studies for as long as 17 years, with high participation of 80% or above. RTSC expansion of translational research will be

enormously facilitated by its vast network of established partnerships with numerous organization and neighborhoods in the area.

Four RTSC research communities are national leaders in community-based translational research: aging and Alzheimer's disease; behavioral interventions in cardiovascular disease; family behavioral interventions; and HIV-AIDS. The RTSC community researchers have developed trusted partnerships with hundreds of community organizations.

H. Translational Technologies and Resources

Program Director: Rick Sumner, PhD

The aims of the Translational Technology and Resources Core (TTRC) are to: 1) increase the ease of access to and utilization of current resources; provide consultation and if necessary the appropriate referral outside the consortium; provide education on new methods; provide sources of unique supplies and equipment; increase interactions and accessibility to collaborating core resources at Rush. 2) Systematically expand the core structures; seek new replacement equipment through NIH equipment grants, philanthropy, and Rush; provide input to the director of RTSC on the need to recruit faculty with critical technology.

One of the goals of the TTRC is to provide mechanisms for RTSC faculty to effectively use all Rush, local and national resources. We have adopted a "portal" approach to promote core utilization by the faculty and to provide education for the investigators on use of specific cutting edge technologies. After several years of planning, the University is putting into place a new website parallel to its clinical website that will have increased function and capacity. Research data from existing departmental websites will include abstracts of funded grants and approved IRB protocols. A PI database will provide a search function for research interests and major research techniques.

I. Research Education, Training and Career Development

Program Director: Paul M. Carvey, PhD

The SLC establish the Support for Translational research Enhancement Program (STEP) to develop a unique and innovative training and mentoring program in translational research.

STEP is a campus-wide program that is being implemented with the active support of all Rush deans. STEP will be realized through the following four Specific Aims: 1) Provide a continuing and self-sustaining infrastructure for Assistant Professors designed to ensure translational research expertise. 2) Provide a continuing and self-sustaining educational program for translational training to supplement competency needs of senior mentees (K-12) and foster a pipeline of affiliate mentees and pre-doctoral fellows (T-32). 3) Coordinate research education across the campus within STEP to ensure that all graduates of Rush have an understanding and appreciation of translational research and their role in it. 4) Educate all health science employees at Rush and the community it serves about the importance of translational research and their role in it using innovative programs and distance learning. The model for STEP was created after a complete redesign of the mentoring committee structure for the current mentoring program. STEP addresses the issues learned from the Provost's Council task force that concluded that while all research performed at Rush is translational, it needs more effective integration, the research training and mentoring programs need to be integrated, translational research is "siloeed" and not multi-disciplinary, and community-base research, while exceptional in impact, is not integrated into the rest of the research enterprise.

The mentoring program in Internal Medicine has now been active for one year. Within that year, mentees within the program published 55 peer-reviewed manuscripts (2.39 publications/mentee); 44

abstracts; submitted 23 applications for NIH grants/foundation support/clinical trials of which 7 were funded. The initial success of the senior mentees reflects the success of the Masters in Clinical Research program since the majority of the senior mentees had already completed the masters program. This demonstrates that the Masters of Clinical Research program is currently and will remain a significant pipeline to the senior mentee program.

In summary, a formal program focused on translational research is now established and will expand campus-wide under the STEP program. Senior mentees will primarily come from the ranks of the affiliate mentee program and have protected research time. Senior mentees will be supported by the institutional K-12 grant as well as by the 4 Rush colleges and Cook County Hospital with 15-21 mentees in the various stages of the program, graduating 5-7/year. Senior mentees will eventually be present in all elements of the RTSC and be familiar with basic, clinical and population-based research design. They will commit to one of three designated tracks: basic/clinical, basic/community based and clinical/community based. The mentees must propose research projects that clearly encompass the two disciplines in their chosen track.

J. Tracking and Evaluating the Progress of the RTSC

Program Director: Denis A. Evan, MD

The evaluation plan proposed is distinctly formative, with strong emphasis on assessing progress toward goals, discovering the obstacles to progress that will inevitably occur, and providing the leaders of the RTSC with the information, on a regular and systematic basis, that they will need to facilitate redirection and overcome these obstacles. Emphasis is placed on measures and sources of data that are objective rather than subjective and suitable for computerized summary, analysis and storage. Plans are proposed to track and evaluate the progress of the RTSC as a whole as well as all of the organizational elements.

III. Implementation Plan and Milestones

The RTSC has been underway for almost two years supported by internal investments from Rush, but as outlined in the grant are additional activities proposed to advance our transformation process. With the resources from the CTSA, we will be able to accelerate our plans to transform translational research.

The SLC is planning for implementation of the RTSC in April, 2008 anticipating the award announcement. A primary goal of this process is to ensure a broad understanding of the specific components of the grants and to allow for institutional support of a successful launch. The administrative leadership of the RTSC will establish a work plan to manage the smooth assimilation of new administrative and research support personnel to implement the objectives of the grant. Translational research is an integral part of Rush. For FY 2008, it clearly states in its goals: Rush will become a recognized leader in translational research. Creation of the RTSC is a milestone in achieving that goal and a critical part of future goals for Rush.