DREXEL UNIVERSITY

CLINICAL AND TRANSLATIONAL RESEARCH INSTITUTE

Moving scientific discoveries into meaningful clinical outcomes

Subcommittee Members

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Mission & Vision Statement

The overriding mission of the Clinical and Translational Research Institute (CTRI) will be to promote and support outstanding research and academic programs leading to innovative science, advanced therapeutic applications, and ultimately to improved clinical care. The CTRI will create and cultivate the rich multidisciplinary infrastructure that is essential for successfully translating biomedical discoveries into effective therapeutics, thereby contributing to the growth of Drexel University by promoting innovative first-class research programs with translational applications.

The long-term objective of establishing the CTRI at Drexel University is to transform and substantially elevate the landscape in which biomedical research is conducted, therapeutic discoveries are made, and advances in clinical care are developed into therapeutic and commercial opportunities.

We anticipate that this initiative will radiate throughout the University, serving as an impetus as well as an adhesive for multidisciplinary collaborative research.

The Institute will have four strategic objectives:

- 1) To elevate the overall scope, infrastructure, and support for basic and clinical biomedical and life sciences research
- 2) To provide a clear organizational Center that will bridge different schools within Drexel University and support interdisciplinary research
- 3) To increase the opportunities for Drexel physicians to engage in clinical and translational research
- 4) To continue to develop innovative educational programs that complement translational research and which lead to new opportunities for faculty and students

Located within the College of Medicine, the CTRI will achieve these objectives by acting as a cross-campus interdisciplinary hub devoted to fostering and sustaining dynamic and productive collaborations among Drexel University scientists, physicians, and educators who share common translational goals. The Center will embrace disciplines in the fields of medicine, biotechnology, biomedical engineering,

drug discovery and development, engineering, and public health. Ongoing programs in innovation and entrepreneurship within the LeBow College of Business will also be of exceptional benefit to the activities we expect will result from these efforts. Synergy among all units of this vibrant, multifaceted community is essential to the success of the CTRI and to the overall mission of the University.

A long-term goal, to be achieved at the completion of the proposed Strategic Plan, is to be in a position of strength to submit an application to the NIH for the creation of a Clinical and Translational Science Award (CTSA). This objective requires that the leadership of the CTRI and the University support the development of the essential components required to compete for a CTSA. The main objective of the creation of the CRTI will be to establish the foundation to stabilize and resource the CTRI, both scientifically and financially, in order to achieve a return on the initial investments and then expand the overall CTRI efforts.

Specific Objectives and Recommendations

The specific objectives of the CTRI are to:

- Establish priorities and funding streams for translational research
- Systematically evaluate and remove impediments to research translation
- Create and make available a research-enabling infrastructure and resources by developing core technologies
- Build bridges to interface with and incorporate other University constituencies as well as pharmaceutical and biotechnology organizations in the health industry
- Train the next generation of clinical translational investigators
- Engage and involve the local community in outreach initiatives
- Define and continuously measure success in meeting the above objectives to fully enable the establishment of a funded Clinical and Translational Research Institute.

The development of a truly transformative biomedical and healthcare initiative that engages the collective educational, scientific, patient, and civic communities available within the reach of Drexel University requires a substantial investment and commitment of funds.

This objective requires an established entity with the mandate to accomplish the objectives outlined above and to fulfill the overall recommendations of the Strategic Plan. It is imperative that adequate financial resources be provided to launch the CTRI, to provide the leadership and oversight that are essential for its implementation and success, and to ensure the visibility and clear function of this institute within the institution. An appropriate infrastructure is needed to support research and to create new funding opportunities in a highly competitive environment. Here we outline specific recommendations for funding, a proposed organizational structure, and the need for a clear "presence" within Drexel University.

1. As a first priority, establish the CTRI.

Financial support will be required to fund a Director, staff, office space, and administrative support. The requested funds are essential to begin the institute's mission to facilitate leadership in clinical and translational research.

Scope of activities:

- a) Conduct CTRI-sponsored retreats; sponsor thematic workshops and symposia designed to embrace the interests and needs of the entire Drexel University community.
- b) Establish and maintain Web-based technology access—listing of core facilities; information and communication; grant application announcements and submissions.
- c) Create rotating seminars and educational opportunities on core technologies, access, and utility to faculty and staff.
- d) Initiate PR, marketing, and education within Drexel and the adjacent community.
- e) Facilitate clinical and basic science research by providing incentives and opportunities for clinical faculty (e.g., postdoctoral support; "buy-out" time for clinical faculty members to conduct research).
- f) Enhance interaction through the CTRI with local biotech and pharmaceutical companies; establish regulatory and clinical trials network (potential for future revenue).

2. Create a seed funding mechanism for competitive research projects.

a) Establish a formal, transparent review process; provide rapid response to submissions; establish multiple deadlines for facilitation of research initiatives.

- b) Encourage the development of pilot projects with specific and concrete goals and timelines.
- c) Develop milestones/follow-up processes/metric of success.
- d) Provide a mechanism of involvement for DUCOM graduate students and/or postdoctoral and medical fellows in translational research.

3. Establish and operate new core facilities and technologies that provide support to translational research initiatives between DUCOM and DU.

- a) Establish a biorepository ("biobank") for collection, storage, retrieval, and distribution of human specimens that will benefit researchers across the University.
- b) Develop and maintain new core facilities (e.g., genomics; *in vivo* imaging; bioinformatics; animal models; high-content screening; development of a uniform clinical registry and health informatics).
- c) Expand and bridge to existing facilities on the main campus in critical areas such as proteomics; medicinal chemistry; computer science; and informatics.
- d) Generate revenues to help neutralize maintenance costs through core facilities fees and access for extramural users.

The amount of funding initially available is not expected to support all of the initiatives proposed above, but these are examples of the priorities that we would evaluate for funding by the CTRI. The intent is to use these funds to build the critical infrastructure to support clinical and translational research.

4. Establish new academic programs for training graduate students and recruiting postdoctoral fellows interested in translational research.

- a) Add or expand interdisciplinary cross-campus translational research and education courses in existing biomedical graduate programs (e.g., pharmacogenomics; genetics; data mining; pharmacoepidemiology and clinical trials).
- b) Expand master's level programs (e.g., Drug Discovery and Development and Molecular Medicine) into PhD programs.
- c) Establish new graduate program in "Translational Science," including "omics" initiatives, systems, network, and computational approaches to biology, pharmacology, and genomics, to enhance competitiveness for funds from Howard Hughes Institute and similar elite sponsorships (see also "f" below).
- d) Publish online spotlights on selected topics (by disease).
- e) Provide travel support for specialty courses (nationally and internationally).

f) Seek and obtain training grants based on consolidation and areas of expertise.

These objectives would be aligned with the University's Strategic Plan to foster interacademic collaborations (e.g., dual programs between the College of Medicine and the School of Public Health and other schools within DU) and to remove the obstacles that currently hinder such collaborations.

The committee also recommends the hiring of key clinical faculty to support the themes and initiatives proposed in this document. The intent here is to foster clinical and translational research in those areas of strength and opportunity. We request that the CTRI be represented on the search committees for these hires.

Rationale and Justification

The overall goal of this proposal is to establish a recognized, authoritative, and visible presence and to emphasize translational research that spans and embraces the Drexel University academic and cultural community.

The successful achievement of this objective will transform and strengthen significantly the capability of Drexel University faculty and students to conduct pioneering research and to compete successfully in an environment that requires high-quality, interactive, technology-driven, collaborative research.

This recommendation has far-reaching consequences beyond research. An inevitable significant outgrowth of this initiative is the further development of one of Drexel University's key strengths: the educational objectives of teaching and training students in all disciplines and in all professional areas.

The synergy to be gained from the proposed dual research and educational advances advocated by the CTRI, and the reciprocity between these academic imperatives, will allow the University to continue to grow in these and in other dimensions and to provide leadership in translational medicine and bridging to the commercial marketplace.

The success of this initiative, which we deem critical to the development of a clinical translational and collaborative research culture within the University, depends on

having a clear office, a dedicated staff, and a mandate to oversee and coordinate the many activities that will be essential to establishing, monitoring, and maintaining this initiative.

We also regard the recommendation to create a *seed funding mechanism* as an essential step in building a strong, vibrant, and competitive research enterprise. At the present time, no such avenue appears to exist by which investigators can seek funding for exploratory projects, enable transitions from one stage to another, or branch from an ongoing line of investigation to pursue potentially interesting and beneficial projects or open other opportunities. The aim of this funding mechanism is to provide a more flexible and timely review and support for research initiatives than is available from the once-yearly tobacco settlement funds.

The ability to conduct high-quality, state-of-the-art research requires that both basic and clinical scientists interested in pursuing translational research have access to specialized *core facilities*. Contemporary biomedical research is increasingly complex and technology driven. The infrastructure for pursuing research of a translational nature is not available within DUCOM and the cores proposed for the CTRI would expand such capabilities for the entire University. Academic institutions that invest in core facilities and provide access to shared instrumentation, expert consultation, and resource support foster collaborative efforts in translational science, aid in submitting competitive applications, and offer training and educational opportunities for students and postdoctoral fellows.

Significant strength as well as considerable potential exist across the University. Our view is that this potential can be exponentially increased by the formation of the CTRI. Compared to other institutions of comparable size and breadth, however, Drexel University lags behind in several dimensions. Translational research initiatives, including formalized managed institutes that oversee the activities outlined above, are now commonplace for universities and medical schools of our size and stature.

The overall aims that have guided this recommendation stem from the desire and commitment of the Subcommittee, as representatives of DUCOM faculty, to forthrightly identify and address these deficiencies and to propose strategic initiatives that will have a profound impact on the future of DUCOM and the entire Drexel community.

Importantly, they will help move DUCOM into alignment with other medical schools that sit within institutions of comparable size and will allow for a more competitive and acknowledged place for Drexel among U.S. academic institutions.

Impact on the University

As noted throughout this document, the CTRI will dramatically increase the diversity and scope of research, technological development, and training in the health sciences throughout the university. The CTRI will also lead to increased competitiveness, awards, and revenue related to the training of predoctoral and postdoctoral students, whose work further enables the success of our proposals for extramural funding. Finally, the CTRI will catalyze the formation of a creative University-wide academic infrastructure needed to obtain a Clinical and Translational Science Award (CTSA) which will have a major tangible impact on the university in terms of resources, national as well as international recognition.

Proposed members of the Administrative Advisory Board

Vice Provost for Research
Dean of the College of Arts and Sciences
Dean of the College of Engineering
Dean of the College of Nursing and Health Professions
Dean of the School of Biomedical Engineering, Science and Health Systems
Dean of the School of Public Health

Proposed members of the Scientific Advisory Board

Senior executive from the pharmaceutical/biotechnology industry
Current director of another academic institution's CTSA
Senior faculty member of the College of Arts and Sciences
Senior faculty member of the College of Engineering
Senior faculty member of the School of Biomedical Engineering, Science and Health
Systems

Senior faculty member of the School of Public Health
Senior member from the Office of Research Technology and Commercialization
Executive from the local venture capital industry
Senior faculty member from the College of Information Science and Technology
Senior faculty member from Drexel University College of Medicine

The intent of the Scientific Advisory Board is to provide a broad-based, interdisciplinary, and cross-campus membership that will provide an overview of the CTRI's initiatives, monitor progress, and provide expert input. This rich diversity will ensure that the spirit and commitment of the CTRI is working to fulfill its main mission and will also ensure transparency throughout the University.