



Transforming Clinical and Translational Sciences *A Roadmap to Lead the Nation in Urban Research Excellence*

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1. INTRODUCTION

Wayne State University wishes to strengthen and expand its capabilities and national prominence in clinical and translational medicine. This report will examine institutional strengths and challenges, changing expectations in the external environment, and opportunities for short and longer term actions to transform Wayne State into a highly competitive, nationally recognized force in clinical and translational science (CTS).

Among academic and administrative leaders at the University there exists a wide variation in opinion on the scope of this challenge and how it can be met. All recognize and appreciate the strength of new leadership in the office of the President, the stated commitment to the research mission of the University, and the specific focus on expanding translational science. Some of the best and brightest of the faculty openly embrace the reason they came to and remain at Wayne State: They see an opportunity to create in Detroit a nationally renowned urban laboratory where actions of the University are mapped to positive changes in the health of a community defined by its ethnic diversity, economic setbacks, and health disparities. This is the University's "vital sign" and it remains vigorous.

Still others are openly skeptical, expressing frustration on a number of fronts. Continued change in leadership in key administrative positions has engendered a lack of confidence that there can be a future where research priorities are made clear and University-wide aligned directions are set. Many have retreated to build their own programs in a way that allows them to remain siloed and insulated from such shifts. Several leaders pointed to the growth in the percentage of aging faculty members whose productivity has declined as compared to new young investigators with promising early starts.

Recent departures of several key investigators have signaled to some a decline in confidence that the institution will be able to adjust to meet the demands of 21st Century Science. No one suggested that next steps would be easy.

Revenue sources to support new hires are significantly constrained. Clinical revenues, contrary to perception, are generally not available to support research through payments back to the departments through the University Physicians Group. Indirect recoveries from funded grants, in

"Detroit has 90% African-Americans and puts our university in a unique position of research based on the well-known and published effect of ethnicity on disease biology. Few universities can compete with us looking into this emerging area of research. Cardiovascular disease, stroke, multiple sclerosis, neurologic recovery, access to health care, etc., are all hot areas of research, we can capitalize on. Recognizing our strengths and investing in those programs is critical. Despite many individuals (multiple sclerosis, hypertension), there has been no defined effort from the university." (Dept. Chair)

"Please do keep in mind that since 1998 (when I was recruited as junior faculty) we have had 5 presidents, 5 provosts, and 5 Deans of the SoM.....average for each top administrator 3.2 years! When the very top changes so quickly and each time new administration comes in with lots of new "policies" but no clear message or direction, it leads to a very resilient faculty that adapts to "reality" (meaning survival) rather than building ambitions and dreams." (Dept. Chair)



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amounts larger than national norms, remain at the Department rather than in the office of the Dean. Likewise, other revenue sources, such as the Fund for Medical Research and Education (FMRE), do not appear to produce available funds at a trans-University level necessary to support recruitment of new faculty into a set of core, distinguishing areas of research focus.

This dichotomous reaction – on one hand, hope and belief that change are within reach, and on the other, skepticism that WSU can adapt -- is taking place in the context of a dramatically changing external environment where the tools, resources, mechanisms, paths and systems for the conduct of clinical and translational science are in a state of rapid evolution. The infrastructure required to conduct translational research is being redefined. The understanding that *translational science is transdisciplinary team science* is now accepted and attention is turning to the need for new cultures and reward systems that recognize these essential competencies.

WSU can equip itself to play this fast catch-up game. It must be sure that its culture and academic system do not turn a blind eye toward – or even reward – siloed behaviors. While good investigators can, on their own initiative, reach across the institution and into regional affiliates to create unique cross-disciplinary teams, as is happening today at Wayne State, this ad hoc forging of collaborations will remain just that. Today, these collaborations appear to be more the celebrated exceptions rather than the research norm at Wayne State. In this changing CTS environment, the WSU infrastructure must provide bridges and paths that invite, support and reward connectivity, both intra-institutionally and across regional affiliate institutions. This design must be defined, established through new master affiliate relationships, and demonstrated through performance.

A set of translational research priority platforms should be identified, confirmed by leadership and resourced appropriately. These will become the defining areas of strength and strategy for the growth of translational science at Wayne State. Other areas of current research strength will remain and be supported through the CTS infrastructure. However, over the next five years of mindful evolution, focused investment into these core research priority platforms should define the scientific architecture of excellence for translational science at WSU. Decisions on the selection of these translational research platforms should be informed by the Battelle Report, by this report, and by faculty input, with the ultimate selection being made and articulated by the President as part of his continuing commitment to creating an institution with local impact and global influence.

The key resources or critical “Cores” that serve translational science should be moved toward “networked” centralization to achieve consistency, provide the highest quality of service to the CTS community, and demonstrate an institutional commitment to the support and training of the WSU

“There is a critical shortage of young promising investigators, clinical or basic. Many clinical departments hired basic scientists who did well in the 1980, 1990s and even early 2000s but as the funding got tighter and focus shifted towards translational work, our model of research remained stagnant in the past. As a result we have almost no young or new investigators who are poised for success in the future given the federal research priorities. Clinical translational approach needs to be a priority.”

(Dept. Chair)

“The lack of money points to the need to focus and hire strategically; we must know what we are and what we are good at.”

(Member of Faculty Committee)



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translational scientist. There will continue to be resistance by those who believe that interference with their program and established processes – even if the core program is recognized as the institutional model – will bring them down rather than raise the level of the tide for all. To drive this centralization of core CTS resources and services, user fees paid for through CTS sponsored research grants will be appropriate. The Huron Report¹ was instructive on how this process should work, and steps by the OVPR in response have been impressive. These should continue and accelerate.

New and expanded CTS collaborations must define the University. With community-based health systems, shared access to de-identified patient level data across the region should be confirmed through Master Affiliation Agreements. Such system wide access is becoming an expected capability today as shifts in the health status of the community can be detected at a systems level. WSU stands in a unique position where, working with its affiliate institutions, it can demonstrate health system uptake of new proven interventions. This shared interest in driving and measuring positive community health impact should be at the core of these Affiliation Agreements.

The unequal burden of many chronic diseases is now better understood by the community that bears this burden. There is an opportunity to nurture a growing shift in the community, from distrust of the clinical research enterprise, to an expectation that through direct community engagement and co-ownership, the CTS system at WSU will become a sustainable part of the community's re-vitalization. Wayne State should embrace this undercurrent of change and consider developing a national, sustainable platform to study and advance research engagement and participation among urban minorities. The undergraduate social science program should play a key role in developing this urban laboratory for research participation.

Industry must see an opportunity to help design and utilize the urban clinical research laboratory that Wayne State will build. Today, major NIH prevention trials require up to 20 percent minority participants,² and the recruitment challenge is daunting. In the FY 14 Appropriations Bill Congress requested that NIH hold a conference in 2014 to examine recruitment into clinical trials with a special focus on recruiting ethnically diverse populations. Similarly, the FY 15 Senate Appropriations Bill has included language directing the FDA to include women, racial and ethnic minorities, and the elderly, to help assure that clinical trials are representative of those individuals who ultimately will use these medical products,³ WSU should be at the center of helping the agencies respond to these Congressional directives.

¹ http://research.wayne.edu/about/continuous_improvements_initiatives/wsu_research_assessment_final.pdf

² <http://alzheimer.wustl.edu/education/berg/berg2012/Slides/Sperling.pdf>

³ *Inclusion in Clinical Trials.-Research has shown that gender differences, as well as differences based on age, race, or other factors, may contribute to differences in the safety and efficacy of drugs, biologics, and devices. The Committee directs FDA to encourage diverse participation, including women, racial and ethnic minorities, and the elderly, to help assure that clinical trials are representative of those individuals who ultimately will use these medical products, and that the products will be safe and effective for people in these demographic subgroups. The Committee urges the FDA to issue the Action Plan required by section 907 of the Food and Drug Administration Safety and Innovation Act and provide a timeline for implementation of the actions FDA will take, in cooperation with industry stakeholders, to ensure that women, minorities, and others are appropriately represented in clinical research, that meaningful subgroup analyses of clinical trials are*



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The external landscape is changing to embrace these new directions. Elias Zerhouni's recent editorial in *Science Translational Medicine* provides a glimpse into how the tectonic plates of translational science are shifting.⁴ His definition of key CTS factors includes several areas of strength at Wayne State (emphasized) which, when strengthened and leveraged through decisive leadership, can position the institution at the front of this defining curve.

*Society's successes in the past century have transformed medicine—and revealed weaknesses in our approach to the treatment of patients and the development of medical products.... **We need a new approach that redirects the research and development (R&D) engine toward deciphering the natural histories of human diseases and using this new understanding to identify therapeutic targets. Such a redesigned drug-development paradigm must begin with the patient.***

Rich patient cohorts coupled with powerful research tools—systems biology, computational modeling, and theragnostic imaging—can illuminate the genetic underpinning of molecular changes associated with human pathophysiology. Only after we lay the groundwork should drug targets be selected for further consideration.

Human tissue samples are crucial in the early validation of one's genetically derived hypothesis, and validation requires precise biopsy methods and serial tissue sampling over the course of the disease. Potent new analytical tools for obtaining and analyzing human materials can facilitate corroboration of ideas: single-cell analyses; clinical-grade liquid chromatography–mass spectrometry; three-dimensional (3D) and 4D cultures; multiplex tissue-based assays and readout capabilities; and next-generation bioinformatics, metabolomics, and proteomics methods.

... Better to scrap the linear model of drug development in favor of a network of activities conducted by smaller maneuverable partnerships fueled by diverse stakeholders and a freer, bidirectional flow of scientific information. Deciphering the complexity of human diseases and finding safe, cost-effective solutions that help people live healthier lives requires collaboration across scientific and medical communities throughout the health care ecosystem. ...

Emphasis supplied.

conducted, and that subgroup specific clinical trial results are made publically available in an accessible and timely manner. Senate report 112-164 (p.84). Report of the Senate Committee on Appropriations on S 2389, Agriculture, Rural Development, Food and Drug Administration and Related Agencies FY 2015 Appropriation Bill (May 22, 2014)

⁴ Elias Zerhouni, *Turning the Titanic*, www.ScienceTranslationalMedicine.org, 1/29/2014 Vol 6 Issue 221 2



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Summary

This report is informed by:

- a series of formal interviews with leaders across the WSU administration and faculty. See **Addendum A** for the full roster of these formal interviews
- countless informal discussions with administrative leaders, all of whom have been generous with their time and thoughtful input
- outreach to certain key opinion leaders
- review of a vast array of internal reports, consultant reports prepared over the past three years at WSU
- external literature relevant to the changing needs and understanding of clinical and translational science
- review of models at multiple academic institutions to regroup to meet the challenges of 21st Century translational science.

See **Addendum B** for a summary of the Methodology for this report. Based on this methodology, this report is intended to inform how Wayne State will chart its course to become a highly competitive and significant force in urban clinical and translational sciences.

Vision, leadership and a new regional engagement must converge to achieve this desired future state:

Vision: *Wayne State will become a highly competitive force in urban clinical and translational sciences, changing the health of the citizens of this region and becoming a national incubator for urban translational science.*

Leadership: *Institutional leadership will create a new infrastructure for urban translational science, define a set of translational research priority platforms, and drive revenue allocation processes to support growth in these focus areas.*

Community: *As Detroit moves toward renewal and redefinition, Wayne State will position itself as the critical, unifying force across public health systems, healthcare institutions, regional foundations, and the community itself for the revitalization of the community's health. This claim of leadership will reflect and respond to the offer of Mayor Duggan, extended at President Wilson's inauguration, to work with his office to place WSU at the center of Detroit's rebirth.*

While many advances have been made to implement this report, the community is still calling for more decisive action. This report, the report from Battelle, and the newly announced Wayne State Strategic Planning effort should converge to support this action and leadership. Drawing upon vision, leadership and community engagement, Wayne State University will emerge as a laboratory and national leader in community-based urban research excellence and equity.



2. EXECUTIVE SUMMARY

Rapid evolution is taking place in the demand for translational research. There is a logarithmic growth in research opportunities across the translational research continuum. Funders, the public and health systems have new expectation for the academic medical center to keep pace and remain on the defining edge of these transformations.

Wayne State is positioned today to be on this cutting edge of opportunity, influence and impact. This report presents an overview of transformation underway today in academic medicine, changing expectations for clinical and translational science, and a picture of CTS at Wayne State today. It challenges Wayne State to own the nexus among translational science, urban research excellence and improvements in health equity across the community.

To do this, WSU's focus on translational science should be developed and coordinated through a new Institute. The Director of this Institute should report -- through the Vice President for Research and the Dean of the School of Medicine -- to the President. A governing board and an external advisory board will oversee and provide strategic input on the directions for the Institute.

The Institute should be centered on **community-based urban research excellence and equity** and should:

1. Coordinate the management of key CTS Cores. Critical tools, resources, and research support systems will remain distributed across WSU Departments and Schools and in some cases regional affiliates, but will be integrated and coordinated centrally.
2. While coordinating and facilitating CTS efforts across WSU, drive a primary focus on six translational research Priority Platforms.
3. Recognize a suite of urban translational research competencies that will work in a multi-dimensional model with the Cores and the Priority Platforms to support the conduct and growth of urban translational science.
4. Consider additional focus on two new, defining centers, one focused on Urban Community Engagement and Research Partnership and the other on Urban Medicine and Population Health.
5. Advance the training of students, researchers and investigators not only in specific core research skills, but in the emerging *science of translational team science* and its measurement, with a specific focus on urban translational science.
6. Lead a partnership with the Detroit community to improve measurably health equity for the citizens of the region.

This report presents ten recommendations as a roadmap for achieving a new level of national prominence in community-based urban research excellence and equity.



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1. Create a New Institutional Home for CTS with a focus on Urban Translational Sciences.

Consider: *Institute for Community-based Urban Research Excellence & Equity (CURE² Institute)*⁵

- 1.1 Position the Institute to report to the Vice President for Research and the Dean of the School of Medicine
 - 1.2 Consider housing the institute in the MBRB
- ### 2. Create a management and governance structure for the CURE² Institute that assures authority and scope of control in the Director (ultimate PI) with accountability for operations executed through a management team responsible for each critical CURE² function and strategic direction provided a Governing Board and an External Advisory Committee
- ### 3. Identify, integrate and support high-performance CTS Cores that will serve the Institute and CTS broadly across WSU
- 3.1 Move the critical “Cores” that serve translational science decisively toward centralization to achieve consistency, provide the high quality service to the WSU CTS community, and demonstrate institutional commitment to support the success of the WSU translational scientist
 - 3.2 Establish a *CURE² CORES Collaborative* that will be the linked architecture for the critical CTS cores that operate today across internal departments and external affiliates
 - 3.3 Develop a mechanism to move into the CURE² CORES Collaborative those Cores that function well today within WSU Regional Affiliates
- ### 4. Through the Office of the President, define the Translational Research Priority Platforms that will be the focus for investment, recruitment and cross-institution invigoration and commitment.
- 4.1 Consider six translational research priority platforms
 - Urban Maternal, Child and Life Span Development
 - Urban Prevalence and Prevention of Cardiovascular Disease

⁵ As a matter of convenience, this report uses the term **CURE² Institute**. WSU may wish to further consider how to name and brand this institute. However, the image presented for the institute should include both concepts of excellence and equity, as a reflection of the driving commitment of the current administration to see both become defining qualities of the University and to embrace other initiatives that are underway nationally through the AAMC and locally in discussion with the Kresge Foundation, focusing on an Excellence to Equity Ecosystem.



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- **Urban Interface of Genes, Environment, Ethnicity and Health**
 - **Bio-engineering in the Urban Clinic and Community Setting**
 - **Brain Science and Neurological Health in the Urban Environment**
 - **Cancer**
- 4.2. Identify a suite of urban translational research competencies**
- 4.3 Build a multi-dimensional model that demonstrates the integration of the CTS Cores, the Priority Platforms, and the deployment of a suite of urban research competencies that span T1 to T4**
- 5. Develop conceptual framework for significant new programs or Centers within the CURE² Institute**
- 5.1 Consider a Center for Urban Community Engagement and Research Partnership**
 - 5.2 Consider forming a Center for Urban Medicine and Population Health within SOM**
- 6. Focus training and career development on the Urban Translational Scientist**
- 6.1 Evolve the roadmap for the CURE² Institute from the current Certificate in Clinical and Translational Sciences into a Master of Translational Sciences**
 - 6.2 Introduce into the Clinical and Translational Science Program a number of courses that will recognize and study the unique aspects of the science of translational science in the urban environment**
 - 6.3 Create a system that engenders respect for the translational science career path and recognizes high performance in team science in promotion and tenure review**
- 7. By 2015, bring a competitive revenue stream into the Office of the Dean and/or the Institute to support development of strategic programmatic development and recruitment**
- 8. Consider examples of restructured Schools of Medicine, but accept incremental, step-wise change**
- 9. Use Affiliation Agreements as a vehicle for shared vision and measurement of community health impact**
- 9.1 Leverage relationships with partner institutions to drive the CURE² Translational Research Priority Platforms**



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10. Develop a CURE² Institute Design Roadmap

10.1 Appoint a President's CURE² Institute Working Group

10.2 Conduct a series of outreach and engagement meetings

10.3 Hold two major meetings to position the Institute in the regional and national mindset: A CURE² Institute Design Symposium and a National Conference on Community-based Urban Research Excellence and Equity

This report, *Transforming Clinical and Translational Sciences – A Roadmap to Lead the Nation in Urban Research Excellence*, presents an aggressive, system-wide roadmap for transformation. These transformations are within reach. The commitment to and process to achieve these results will be invigorating for a large array of Wayne State leaders who are ready for and committed to be part of this positive movement forward.



3. OBSERVATIONS

3.1. Institutional CTS Background

Wayne State University, growing out of a teacher's college and urban education tradition, is today one of the nation's leading urban-serving research institutions. In 2012, the University attracted over \$145 million in external research funding. WSU's commitment to research is noteworthy in light of the obvious demands for basic education served by the University. WSU has a total enrollment of nearly 29,000 students, among whom about 35% are from racial/ethnic minority groups; 20% of these students are pre-science or pre-professional majors.⁶ WSU also has one of the largest Arab American student populations in the US. About 45% of all undergraduate students and 20% of graduate/professional students are from the City of Detroit. WSU is a nationally recognized urban center of excellence in research, one of only two urban public universities holding both the Carnegie Research Foundation "Very High Research" and "Community Engagement" designations.⁷

WSU has shown particular strength in health and medical related research through the School of Medicine (SOM). The SOM is the largest single-campus, allopathic medical school in the US, with over 1,000 students. Despite accounting for nearly \$110 million of the total of all sponsored research, the SOM faculty is more oriented to teaching and clinical practice than research, at least in comparison with other peer schools. Several factors underscore this trend. One factor is that the SOM and the University do not have their own hospital. As a result, the SOM undergraduate and graduate trainees rotate through a variety of Detroit hospitals, many of which are in close geographical proximity to the SOM. This provides a wide range of solid experience for interns and residents, but it does not provide a direct span of control for the University that would facilitate a seamless clinical research program.

Total WSU research expenditures increased steadily from 2006 to 2011, but dropped slightly in 2012. This recent drop likely reflects certain productive faculty departing and more current year totals when available will also reflect sequestration. These research totals place WSU approximately 55th in public university rankings and 75th in all university rankings. WSU remains a much stronger research university than it was ten years ago, but with stalled research growth (and continued growth in other institutions) its national ranking has slipped.

The SOM has 305 tenure track faculty; but the number of research faculty and the number of faculty with active research funding are both declining. A high number, 82 %, of the SOM faculty is already tenured, with only 18% working their way through the tenure track.

Despite these recent downward trends, many strengths define the Wayne State research enterprise. Adopted in part from the report of the Dean of the School of Medicine to President Wilson addressing the decline in research funding in 2013, these notable biomedical enterprise-wide strengths include:

⁶ Wayne State University Fact book 2013 <http://wayne.edu/factbook/factbook2013.pdf>

⁷ http://classifications.carnegiefoundation.org/lookup_listings/institution.php



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Within the SOM, as examples,

- The Wayne State University School of Medicine (SOM) is responsible for 67% of WSU research funding.
- It houses the only NIH intramural program outside Bethesda, (Perinatology Research Branch PRB) and successfully re-competed last year for a 10 year extension.
- The SOM is also home to three NIH T32 (cardiovascular, oncology and diabetes and endocrinology); two NIH Center grants (the Comprehensive Cancer Support Grant and the Core Vision Grant in Ophthalmology); multiple network grants including the longest running Neonatal Network grant, as well as multiple other noteworthy achievements.
- The SOM is also home to the trans-disciplinary Michigan AHEC grant, led jointly by the Deans of Nursing and Medicine, with participation by two other WSU schools and three other Michigan Universities.
- In collaboration with schools across the campus and the Henry Ford Health System, the SOM is building a state-of-the-art multi-disciplinary biomedical research building (MBRB), which will house 65 teams of researchers starting in 2015.
- A signal of sustainable growth, The National Institute of Neurological Disorders and Stroke has renewed a five-year, \$1,662,500 million grant to Wayne State University School of Medicine led by a Professor of Pediatrics to develop better diagnostic tools for a rare disorder present at birth that affects the brain, eye and skin in the form of venous blood vessel malformations.

Led more widely through the OVPR, as examples,

- Center for Urban Responses to Environmental Stressors (CURES) has recently been selected for P30 EHS Core Center funding.
- The city of Detroit tapped Wayne State University and other key partners for a new initiative to provide expectant mothers in Detroit with consistent pre-natal care to deliver healthy full-term babies. The project is co-led by the Associate Dean for Maternal, Perinatal and Child Health.
- The WSU Graduate School is one of 10 institutions selected by NIH to lead a five-year initiative aimed at strengthening the research workforce in the United States. NIH's Broadening Experiences in Scientific Training (BEST) award is to implement a new program that prepares graduate and postdoctoral students to enter research careers outside of academia.

3.2. Translational Science

Translational science is expressed and understood in a number of ways. In this report and in the report delivered recently by Battelle, terms such as **translational, implementation, applied, use-inspired** are all used to modify "science." Together, these terms convey the essential closed loop between "bench to bedside" (in clinical terms) and "bench to trench" (in public health terms) and back to the university lab to assure that advances in discovery respond to the real needs of the end user, be this the clinician or the patient, and deliver ultimate health impact.



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Translational sciences is defined in the **NCATS Advisory Council Working Group on the IOM Report: The CTSA Program at NIH**, delivered on May 16, 2014, (the NCATS CTSA Working Group Report) as the “field of investigation focused on understanding and addressing the scientific and organizational challenges underlying each step of the translational process. ... *Along the long and complex road from promise to impact, translation science works to improve the health of individuals and the public – from therapeutics to medical technologies to medical procedures to behavioral changes.*”⁸



Translational Science is commonly recognized as having four key components:

- T1: moving basic research– whether on a new targeted molecule, a behavioral intervention, or a potential public health reform – from early theory in the lab into pre-clinical and proof of concept testing to confirm the potential application to humans or human systems
- T2: moving the proven proof of concept observations through larger scale testing in clinical trials, systems, or targeted communities
- T3: disseminating and driving uptake of a proven innovation into clinical practice or into wide spread public health adoption. In the case of clinical practice, this trajectory has been shown to take up to two decades⁹
- T4: assuring that the proven innovation in treatment, care or public health intervention is accessible to all populations and has the power to improve population health.

Implementation research, a relatively new discipline, is critical to the T2 and T3 components of the translational research cycle and is fully embraced by NIH - NCATS. Healthcare providers and the public are increasingly aware that promising research results do not easily translate into improved human health. The science of implementation and dissemination comprises a multidisciplinary set of theories and methods aimed at improving this process of translation from research evidence to everyday health-related practices. Implementation research, in particular, examines how interventions can be better integrated into diverse practice settings, and emphasizes direct engagement with the institutions and communities where health interventions are introduced.

This field includes the study of influences on healthcare professional and organizational behavior.¹⁰ The intent of the discipline is to create generalizable knowledge that can be applied across settings

⁸ <http://www.ncats.nih.gov/files/CTSA-IOM-WG-Draft-Report.pdf>.

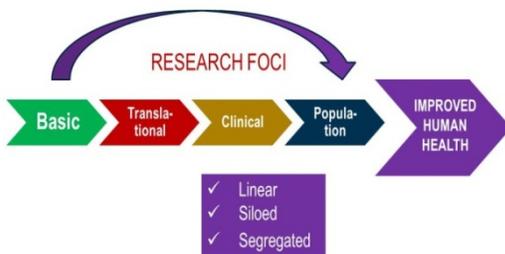
⁹ AHRQ: Translating Research into Practice II. www.ahrq.gov/research/trip2fac.htm



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and contexts to answer central questions. *Why do established programs lose effectiveness over days, weeks, or months? Why do tested programs sometimes exhibit unintended effects when transferred to a new setting? How can multiple interventions be effectively packaged to capture cost efficiencies and to reduce the splintering of health systems into disease-specific programs?*

Use-inspired Research, as noted in the Battelle Report, recognizes the relationship between basic science and technological advance. This interaction is not a forward, linear continuum, but relies upon basic science being inspired by significant societal need. In Pasteur’s Quadrant, the understanding of needs and uses move basic research into new directions and moves existing technologies into improved new applications. Battelle notes, “the connection between biomedical product advancement and clinical care is not simply one of advancing a supplier and buyer relationship. Instead there is a close and necessary interface of “bench and bedside” for biomedical innovation to move forward ‘Information flow at this interface is bi-directional, requiring a close interaction between clinical and bench scientists’.”



The fallacy of viewing translational research as a linear process is recognized broadly today. As presented by NCATS, the traditional view that there would be a linear progression of science and understanding through the gates of translational science relied upon the assumption that each step in the process would feed into the next with resultant impact. The model, while strong in principal, has not served to break down the siloes of academic medicine.

Today, both theory and vision support a changing model that enforces a direct closed feedback loop from patient- or user-based experience to drive design that will service uptake into practice, and adherence in treatment. The feedback loop extends to encompass the design of and findings from clinical trials and community/population-based research back into the academic laboratory.



3.3. Clinical and Translational Sciences at WSU Today

For several years WSU has pursued a commitment to clinical and translational science. The institution, however, never competed successfully for a General Clinical Research Center (GCRC). Thus, when the NIH responded to the directions proposed in the NIH Roadmap for Biomedical Research and evolved the GCRC program into what is known today as the Clinical and Translational

¹⁰ **Welcome to Implementation Science** Martin P Eccles*1 and Brian S Mittman2,3. Published: 22 February 2006 *Implementation Science* 2006, 1:1 doi:10.1186/1748-5908-1-1 Received: 03 February 2006 Accepted: 22 February 2006



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Science Award (CTSA) program, Wayne State arguably was at a relative disadvantage as compared with those institutions that then housed one or more of the 83 legacy GCRCs. However, WSU did receive a CTSA planning grant in 2006, which allowed it to focus on establishing academic "discipline" of Clinical and Translational Research.

WSU and partners submitted proposals for a CTSA in 2008, 2009 and 2010. The 2008 and 2009 submissions were quite similar, proposing, with the Henry Ford System, an integrated CTS platform focused on urban health.¹¹ Both proposals received modestly enthusiastic rankings from NIH. NIH was generally complementary of the concepts of the CTSA proposal, and of many of the individual elements. However, NIH comments noted that certain required or important core or related capacities were not sufficiently strong. More significantly, NIH criticized the lack of articulation of how the various parts of the WSU CTS enterprise would work together and be integrated. Reviewers reflected a concern that WSU was seeking funding to accomplish a "future vision" for a CTS program, rather than presenting solid evidence of a current ability to accomplish the aims of the application.

The 2010 proposal, essentially a co-proposal with Michigan State University (MSU), was a departure from the previous two attempts.¹² The proposal was unclear on many key details as to how the universities would work together on an integrated CTS program. The proposal did not score well at NIH.

In 2010, just before submission of its third CTSA proposal, WSU established its Department of Clinical and Translational Science (DCaTS). DCaTS is not a part of the School of Medicine, but housed under the University Provost. The purpose for the Department was to coordinate clinical research training under one umbrella Department and to create a centralized home for CTS that could operate in the context of a unique cross-institutional collaboration, the distinguishing feature for the 2010 application. The trans-institutional alignment with MSU through DCaTS, anticipated in the 2010 application, has not been achieved. Post application, DCaTS remained within the office of the Provost at WSU.¹³

While the reporting structure for the various institutional homes for the 62 currently funded CTSA is not always explicit to the public and could be something other than the name implies, the majority are denominated as a "Center" or "Institute."¹⁴ It does not appear that any of the current

¹¹ The applicant was WSU-HFHS Detroit Regional Institute for Clinical and Transnational Research (DRTCTR). "Our vision is to become a national model for the conduct of clinical and translational research in an inner city setting, by creating a comprehensive, coordinated, collaborative and integrated model for researching components of urban health." (6/13/2008)

¹² The proposal was in the name of a consortium, the Michigan Alliance for Clinical and Translational Science, which included, beyond WSU and MSU, Henry Ford Health System, the Karmanos Cancer Center and the Van Andel Research Institute.

¹³ <http://prognosis.med.wayne.edu/article/wsu-establishes-new-department-to-accelerate-clinical-and-translational-research> Aug 16, 2010

¹⁴ <http://www.ncats.nih.gov/research/cts/ctsa/about/institutions/institutions.html>



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CTSAs operate under the auspices of a University Department for Clinical Research. This is true even when significant cross-institution collaboration is part of the paradigm, such as with Emory.¹⁵

3.4. Transformations in Academic Health Systems

While WSU operates through a distributed network of hospitals and hospital systems, it must think and act like an integrated academic health system. The AAMC's 2014 report, *Advancing the Academic Health System for the Future*, presents eight themes pertaining to Academic Health Systems.¹⁶

These themes either apply directly to WSU or present a blue print for WSU's symbiotic relationships with its affiliated hospital systems through which it must deliver on its promise of community health impact:

1. The AMC of the future will be system-based, with a broad regional presence and clinical services aligned across the continuum of care.
2. Academic health systems require strong and aligned governance, organization and management systems committed to a unified direction, transparency, and internal and external accountability for performance.
3. University relationships will be challenged to evolve as academic health systems grow and develop, requiring leadership and structure to support clinical expansion, community engagement, alignment on financial requirements, and implementation of productive industry relationships.
4. Growth and complexity of academic health systems requires an enhanced profile and responsibilities for department chairs, new roles for physician leaders, and evolution of practice structure to focus on organizational leadership designed to lead clinicians into a new era.
5. Transparency, quality outcomes and financial performance across the academic health system is central to high achievement that is demonstrable to patients and purchasers.
6. Competitive viability and long-term mission sustainability will require radically restructuring the operating model for cost and quality performance.
7. Academic health systems must begin to move to population health now, as purchasers look to reward organizations that can demonstrate improved outcomes for attributed populations of patients, and as community leaders address the social determinants of health.

"While our core values and purpose as academic medical centers are immutable, all else in academic medicine is changeable – in fact, needs to be changed – to accommodate a changing world. Everything about how we are structured and organized must be in play. Everything about our academic culture, with the regents, provosts, deanery and the academic senate ... is in play. Everything about how we educate students and residents, how we deliver care, how we organize ourselves for research is in play."

*(Recent AAMC Chair,
AAMC Report: Advancing the Academic
Health System for the Future*

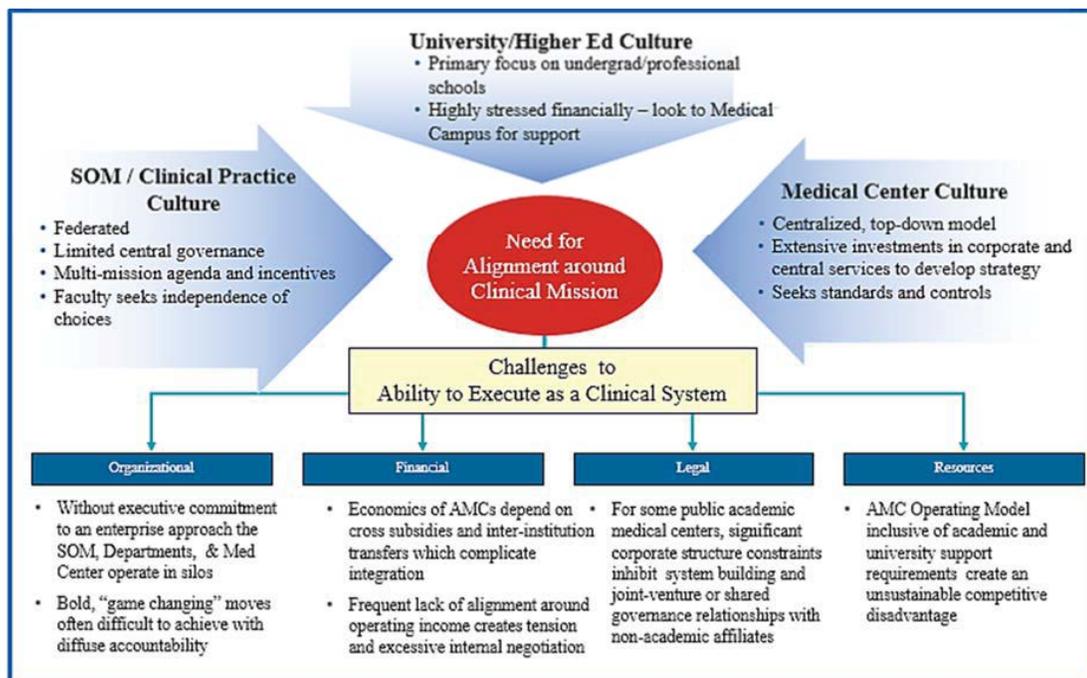
¹⁵ The Atlanta Clinical & Translational Science Institute (ACTSI) partners Emory University, Morehouse School of Medicine and Georgia Tech in a consortium, funded by the NIH CTSa program. www.actsi.org

¹⁶ <https://www.aamc.org/initiatives/patientcare/aphc/357864/academichealthsystem.html>

8. Academic health systems must conduct candid assessments of strengths and weaknesses essential to achieve change; and must revamp organizational culture if necessary.

The barriers to this transformative change are sizeable and shared across academic health and medical systems. As noted in the AAMC’s 2014 report, the higher education culture looks to the medical campus for support while retaining a primary focus on undergraduate and graduate professional schools. Schools of medicine are often defined by the federated, segregated clinical practice cultures. Medical centers, whether within the institution or affiliated, invest in corporate and central services rather than in collaboration. **And, “without executive commitment to an enterprise approach, the SOM, Departments and Medical center operate in silos.... Bold, ‘game changing’ moves are often difficult to achieve with diffuse accountability.”**

The interplay among these various pressure points is portrayed in this figure from the AAMC report:



While WSU does not have its own hospital systems, the pressures represented above -- coming internally from the SOM/Clinical Practice Culture and the University /Higher Ed Culture and externally from HFHS, DMC and KCI – are operating with force. All is in play. Transforming the WSU translational research enterprise is dependent upon transformations that will occur through strong leadership within the institutional culture across the regional network of affiliates.

The inter-dependency of the regional institutions, while the source of significant challenges, must become the tool for centralized alignment around a shared clinical mission, embracing these new determinants of health system performance for WSU’s hospital affiliates and creating the essential platform for CTS at WSU.



3.5. The Changing Expectations for Clinical and Translational Sciences and Opportunity Presented

This institutional transformation must take place within the culture of the campus but also in response to external trends and expectations for CTS. The Draft 2013 Report of the SOM on ***Community-focused approach to research and graduate training: Improving health through Discovery and Service*** aptly summarizes many of the scientific breakthroughs and realizations of the past decade that underpin today's demand for a more effective translational research enterprise:

- Mapping of the human genome affording opportunities for improved prevention and individualized treatment
- Increased recognition of long biologic memory in terms of exposures and their impact later in life and in the life of our children and our children's children
- The relationship between emotional state and biologic health
- The concept of resilience in biologic, socio-economic, cultural and emotional terms
- The interplay between environment and the organism at the micro, macro and systems level, including seemingly subtle or trivial influences with broad consequences
- The unevenness in improvements in health outcomes across all sectors of our society.

In January 2014, the Faculty CTS Committee discussed an overview of the changing external landscape and expectations for the conduct of clinical and translational research. (See **Addendum C** for the full FaegreBD Consulting presentation.) The overview drew from comments of the Director of National Center for Advancing Translational Science (NCATS):

- *While fundamental science has advanced with breathtaking speed, there remains a continued poor transition of basic or clinical observations into interventions that tangibly improve human health.*
- *The drug/device/diagnostic development system is in crisis with increasingly poorer returns deriving from a higher and higher investment in R&D.*
- *Today's clinical trials system operates with inefficiencies, redundancies across differing institutional review systems, and disturbing lack of reproducibility of results when moving from academic into industry settings.*
- *Despite a decade of investment in the CTSA infrastructure there remains a disturbingly poor adoption of demonstrably useful interventions across clinical communities leading to low impact on the health of the community that should be served by the academic institution.*

As seen by NCATS, today's translational science enterprise must be served by new tools, technologies, systems and resources: Big data; personalized medicine; high throughput screening; sophisticated imaging technologies; electronic health records; streamlined IRBs; and a new understanding of vital role of community in research engagement, design, registries, cohorts, ownership, and outcomes.

The 2015 CTSA RFP will be refashioned to respond to the NCATS CTSA Working Group Report. Anticipated changes include:



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- Fund priorities rather than infrastructure
- Fund more sites with smaller grants – recognize that more than 63 communities need to be touched by the CTSA
- Fund only those programs that support inter-disciplinary team science in the conduct of clinical and translational research
- Recognize the value of the non-traditional and unique contributions to the national CTSA platform
- Present new national models for patient-oriented clinical research, addressing challenges of how to engage people most affected by a disease and how to engage these populations in the primary design of research that will change their health status
- Fund infrastructure that enables the proposed science, not infrastructure that exists for its own sake

Further, WSU should anticipate:

- Clearer expectations of short and longer term scientific and organizational outcomes
- Evaluation measures that comport with academic advancement but move beyond papers and grants
- A clear path for moving novel intervention into the community with demonstrated public health impact

Winning strategies for CTS in FY 2015 and beyond will include:

- A focus on solving daunting clinical problems in the translational space
- The adoption of novel strategies for academic incentives to promote and encourage excellence in CTS
- Deploying health systems in context of translation into the community
- Applying empirical scientific thinking to solve major translational research challenges and to advance the “science” of the CTS process itself
- Conducting team-based projects across different disciplines

NCATS will look for translational research structures that do not reward or tolerate siloed, linear progression across the translational research continuum, but force behaviors into a new closed loop from the bench to the design of patient-centered (not academically-driven) research, into clinical trials and then into community adoption with surveillance and feedback that brings new questions and hypotheses back into the research laboratory.

The “linear” is being replaced with the complex systems strategy across translational science. To repeat the observation of Elias Zerhouni, cited in the introduction:

Better to scrap the linear model of drug development in favor of a network of activities conducted by smaller maneuverable partnerships fueled by diverse stakeholders and a freer, bidirectional flow of scientific information.



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3.6. Owning the Nexus among Translational Science, Urban Research Excellence, and Health Equity in Detroit

Economic and environmental challenges contribute to public health stresses in an unusually diverse Detroit urban community. The community presents an obvious microcosm for understanding the determinants of health and national laboratory in which to test interventions that hold promise for a new level of health equity for those affected by this profound economic decline and health disparities. Comments from leaders across the institution were consistent that WSU should own this challenge.

The value of clinical and translational science cannot be fully tested within the boundaries of the medical school. Translation occurs across health systems and is directly affected by policy, new incentives for reform and shared accountability for health outcomes. In Detroit, the picture is compelling¹⁷:

- Once characterized by the very affluent, today Detroit suffers from a high unemployment rate (18.8% July 2013).
- Standard employer based health insurance coverage has been lacking and access to publicly supported healthcare is challenged.
- Infant and child mortality occur at a higher rate in Detroit than in several Third World countries. The infant mortality rate is higher than the rates in Panama, Romania, and Botswana.
- Between 2000 and 2011, 2,300 infants died within their first year. The number one factor impacting Detroit's high child death rates is prematurity, followed by a culture of violence.
- Detroit is the only U.S. city with more than 100 deaths per 100,000 children. In what one doctor declared a "public health emergency," 120 out of every 100,000 children in Detroit died in 2010.

*"The structure of basic science research in the SOM is based on the 1970-1990's model of research in wet bench labs."
(Member, Faculty Committee)*

*"Detroit has 90% African-Americans and puts our university in a unique position of research based on the well-known and published effect of ethnicity on disease biology. Few universities can compete with us looking into this emerging area of research. Cardiovascular disease, stroke, multiple sclerosis, neurologic recovery, access to health care, etc, are all hot areas of research, we can capitalize on. Recognizing our strengths and investing in those programs is critical. Despite many individuals (multiple sclerosis, hypertension), there has been no defined effort from the university."
(Dept. Chair)*

These data are a rallying cry for an urban translational research agenda that will define WSU. Advancing urban translational research excellence at WSU is far more about investment and growth of the WSU research program than about creating a competitive platform for a CTSA proposal. The former will lead to the latter. Not the reverse.

¹⁷ *Detroit News* (Jan 30, 2014)

<http://www.detroitnews.com/article/20140130/LIFESTYLE03/301300007#ixzz2rtxd2rR9>



3.7. Academic Analogues: Restructuring for Success

WSU is not alone in facing the challenge of examining how its School of Medicine should be structured to respond and succeed within a 21st clinical and translational science environment. **Addendum D** traces the work undertaken at the University of North Carolina at Chapel Hill, at Duke and at Northwestern to guide the redesign of their Schools of Medicine to conduct 21st century clinical and translational science. The experiences of other Universities provide key data points for consideration as WSU designs a new and vibrant CTS enterprise. These will inform the strategic planning process that WSU is soon to undertake.¹⁸

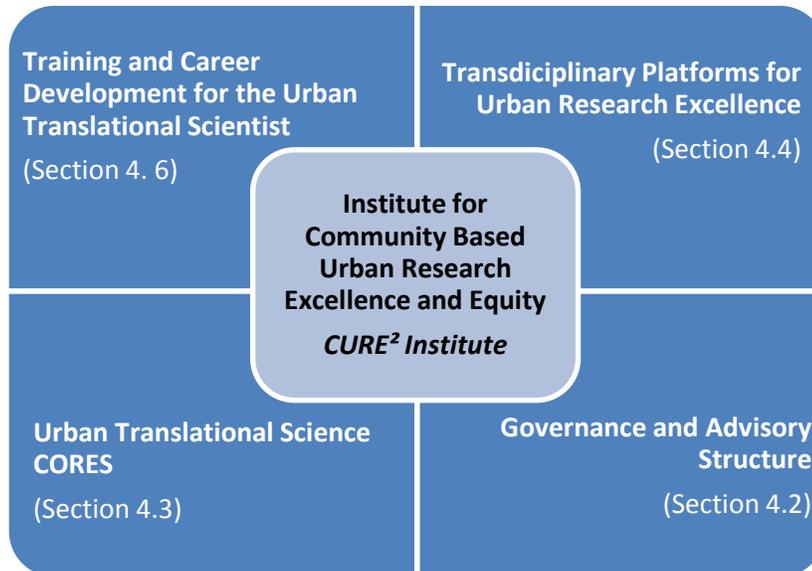
¹⁸ AAMC: *Incorporating clinical and translational science into the traditional medical school curriculum.*
<https://www.aamc.org/download/283616/data/kelly-incorpcinicalandtranssci.pdf>



4. RECOMMENDATIONS

4.1. Create a new Institutional home for CTS with a focus on Urban Translational Science

Consider: Institute for Community-based Urban Research Excellence & Equity
The CURE² Institute



Interviews and discussions with faculty and administration, coupled with analysis of national trends and opportunity, drive the principle that WSU should focus its translational research enterprise on the challenge of defining, excelling and claiming national leadership in urban translational science. The conclusion presented itself at every turn.

Wayne State University should form a new institute focused on urban translational science. This report suggests that this institute be called the **Institute for Community-based Urban Research Excellence and Equity, or the CURE² Institute.**¹⁹ While this name is used for convenience, the ultimate public-facing presentation of the institute should include concepts of excellence and equity. This comports with the President’s inaugural vision and with increasing demands through the AAMC and the Association of Urban Serving Universities that the urban academic medical center not only improve population health ‘writ large,’ but work to address the determinants of health at the community level.²⁰

The Institute would have an umbrella platform, integrating and networking programs, current centers and institutes that support a set of translational priority research platforms or clusters. The

²⁰ See AAMC’s Urban Universities for Health, <https://www.aamc.org/initiatives/diversity/portfolios/332402/uuhealth.html>, a program in which President Wilson has a leadership role.



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Institute would serve as the locus for CTS sciences across the WSU Enterprise. While it will have a primary focus on leading the nation in urban translational science, the CTS cores, that will be networked and aligned through the Institute, would serve CTS across the university regardless of the area of research concentration.

This focus on urban translational science comports with the guidelines for multi-disciplinary research presented in the Battelle Report:

- Leveraging of multiple major core competencies, especially those comprising world-class areas of strength at the University
- A line of sight to impacting Detroit Metro Area/Urban industry and community challenges and opportunities
- A line of sight to impacting global challenges and opportunities

The vision for the Institute aligns tightly and reflects the four strategic goals for the CTSA program at NIH NCATS, as recommended in the CTSA Working Group Report delivered on May 16, 2014 to NCATS Advisory Council. Because of this strong alignment between the proposed WSU translational research institute and the NCATS CTSA Working Group recommendations, the goals and objectives presented in its report are included below:

Workforce Development

Goal: The translational science workforce has the skills and knowledge necessary to advance translation of discoveries.

This goal focuses on:

- Building an environment that supports and values translational science as “the place to go” for those who want to pursue high-impact careers in health sciences.
- Training and educating a world-leading, continuously learning workforce.
- Developing a translational science workforce that can meet the needs of today and tomorrow.

Collaboration/Engagement

Goal: Stakeholders are engaged in collaborations to advance translation.

This goal focuses on:

- Engaging stakeholder communities so they contribute meaningfully across the translational sciences spectrum.
- Enabling team science to become a major academic model.
- Ensuring that all translational science is performed in the context of collaborative team science and that shared leadership roles are the norm throughout the entire translational science process.

Integration

Goal: Translational science is integrated across its multiple phases and disciplines within complex populations and across the individual lifespan.

This goal focuses on:



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- Integrating translational science across the entire lifespan to attain improvements in health for all.
- Launching efforts to study special population differences in the progress and treatment of disease processes.
- Developing a seamless integrated approach to translational science across all phases of research.

Methods/Processes

Goal: The scientific study of the process of conducting translational science itself enables significant advances in translation.

This goal focuses on:

- Enabling CTSA programs to function individually and together as a research engine transforming the way translational science is conducted across the nation to make tangible improvements in the health of individuals and the population.
- Rapidly translating CTSA-generated new knowledge and technologies into health interventions in real world settings.
- Developing technologies, methods, data, analytics and resources that change the way translational scientists approach their work.
- Generating and curating comprehensive data sets or other resources that catalyze science.

WSU cannot expect to accomplish overnight what this report presents as the goals for the largest single NIH program to be accomplished over the next many years. **However, the lack of ensconced translational research legacy systems provides an enviable opportunity for WSU to ‘seize this national moment,’ hear what is being said, and create a responsive, forward-leaning, ‘eye-catching’ WSU translational science platform.**

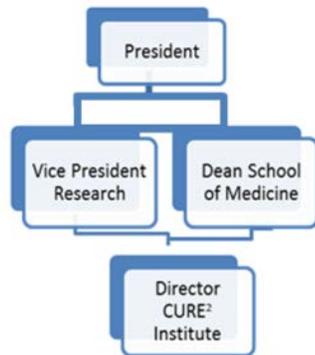
This report takes this ‘fresh slate’ view of the WSU opportunity and provides recommendations on each of the following:

1. **Create a new institutional home for CTS (this Section 4.1)**
2. **Establish a transparent and highly functioning governance structure for the Institute (Section 4.2)**
3. **Identify, integrate and supporting high-performance CTS Cores that will serve the Institute and CTS broadly across WSU (Section 4.3).**
4. **Establish through leadership by the President a set of CTS research priority platforms (Section 4.4)**
5. **Develop a conceptual framework for new programs and centers that will drive the urban research excellence and equity platform (Section 4.5)**
6. **Focus training and career development on the urban translational scientist (section 4.6)**
7. **Bring a competitive revenue stream forward to support the vision for urban research excellence and equity (Section 4.7)**



8. Evaluate models to inform how the School of Medicine might be structured in the future to meet the objective of training the urban physician and scientists of the 21st Century (Section 4.8)
9. Use agreements with regional affiliate/partners to drive a shared vision for investment, measurement and ownership of results in community health impact (Section 4.9)
10. Develop a roadmap for input, decision processes and execution

4.1.1. Position the Institute to report to the Vice President for Research and the Dean of the School of Medicine



In setting up a new Institute for Community-based Urban Research Excellence and Equity, the Director of the Institute should function under two lines of direct report: one to the Dean of the School of Medicine and one to the Vice President for Research. As an alternative, if a co-report arrangement is deemed not workable, the single report then should be to the VPR to assure the vision to cross-institution engagement in CTS.

While the focus on CTS exists primarily within the School of Medicine, there is a strong sense across the institution that CTS can and

should be “inter-collegiate” at WSU. Pharmacy, health sciences, engineering, nursing, liberal arts, behavioral and social sciences – all should have a piece of this centrally-coordinated cross discipline function. The inter-disciplinary nature of the CURE² Institute will also serve to reduce the “Woodward divide.” The Institute will have the ability and commitment to reach into the undergraduate programs in STEM and social sciences to support the translational career development pipeline, as discussed below. Either way, strong CTSA programs assure a short, direct line of report up to the President.

As an example for reference of a single reporting line up through the VPR to Chancellor to the President, the line of authority for the clinical and translational PI at the University of North Carolina is: **CTSA PI --> VC Medical Affairs --> Chancellor --> President**. However, a hybrid but workable arrangement continues at the University of Colorado, where the Director of the CCTSI reports simultaneously to the Vice Chancellor for Research and the Dean of the SOM.²¹ A similar arrangement is proposed for the CURE² Institute.

²¹ The Colorado clinical and Translational Science Institute (CCTSI) is based at CU-Denver, where the Vice Chancellor for Research and the SOM Dean, who also serves as the Vice Chairman for Health Affairs, each report to the Executive Vice Chancellor of the Medical Campus, who reports to the CU-Denver Chancellor.



4.1.2. Consider housing the institute in the MBRB

Placing the CURE² Institute in the Multidisciplinary Biomedical Research Building (MBRB) will be consistent with the purposes for the building and will send a message of community synergy with the Henry Ford Hospital System (HFHS). A consensus among the array of individuals interviewed is that the MBRB should announce through its formation a “clearly evident rationale to promote integration of urban translational research between both institutions and with the community.” The building “should be a fulcrum for risk reduction and disease prevention in the community.”

4.2. Create a management and governance structure for the CURE² Institute that assures authority and scope of control in the Director (ultimate PI) with accountability for operations executed through a management team responsible for each critical CURE² function and strategic direction provided through a Governing Board and an External Advisory Committee

The integrated home for the CURE² Institute must provide an infrastructure to support the broad range of translational science across the WSU SOM Departments, other WSU graduate and undergraduate schools, and partnering affiliates. The CURE² Institute is intended to be the WSU foundation for training and developing the next generation of clinical and translational investigators. A responsive and supportive governance structure will enable high quality, efficient and cost-effective research to flourish.

Authority

The CURE² Institute should have the authority and reach to forge relationships within WSU and with outside partners, including affiliated health systems and hospitals, industry and local communities. The Director of the CURE² Institute should have autonomy to implement the programs and functions of the Institute, to hire, promote and release CURE² direct personnel, and to manage the space assigned to the CURE². This will require cooperation and agreement from relevant WSU deans and leadership, informed by input and advice from partner hospitals, community members, business leaders, and the faculty and researchers.

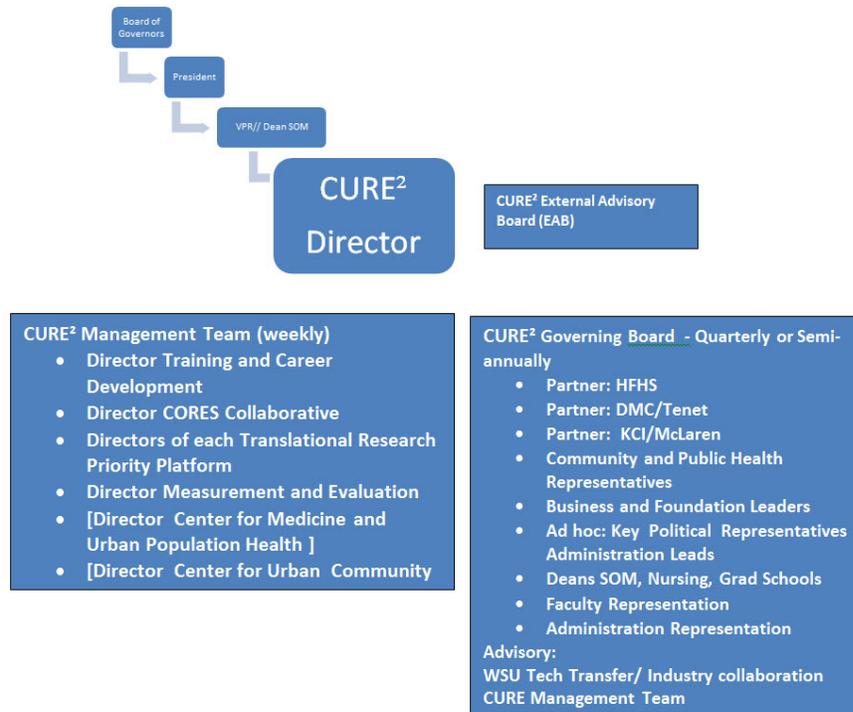


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Structure and Oversight

The Director should have a Management Committee representing the leads for each of the critical functions for the institutes. An overview of the proposed operating infrastructure, developed in the recommendations below, is represented in the following figure:



Advisory Board and External Advisory Committee

The CURE² Director would call upon two committees for oversight and strategic guidance: A cross-sector Governing Board, with highly placed Executive Committee, and an External Advisory Board.

The CURE² Governing Board (CGB)

The CURE² Governing Board would include Deans of the WSU SOM, Nursing, and relevant Graduate Schools; CEOs of each affiliate hospitals; representatives from business/corporate/foundations, community and public health authorities, patient communities, including leading organizations within underserved populations; and ad hoc representatives from significant political entities, including the Office of the Mayor. Key leaders, such as the Director of the WSU Technology Commercialization Office and the members of the Management Team would advise the Board.



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The CGB should meet quarterly or no less often than twice per year and be chaired by the CURE² Director. This Council will provide the opportunity for the collaborating schools and institutions to be informed about CURE² priorities and progress, provide input to the CURE² leadership, and recommend strategies for further action.

A small subset of the CGB, primarily WSU internal senior administration, should serve as the Executive Committee.

The External Advisory Board (EAB)

The EAB would be comprised of at least eight nationally renowned scientists with significant experience and leadership positions in CTS would meet at least annually. The CURE² Director would report to the EAB on the year's accomplishments and challenges. The EAB would provide an annual review to the Director, President, Provost, Vice President for Research and Dean of the School of Medicine on the performance of the Institute. EAB members will ideally have deep knowledge of science and research, and also be able to speak to best practices in community engagement and implementation research, clinical research management, and education, training, and career development.

Promotion, Appointment, and Tenure

The NCATS CTSA Working Group Report identifies as a primary goal "Building an environment that supports and values translational science as 'the place to go' for those who want to pursue high-impact careers in health sciences." The report calls for "The systems for staff development and faculty promotion at academic health centers recognize and reward the collaborative nature of translational science." (See Section 4.6 for a discussion of Training and Career Development of the urban translational scientist and strategies to recognize leadership and excellence in "team science" as a criterion for independence and scientific leadership, key requirements for promotion.)

Although the responsibility for appointments and promotion would continue to reside with individual schools and departments, the CURE² Director should submit letters of support for faculty members who have made strong contributions or participated in WSU CTS activities through the Institute. The CURE² Director or his/her designee would attend each primary Department's Promotion Committee meeting as needed, to speak on behalf of the faculty member.

4.3. Identify, integrate and support high-performance CTS Cores that will serve the Institute and CTS broadly across WSU

Today, strong sentiment exists that the needed tools for translational science do not exist, are not known, or are not shared. Breaking this log jam must be a key priority for the transformed CTS enterprise at WSU.



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There will be push back. As stated emphatically in one interview,

There are several examples: Department of Clinical Translational Research, previous ill-organized CTSA applications, enforcement of central software database without any thought into its utility for us. Ironically, rarely, have there been efforts to learn from successful program leaders as to how they succeeded at WSU and what could one learn from those individuals to help the future young successful clinicians. A "forced" repository of clinical research data base and "taxed" software for every one doing clinical or basic research is doomed to fail as it provides no incentive for successful programs to participate and no support for the "beginners" to participate. This is another example of the "top down" approach. More than half of the successful CTSA institutions don't have such a centralized system.

This perspective holds nuggets of insight but also seeks to dismiss the importance of “top-down” leadership in assuring the coordinated functioning of a set of CORES to support translational science. In successful programs, authority and accountability for performance of these critical core services has rested within the CTSA infrastructure.

4.3.1. Move the critical “Cores” that serve translational science decisively toward centralization to achieve consistency, provide the high quality service to the WSU CTS community, and demonstrate institutional commitment to support the success of the WSU translational scientist

A comprehensive set of Core Services is in place today at WSU. Those Cores that will serve CTS at WSU should become institutional-serving cores as opposed to isolated, protected assets. The incentive to behave differently must come through financial gain through cost-sharing as well as other rewards that recognize the behaviors of a valued, high contributing WSU academic citizen. While the movement toward centralization can be stepwise, the vision and requirement for this future state should be non-negotiable.

This recommendation moves beyond the more cautious or conservative view expressed in the February 2012 Huron Report: “*Wayne State University: Operational Review of Research Administration.*” In its report, Huron noted:

Opportunities at Wayne State exist for improved, proactive management and administrative support of core research facilities. While many institutions have moved toward significant core facility centralization, Wayne State’s culture, needs, and trajectory suggest that the best approach involves development of a coordinating infrastructure that aim to preserve flexibility and entrepreneurship.
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Moving the CTS cores into a centrally governed, albeit networked, wheelhouse is a critical step to provide an assured level of support for the conduct of clinical and translational science. This is the essential infrastructure to become a transformed, nationally competitive operation. There will be resistance by those who believe that – even if their core activity is recognized as an institutional model and brought into the CORES Collaborative – this move will be unnecessarily disruptive.



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Efforts coordinated by the OVPR have advanced WSU-wide core coordination. But a strong CTS program cannot depend on core services at the programmatic level. As recommended by Huron, top down approach to CTS organization and core functions is the foundation for scientific flexibility, growth and entrepreneurship across the system.

The Huron Report provides excellent guidance on: (i) the need for a transparent system where compliant, user-fees support the utilization of the CTS core facilities, (ii) how to assess the University's investment in its core facilities to support these charges, (iii) the value of consistent and enforced metrics for performance, and (iv) the need for expanded capacity in the office of Core Facility Operations in the OVPR.

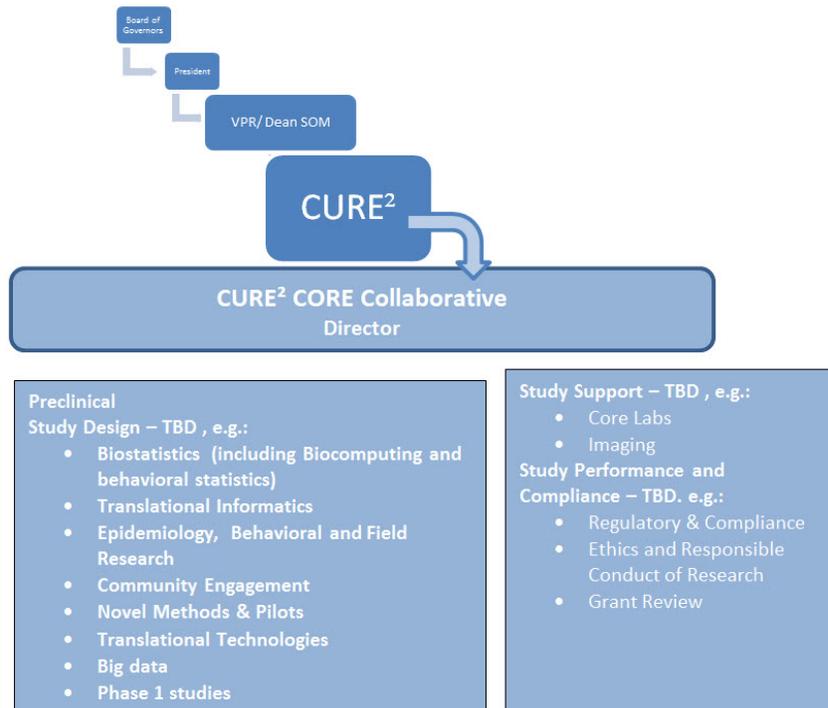
Following the receipt of the Huron Report and several coordination and centralization initiatives led by OVPR, the SOM produced a *Research Strategic Planning Report*, followed one year later by report on *Year 1 "Measures of Success."* Among many actions undertaken, with respect specifically to core facility needs, the following was accomplished:

- Funding and current recruitment of a University-wide director of University Cores and a financial officer dedicated to core funding and pricing
- Expansion of the University Core Committee
- Development of standardized methods of budgeting and establishing cost of core facilities adopting methods developed by KCI
- Development of a consensus definition and list of University Cores
- Movement towards use of common program for accessing and paying for services from University Cores (iLab)
- Hosting a Core Retreat to obtain input from high volume faculty users of cores
- Offer a PAD seminar of University Cores to provide more information to faculty

These reported gains in one year are important and impressive. Building on these gains, this report suggests aligning the clinical and translational science CORES in groupings of: ***Preclinical; Study Design; Study Support; and Study Performance & Compliance.*** This is presented for consideration in the following figure:



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4.3.2. Establish a *CURE² CORES Collaborative* that will be the linked architecture for the critical CTS cores that operate today across internal departments and external affiliates

Given the current state of dispersed functioning of translational science cores across the WSU system, an essential position within the CURE management team will be the Director of CURE² CORES Collaborative – the effort to forge a platform for the integration, shared access, standards and rewards for CTS Cores functioning across the institution. Within the first 18 months of operation, the Director, along with the Director of the CURE² CORES Collaborative, should consider steps such as:

1. Create the networked architecture for the CURE² CORES Collaborative, with a high functioning CURE² Core Collaborative Operating Council, consisting of the leaders of the Cores that come into the Collaborative
2. Create standard terms for participation in the CORES Collaborative
 - a shared systems for transparent, compliant and consistent user-fee arrangements that provide a clear incentive for collaboration and performance, with the provision of fully delineated exceptions where appropriate,
 - the stability of the fee structure during the term of any sponsored research agreement issued dependent on the negotiated fee structure



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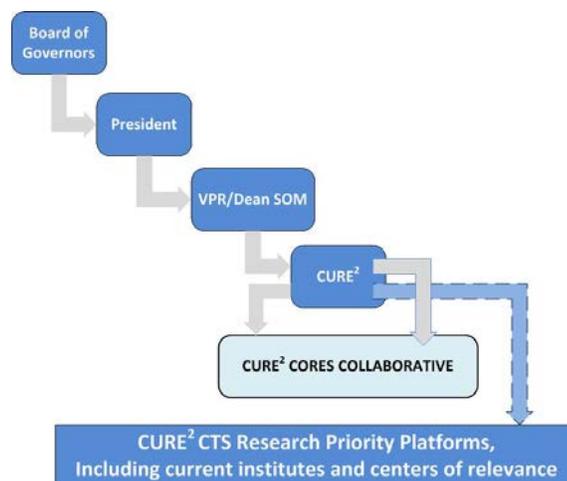
- shared metrics for access and performance
- 3. Consider the value of rewarding early adopters, such as the noted high performing clinical trial data management system within the Department of Neurology
- 4. Secure the commitment from program leaders to bring the key set of CTS cores into the CURE² Core Collaborative
- 5. Consider linkage with CARMA, the Center for Advance Research Methods and Analysis at the Business School
- 6. Drive consistent behaviors, such as:
 - a. Register all Clinical trials in central WSU database (ONCORE)
 - b. Participate in SCI VAL and ResearchConnect!, as a key function of CURE².
- 7. Build and expand the common program for user fees through iLabs
- 8. Create a lower bar for access and use by the young investigator

4.3.3. Develop a mechanisms to move into the CURE² CORES Collaborative those cores that function well today within WSU Regional Affiliates

The Core Collaborative will recognize that, while the majority of CTS Cores will exist within WSU, some may be located within affiliate institutions. Where this is the case, shared access and service arrangements should be formalized through the Master Research Services Agreements that are under negotiation with these regional hospital affiliates.

Any CTS Cores associated with areas of research emphasis that are moved into the MBRB, such as imaging, should immediately become part of the Core Collaborative as part of this institutional emphasis and investment.

4.4. Through the Office of the President, define the Translational Research Priority Platforms that will be the focus for investment, recruitment and cross-institution invigoration and commitment





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Wayne State University expends about \$250 million annually on research. Of that about \$185 million is focused on life science and related fields.²² To leverage this investment and build a successful translational science enterprise, the President is being called upon to identify a core set of thematic areas, where current competencies can be clustered, investment focused, and the ability to compete advanced.

Defining these areas will require the President to weigh the current status of WSU research investment, the recommendations of Battelle, and of this and of other ongoing analyses. Further, the strategy and vision for the investment in these core priority research clusters should be vetted with the Faculty CTS Community and across the WSU leadership. All of this needs to be done in a manner that reserves and conveys the intent of the President to render a final, timely decision on these directions.

Integration with Battelle's Findings

The Battelle report offers critical quantitative assessment of the WSU research assets that stand out from a research success perspective. The publication analysis is a "results-oriented" indicator of research quality and quantity. Although there is a robust debate as to whether higher research funding improves the quality of research,²³ that Wayne State ranks significantly higher in publications than it does in research funding in several fields shows that certain areas of WSU research activity are clearly "punching above their weight."

The Battelle assessment of research competencies generally reflects the findings of the publication cluster analysis. Battelle identifies six research competencies as "top tier" or "upper tier".

"Leaders must become agents of change rather than protectors of the status quo..... The added complexity of aligning an expanding clinical enterprise to educational and research programs also in need of re-engineering create a further challenge for leadersLeaders must therefore rally all the constituents in their institutions around a far-reaching agenda for change."

AAMC Report
Advancing the Academic Health System for the Future.

"We need clear focus from the university re: the research mission and where the university plans to invest its focus/dollars over the next 5 years. For example, numerous random email messages fly around informing the faculty about national RFA e.g. President Obama's Brain initiative. But there is no effort from the university in planning and supporting this initiative or similar other initiatives. This should be priority and requires significant discussion."

²² Life science was \$ 180.7 M and bioengineering \$4.9 M in 2012, per NSF data.

²³ A recent paper found "Impact was generally a decelerating function of funding. Impact per dollar was therefore lower for large grant-holders. This is inconsistent with the hypothesis that larger grants lead to larger discoveries. Further, the impact of researchers who received increases in funding did not predictably increase. We conclude that scientific impact (as reflected by publications) is only weakly limited by funding." Jean-Michel Fortin, David J. Currie, Big Science vs. Little Science: How Scientific Impact Scales with Funding, (June 19, 2013) <http://www.plosone.org/article/info%3Adoi%2F10.1371%2Fjournal.pone.0065263>. See also Bruce Alberts, The End of "Small Science" Science (Sept 28, 2012), <http://www.sciencemag.org/content/337/6102/1583.full>



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1. Reproductive Medicine
2. Cancer Research
3. Cardiovascular Research
4. Basic and Behavioral Neurosciences
5. Psychiatric and Neurological Disorders
6. Child and Adolescent Health

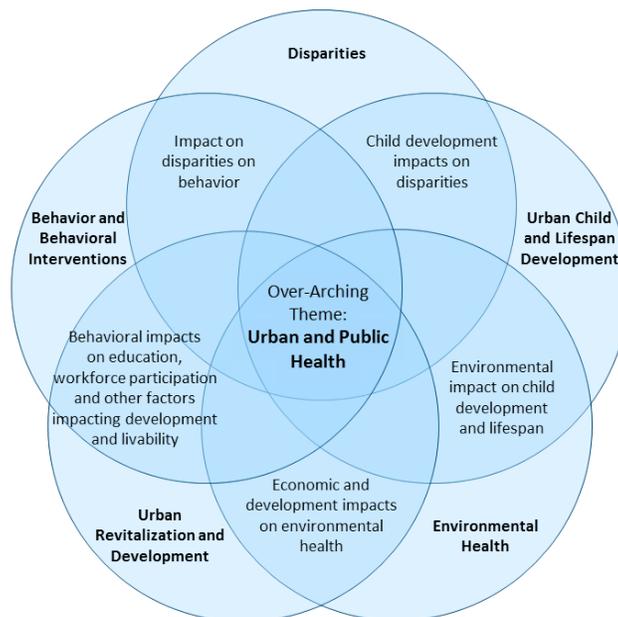
As noted above, Battelle suggests that the potentially strong multi-disciplinary research platforms will lie at the intersection of three elements:

1. Leverage of Wayne State Core Competencies
2. Detroit Metro Challenges and Opportunities
3. Global Challenges and Opportunities

Based upon these elements, Battelle identifies the following Multidisciplinary Research Platforms:

1. Urban Child and Lifespan Development
2. Disparities
3. Environmental Health
4. Behavior and Behavioral Interventions
5. Urban Revitalization and Development

The Battelle Report identifies the convergence of these platforms as the over-arching theme of Urban and Public Health in Figure 4 of its report:





4.4.1. Consider Six Translational Research Priority Platforms

These platforms – urban child and lifespan development, disparities, environmental health, behavior and behavioral interventions, urban revitalization and development – point to, and support the following six translational research priority platforms. The Priority Platforms will become the focus for investment, recruitment and distinction in Community-based Urban Research Excellence and Equity:

- 1. Urban Maternal, Child and Life Span Development**
- 2. Urban Prevalence and Prevention of Cardiovascular Disease**
- 3. Urban Interface of Genes, Environment, Ethnicity and Health**
- 4. Biomedical Engineering in the Urban Clinical and Community**
- 5. Brain Science and Neurological Health in the Urban Environment**
- 6. Cancer**

Some programs of proven strength may not immediately see themselves in these six translational research priority platforms. However, subject to review and potential refinements, these research priority platforms are recommended to define Wayne State’s impressive areas of research strength in urban translational science.

The following factors were used to develop, and should be used to further pressure-test, these recommended translational research priority platforms:

- 1. Objective data criteria**
 - a. Current strength program grant portfolio:
 - i. amount of sponsored research and sources of funding
 - ii. nature of research, from RO1s to training grants
 - b. Program performance within Battelle cluster analysis
 - c. Exhibited scientific excellence of program leadership
- 2. WSU Internal-facing criteria**
 - a. Established synergies with other WSU programs
 - b. Multi- or Trans-discipline nature of the program
 - c. Demonstrated platform for shared research resources
 - d. Recognition of program leader as a WSU “citizen”
 - e. Breadth of mentorship within the program
- 3. Community and external-facing criteria**
 - a. Relevance to Wayne State Community
 - b. Established mechanisms for community engagement
 - c. Assurance that investment can be tied to measurable impact in community
 - d. Assurance that the investment will lead to national distinction in community-based urban research excellence
 - e. Current trends that make the area one of rising community or national significance, as opposed to declining emphasis



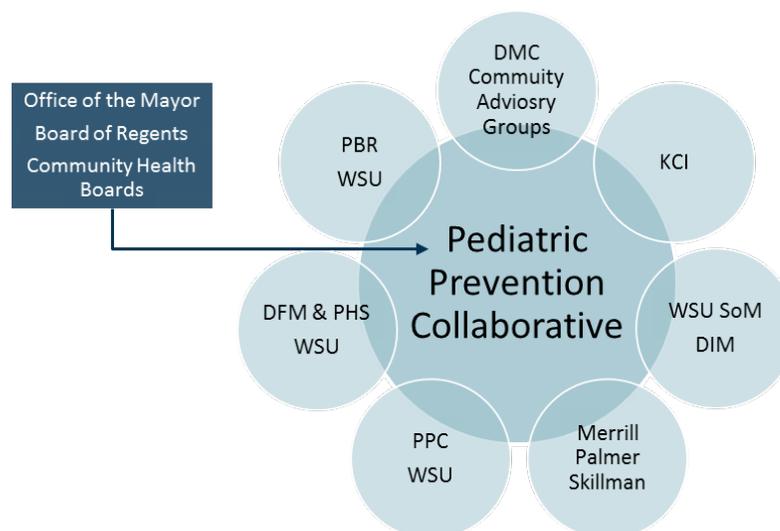
- f. Critical nature of the program to partnerships with community affiliates
- g. Opportunities to attract community-based funding

Each of these proposed areas reflects these criteria, with additional comments noted below.

1. Urban Maternal, Child and Life Span Development

- WSU’s strength in reproductive health and child and maternal health is evident and uniquely broad – spread across a multitude of institutes and programs.
- The strong WSU performance in this area is largely but not exclusively focused within the NICHD Perinatology Research Branch, hosted within the Ob/Gyn facilities at WSU and Detroit Medical Center. In 2013 NICHD/NIH awarded a ten year extension of the PRB at WSU. This is the only NIH intramural program located off of the NIH campus and is a source of distinction for WSU, DMC and Detroit.
- Given that the PRB stands as a separate NIH intramural program, there are obvious limits on mechanisms for collaboration. However, the scientific interchange and research relationships with the NICHD Perinatology Research Branch can and should be better leveraged through this platform.
- CURE² should closely collaborate across the multiple programs that affect child health and human development in the region. This coordinated platform might lead to a more focused formal Collaborative that knits together all of the Maternal, Child and Life Span Development programs to ensure a new level of synergy, performance, and shared ownership of the changes in health impact for children, perhaps the most needy of those within the Detroit community. The current PPC might be the appropriate primary lead to accomplish this larger networked platform.

This program is represented as follows:





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2. Urban Prevalence and Prevention of Cardiovascular Disease

- WSU has already demonstrated its focus and commitment to CTS cardiovascular research by establishing the Cardiovascular Research Institute (CVRI), with a strong track record of basic and clinical research. As a strong proponent for collaborative research in an area key to the Detroit urban community, the CVRI and cardiovascular research should be a central focus of CURE².

3. Urban Interface of Genes, Environment, Ethnicity and Health

- Environmental and urban population health is a tremendous potential and actual strength and distinguishing characteristic of CTS at WSU. The WSU Center for Urban Responses to Environmental Stressors (CURES) has been selected by NIH for P30 EHS Core Center funding.
- This focus comports with the Battelle findings and with an overall growing research-funder interest in genetic components of health, health disparities, disease causation and treatment efficacy.

4. Biomedical engineering in the urban clinic and community setting

- The NCATS CTSA Working Group Report reminds that “translational science must evolve from the sequential to the parallel; from linear to bidirectional; from single discipline to multidiscipline; from single institutions to collaborative, integrated networks of institutions.”
- WSU, with its Detroit history and departmental strengths, has significant bioengineering competencies. Many concur that a new means of direct engagement among the bioengineering and SOM faculty should be part of WSU translational research emphasis.
- Placing the biomedical engineering program in the MBRB will provide an opportunity to catalyze this new translation research priority platform through the CURE² Institute, assuring an ability to bring observations in the clinic and in the community – driven by patient/ user-engagement from the inception of research design – into the lab.
- This vision is consistent with Battelle’s discussion on the growth in use-inspired research.

5. Brain science and Neurological Health in the Urban Environment

- Brain science and neurological health was unambiguously identified by Battelle as a significant research strength at WSU, with a broad spectrum of success in basic and clinical research, as well as a major engagement with new translational challenges such as traumatic brain injuries.
- Not only is this a strong research area for WSU, but it is a growing focus for sponsored research in programs such as, e.g., the “big science” BRAIN initiative and the VA funding on TBI and its sequelae.



6. Cancer

- Cancer research is an important translational emphasis and is tied to the research focus at KCI and the clinical delivery focus at HFHS.
- Regardless of the political shifts in the relationship with KCI, scientific integration will always be critical to the translational scientist at WSU and to the conduct of community-based cancer research in a region where disparities across many forms of cancer persist at an alarming rate.
- NCATS wants to see that cores, data, and platforms funded by NIH in large comprehensive cancer programs are not re-invented, duplicated and paid for twice. The role of KCI in this Cancer translational research priority platform, in the CORES Collaborative, and in supporting the programs across the CURE² Institute will be important to assure the visible optimization of institutional resources.

4.5. Identify a Suite of Urban Translational Research Competencies

As suggested in the *Community-focused Approach to Research and Graduate Training: Improving Health through discovery and Service*, prepared by the WSU SOM in the Summer of 2013, the multidimensional construct for translational science integrates across the Translational Research Priority Platforms areas of competence in urban translation science. Building on the Battelle report and interviews, these applied competencies might include:

- Molecular Genomics and Epi-genetics
- Community Engagement
- Behavior and Behavioral Health
- Diagnostic and Theragnostic Imaging
- Implementation Science
- Immunology
- Health monitoring technologies
- Epidemiologic, public and population health

4.6. Build a multi-dimensional construct for the integrations of the Research Priority Platforms, the CORES, and the suite of key urban research competencies that span T1 to T4.

Community-based Urban Research Excellence and Equity
A Multi-dimensional Model of Integration, Dependency and Synergy





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The Report, *Community-focused Approach to Research and Graduate Training: Improving Health through discovery and Service*, prepared by the WSU SOM in the Summer of 2013, calls for multi-dimensional “Rubik’s Cube” view of WSU’s translational research platform. In the same way that that report works with the “X,” “Y” and “Z” axis of this multi-dimensional paradigm, the (i) CORES, (ii) Translational Research Priority Platforms, and (ii) suite of competencies that drive urban research excellence should be viewed as the required dimensional platform to support a higher level of performance in research excellence and community health impact.

Decision Path Forward

Wayne State University has a culture which gives high value to analysis and internal review. Although members of the WSU research community may not unanimously agree or disagree with specific recommendations in this or the several other ongoing analyses of various aspects of the University’s research activities, a fair, informed but expedited decision-making process should define and implement specific steps to build a unified CTS platform.

Section 4.10 below presents the concept for a President’s *CURE*² Institute Working Group to provide input on all areas that will form the center pieces for this new translational research platform.

4.7. Develop conceptual framework for significant new programs or Centers within the *CURE*² Institute

4.7.1. Consider a Center for Urban Community Engagement and Research Partnership

This Center would build on multiple strengths in community engagement across WSU, including the practice-based research network of family medicine practices (MetroNet). It would:

- tether under-graduate and graduate students in social and behavioral sciences to clinical and translational investigators to study, engage, design, test and publish on methods and means of community engagement in research among members of urban populations defined by their health disparities
- train, with the eye toward potentially incubating a nonprofit enterprise, undergraduate and graduate students – possibly deploying gender, ethnic and racial matching – to become translational science interviewers and research participant recruiters across Detroit’s diverse and under-served communities
- have a focus on understanding risk – perceived and real – posed both to individuals and communities as a result of community-based research and participation
- include the CTS program practicum on: *Recognizing, engaging the community from the inception of research design and hypothesis formation across the full continuum of urban translational science; Creating new community-driven*



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inputs on linkages among the environment, genes, ethnicity and health outcomes in the urban setting.

As presented to us by an impressive faculty leader, this concept has the potential to address the following needs:

[WSU had] organized a community advisory board that worked with a number of projects at Wayne State, notably the practice based research network of family med practices (MetroNet) and this is still ongoing. I would say community engagement at multiple levels and across many units of the university is a strength of WSU. How could this enhance a CTSA? I had an idea many years back that I have not been able to bring to fruition but might fit here.

...In my work, I have always hired staff and interviewers from the community, usually race and gender matched, due to the nature of the questions on racism, stress, and environment. I would like to see the university consider "incubating" or "coaching" the creation of a nonprofit research business in Detroit that WSU would help with initial training of the employees on interviewing skills, biospecimen collection, data systems, etc. This could also involve our students.... In turn, WSU and perhaps our University Research Corridor partners (UM, MSU, etc.) might pledge to utilize their services for a certain percentage of projects to get it up and running.

We bring so much money (not enough!) from NIH, etc., to study issues in the community but much of it doesn't directly and immediately impact the community. I realize this may be a long term investment but I think it would pay dividends in enhancing our recruitment, improving our ability to recruit in the neighborhoods and not just in the clinics, insight into research questions, etc. ... These are the sorts of approaches I think WSU should be considering if they want a role in CTSA. Thanks again for listening!²⁴

Developing a Center focused on Urban Community Engagement in Research would speak to many remaining unmet needs that are the focus of national attention. As recently as April 2014, Ann Bonham, AAMC Chief Scientific Officer, made the following points at an FDA meeting focused on inclusion in clinical trials:

"The AAMC's specific recommendation fall into two categories: 1. Targeting clinical trial enrollment of populations who are hardest hit by health disparities and incentivizing study designs that plan for robust subgroup analysis for these populations; and 2. Subsequent communication and dissemination of relevant information to those who will most benefit.

The regulatory and research community recognize that recruitment is not the first step, but rather that building and sustaining trust with the communities is the first step. "The boom-bust engagement with communities linked to funding will undermine developing effective partnership for minority groups to benefit from discoveries.

²⁴ Dawn Misra, email December 11, 2013



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Increasing the participation and sense of belonging to a broadly defined health and research-ready community will require providing incentives, expectation and resources for engaging and learning from communities to build ties and trust.”

Recruiting a diverse group of research subjects is a good step, but in and of itself will not be sufficient to close the disparity gaps; participants in research must also have access to the information generated by the research through appropriate evidence-based dissemination strategies.” “Literature shows that minority communities willingly engage in research when results are shared back with their communities.”²⁵

The AAMC, in its Letter to NCATS responding to the request for comments on the CTSA program,²⁶ notes:

“Regulatory and community engagement stakeholders should partner to address some of the inherent regulatory challenges with community-engaged research. ... Many IRBs are unfamiliar with the process of engaging communities and many IRB policies are not interpreted to allow this review body to approve research developed through an iterative process. In addition, while IRBs members focus their work on protections of and risk analysis for individual human subjects, they are not as familiar with the potential risks and benefits facing communities who are engaged in research. The AAMC has been working with member institutions to identify best practices for IRB review of research involving communities and is developing a set of case studies addressing these issues.”

This Center would anticipate the heightened focus on the science of community engagement, a topic certain to be included in the 2015 CTSA RFP developed in response to the NCATS CTSA Working Group Report. The NCATS CTSA Working Group Report is replete with observations, goals and objectives for new methods and processes, and systems to ‘identify and effectively engage relevant and diverse stakeholders across the translation spectrum.” The NCATS Report recognizes what is understood within many of the exceptional programs today at WSU and is ready to be marshalled into the focus of a cohesive nationally recognized Center:

- *“The current system (structure, hierarchy) is not built for the science of engagement. Rather, engagement is viewed as a service to the community instead of a part of the research activity.”*
- *“The current structure facilitates grant-initiated research; the grant recipient calls the shots and little is generated by the community.”*
- *“The practice of community engagement in translational science is often limited to community outreach for recruitment of study participants, particularly minority populations. “*

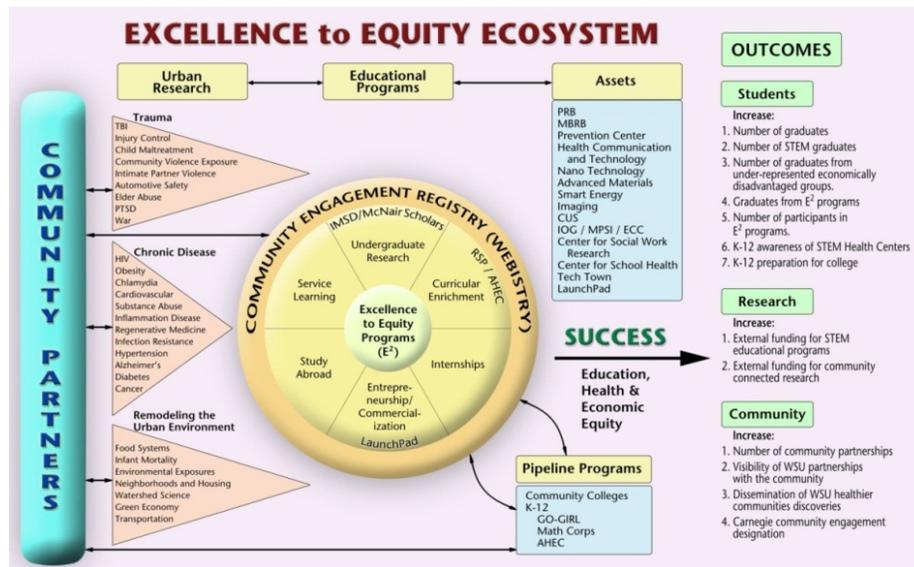
²⁵ April 1, 2014 Ann Bonham PhD. AAMC. FD, Presentation on inclusion. White Oak Campus <https://www.aamc.org/download/375790/data/preparedremarksofdr.annbonhamaamctofdaonengagementandinclusion-.pdf>

²⁶ *Request for Information: Enhancing Community engaged research through the Clinical and Translational Science Awards Program*, November 14 2012



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The focus of this Center may directly align with the platform proposed by the VPR to the Kresge Foundation for the Excellence to Equity Ecosystem:



Finally, elements of a program such as that conducted at Columbia University through its **Center for Evidence-Based Practice in the Underserved, funded by the National Institute for Nursing Research**, may be instructive.²⁷

4.7.2. Consider forming a Center for Urban Medicine and Population Health within the SOM

A CURE² Center could become the central hub for the Masters in Public Health Program. The DRAFT (2- 27-14) Report, *The Future of Public Health in Detroit: The Henry Ford Health System/Wayne State University Public Health Collaboration* presents a vibrant and impressive array of assets across the two institutions. The Report calls for a cross institution collaboration that would be reflected in this Center and posits four central facts, summarized as:

"... Our current MPH program is significantly understaffed and lacks much in terms of resources. It is difficult to mount (any) new program with the same group that is struggling to keep the MPH going."

1. *The combined institutional strengths produce a synergy that exceeds the sum of the individual strengths*
2. *Combined and increased disciplines and resources (epidemiology, biostatistics, health administration, environmental health and social/behavioral health) will enhance effectiveness across multiple disciplines*

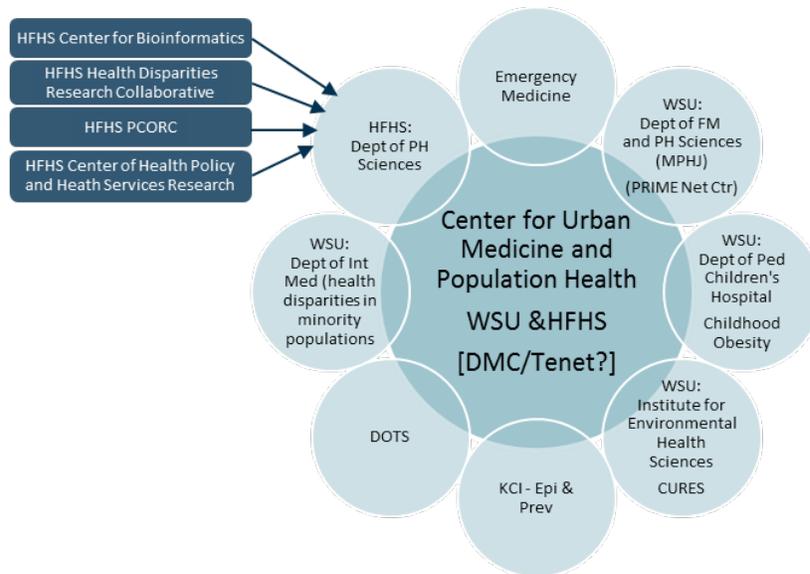
²⁷ <http://www.cumc.columbia.edu/dept/nursing/ebp/>



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3. Detroit will benefit dramatically from the cross-institution partnership which will provide a major laboratory for urban health improvement, valuable nationally
4. The partnership will substantially increase competitiveness for both institutions.

The figure below presents one view of the assets that could be coordinated through this Center.



There is considerable and diverse opinion on the formation of a WSU School of Public Health. The approach taken recently at Northwestern reflects the future state for the convergence of clinical medicine and public health. Northwestern University (NWU) within this past year formed the Institute for Public Health and Medicine (IPHAM), positioned within the Feinberg School of Medicine.

The stated goal of the IPHAM is to accelerate innovation at the interface of medicine and public health and achieve measurable improvements in health for patients and populations. The integration of medicine and public health assures that these otherwise separate disciplines work together, not as siloed departments. This is reflective of the national emphasis on the intersection of clinical care and public health and is central to implementation science.

NWU took assets it possessed across the SOM and brought these under a central unified structure to assure the use and optimization of shared resources and new synergies between medicine and public health – all critical to success in today's environment. IPHAM includes the following Centers:



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Centers

Behavior and Health

Buehler Center on Aging, Health and Society

Community Health

Engineering and Health

Global Health

Healthcare Studies

Patient Centered Outcomes

Population Health Sciences

Significantly, Northwestern elected to move a larger percentage of the institution's indirect costs recovery from the departments into the office of the Dean in order to provide resources to support the new center. **(For more details on IPHAM, see ADDENDUM D.)**

This convergence of clinical medicine and public health is a movement that will not turn back. (See **ADDENDUM E** for an expanded discussion of this emerging intersection between public health and clinical medicine.) This convergence responds to the pressures on accountable care organizations (ACOs) to work in new ways with the community where the practical impact of clinical decisions plays out in real populations with a real effect on the bottom line of an organization seeking to demonstrate shared savings with CMS. Today, patient compliance, adherence and post-acute coordinated care— concerns that the hospital clinician used to pass along to the primary care setting once a patient was discharged – are understood as directly linked to new incentives to decrease readmission rates and increase shared system-wide savings. The “accountable care community” is the new focus for each of the hospital systems with which WSU works. This shift toward community health provides an opportunity for shared value with Tenet and McLaren. Establishing new alignments with affiliated healthcare systems to structure an accountable care community would be an objective for the new Center.

WSU is well-positioned to consider how it might design its translational science program to embrace this emerging trend. Again, not being hampered by the prior positioning of a School of Public Health provides the latitude needed to consider this strategy.

4.8. Focus training and career development on the Urban Translational Scientist

Education in clinical and translational Science spans Schools of Medicine, Nursing, Dental, Pharmacy and other Graduate Schools. It reaches into undergraduate fields of relevance across the hard sciences, social sciences, and language arts. It reaches into the community and can touch K – 12 students who are challenged to see their opportunity to stay, learn and improve the health and lives in their communities.



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As the NCATS CTSA Working Group report states,

“Educational opportunities must be provided to all members of the team to advance translational science goals. ... In addition to sustaining and building on graduate and postdoctoral education, further work is necessary to expand training and continuing education opportunities for faculty, professional staff and community partners.”

That WSU is already thinking in this direction is underscored by the Graduate School Dean Mathur’s success in achieving one of ten NIH Broadening Experiences in Scientific Training (BEST) awards to promote training of research professionals.

“Nurturing trailblazers

Education and training is a major focus of the CTSA network, which spends an estimated \$50 million or so on trainee stipends annually. Typically, CTSAs have an institutional career-development (K award) program that provides 2 or 3 years of career-development support to young investigators. Although several innovative programs are emerging to train a new cadre of investigators skilled in the entrepreneurial, business, pharmacometrics, or biomedical device arenas (4, 5), the majority of K awardees have been young investigators whose metrics of success were obtaining an individual K or R grant from another agency (typically an NIH IC) and who have moved on to become independent investigators with “traditional” academic careers. Thus, a substantial fraction of the CTSA investment ends up providing an extension of the typical 5-year career-development runway from which to launch junior faculty on traditional research careers, instead of creating pioneers who will forge new paths to address translational research challenges. One solution may be to set aside a portion of the CTSA training funds to supporting faculty “trailblazers” with K or R awards who have established independent research to pursue new paths for translating their discoveries toward product development or implementation.”

(Anantha Sheker, Science Translational Medicine)

As discussed in Section 4.7 below, the University may want to consider steps to re-shape the School of Medicine’s curriculum to better comport with the conduct of 21st Century science. However, except for general observations presented below, this topic requires a separate thorough analysis. **What is within the purview of this report is to assure that training a new cadre of high-caliber urban translational scientists becomes a defining core focus of the CURE² Institute.**

Training the Clinician Scientist

Training and having a phalanx of MD/PhD investigators is of obvious importance. Expert analysis has already been conducted on issues related to the CTS training opportunities at WSU. In their report “Wayne State University MD-PHD Program External Advisory Visit; Robin Lorenz, Director UAB MSTP and David Engman Director Emeritus, Northwestern MSTP, suggest the need for expanded admissions, greater administrative support, better availability of mentors and new levels for rigor (publication requirements and the requirement for advance course work in the specific areas of scientific interest) and consistency across the PhD programs that a MD PhD candidate might chose:



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In order to achieve these ‘common’ requirements, either the individual PhD Programs can agree that the MD-PhD students will have more strict requirements than some of the PhD students, or an umbrella interdisciplinary biomedical PhD program based on research themes can be instituted. This type of program was recently instituted at AUB specifically to address uneven requirements across the departmental PhD Program and to better train students for the interdisciplinary research of the future. (Emphasis supplied)

Further the report concludes: “there is a conspicuous shortage of underrepresented minority students, particularly given the relatively large number in the medical school.” A Pipeline Program, established through the CURE² Institute, is one step in addressing this problem.

4.8.1. Evolve the current Certificate in Clinical and Translational Sciences into a Master of Translational Sciences

Today, the WSU Bridge Certificate in Clinical and Translational Science is designed to train MD/PhD Students in the key elements of clinical and translational science. The curriculum for this certificate includes courses in “biostatistics; epidemiology; development of novel clinical and translational methodologies; designing and implementing clinical trials and clinical research; understanding the clinical presentation, diagnosis, management and treatment of patients in the context of cutting edge research methodologies; adhering to federal regulatory and ethical requirements in conducting clinical and scientific research; and preparing, writing and submitting competitive fellowship and grant applications to national and federal peer-reviewed funding agencies; as well as performing research.”

“We need to teach graduate students how to work in teams. Today, WSU offers a graduate Certificate in CTS not a PhD or a Masters. WSU does have a Master of Research.”

Suggestions presented in the Report from May 2013 *Graduate Programs: Proposed Actions* include

- *Expand the IBS core curriculum to include competencies including biostatistics, research methodology grant writing, etc.*
- *Inventory courses in all departments for inclusion in a revised core curriculum, e.g. grant writing, systems biology) and regroup these courses into research themes*
- *Enable “opt-out” of IBS core curriculum for those with intensive prior training or for those enrolled in programs not requiring this curriculum.*

The Bridge Certificate in Clinical and Translational Science requires 15 credits in the required didactic courses, which hours can be combined with 15 credits of research (not dissertation) to obtain an optional Master’s of Science in Medical Research degree.

WSU has an opportunity to elevate the training of the Urban Translational Scientist from a Certificate to a Master’s degree in Clinical and Translational Science. This program would include, as an example, a minimum of 30 credit hours of didactic work, of which 4 – 6 credit hours are



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thesis/publishable paper research hours with a focus on a question of significance to urban translational science. This Masters level degree opportunity is consistent with the vision of the NCATS CTSA Working Group Report that includes as a measurable objective for the CTSA program to have degree programs in translation science widely available and to have Certificate programs in sub-disciplines of translational science also available.

As a final analogue, WSU might note the training programs at UCSF: *Translating Evidence into Practice, Policy and Public Health*. UCSF offers both a Certificate Program and Master's Degree in Implementation Science. These programs are defined as:

Certificate Program in Implementation Science

A one-year, part-time program offering a series of courses focused on applied methods of implementation, particularly as they relate to developing more effective interventions. Ideal for people with a master's degree in public health or clinical research, or the equivalent, and who are currently engaged in the development, implementation, and evaluation of health-related programs.

Master's Degree Program in Clinical Research, Implementation Science Track

A rigorous, two-year course of study intended for advanced pre-doctoral fellows, post-doctoral fellows, and faculty members who wish to master clinical research methods and pursue independent research careers. Implementation science track scholars take most of the same -courses as those required for the standard Master's program, in addition to a series of implementation-specific electives.

4.8.2. Consider including in the Clinical and Translational Science Program a number of courses that will recognize and study the unique aspects of the science of translational science in the urban environment

Through the CURE² Institute, training of the urban clinical and translational scientists could include a range of programs or courses that recognize and address issues unique to CTS in the urban environment. Examples might include:

- Defining and Exploring the Science of Urban Translational Science
- Knowledge, Translation and Dissemination in Urban Implementation Sciences, covering the main theories of translational science, with a special focus on the challenges to urban health care delivery, uptake of evidence-based interventions in the context of health system transformations moving from volume to value
- Cultural and community sensitivity for the urban clinician scientist; unique applications of Ethics and the Responsible Conduct of Research among Detroit minority, ethnically diverse patients and communities
- Recognizing, engaging the community in the full continuum of urban translational science, and creating new community-driven hypothesis on the



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linkages among the environment, genes, ethnicity and health outcomes in the urban setting

In this regard, the NCATS CTSA Working Group report notes that:

“There is a need for extensive integration with collaborators outside academic institutions. There are a host of individual, teams and network of volunteers (citizen scientists) who are eager to help. These stakeholders provide unique and valuable viewpoints - regardless of whether those individual are patients or members of foundation, community programs, governmental agencies, community health practices, non-profit organizations or other entities.” (Page 7)

- Recruiting, mentoring and retaining the urban translational scientist:
 - understanding the stressors in the community and the transference and reflections of these stressors on the urban translational science and clinician
 - creating and assuring personal satisfaction and career continuity, with focus on high risk inflection points in the career of the urban clinical and translational scientist
- Creating a Pipeline Project for under-represented minority clinical and translational scientists, bringing undergraduate students into the urban CTS laboratory, enhancing the applicant pool for the pre-doctoral programs
- Designing a comprehensive multi-day seminar that enhances the leadership and performance of effective team-based translational research studies, including the incorporation of new mechanisms for tracking contributions across a range of functions and team members

Team Science



AAMC



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The need for team science to conduct CTS — and the concomitant need to recognize leadership and competence in the performance of team-based science in promotion and tenure reviews — has been the subject of considerable discussion over the past five years. The AAMC has stated a number of views on this need and challenge.

October 7, 2011. *Recommendation to NIH Workforce Training Group: “Promote training programs with team-based focus, and encourage interdisciplinary training and collaborations. Set programmatic and funding priorities for trans-disciplinary programs overcoming organizational or mission boundaries and target programs to span extramural boundaries — across colleges and universities, etc.”²⁸*

December 2012: *“Basic scientists are the foundation of the biomedical research enterprise.... Unfortunately, at many institutions the training research and funding environments do not encourage basic science investigators to participate in translational science...”*

“Research institutionsshould examine their appointment, tenure and promotion policies to ensure that basic scientists — indeed all scientists—who make valuable contributions to translational, team-based and interdisciplinary research are recognized and rewarded for their contributions.”²⁹

“The health needs of the nation call for a generation of scientists trained in ‘interdisciplinary, transformative translational research’ and in the leadership and team skills to engage in effective collaborative partnerships.”

*IOM Report on CTSA program,
page 5*

January 2013: *“In the past decade, the National Institutes of Health (NIH), several medical schools and teaching hospitals, and private organizations have emphasized team-based science. According to the 2010 NIH report Collaboration and Team Science: A Field Guide, team science is becoming the “primary mode” of research for many scientists and physicians. ...*

According to the AAMC Curriculum Inventory and Reports, in 2007, fewer than half of medical schools had required or elective courses in translational research, which embodies team-based learning and science. By 2012, that percentage had increased dramatically, with 85 percent of medical schools requiring a course in translational research and 50 percent offering elective courses. ...

But as more students begin their careers prepared for team-based work, the promotion and tenure policies at many institutions continue to focus primarily on individualized accomplishments. Some medical schools and teaching hospitals have revised their promotion and tenure policies to reflect the increase in collaborative science. According

²⁸ AAMC letter to NIH: Request for Information to the Work Force Working Group, NOT-OD-11-106.

²⁹ AAMC Reporter: Viewpoint: The challenge of Engaging Basic Scientists in Translational Research. Judith S. Bond, PhD, President FASEB; RA Galbraith, Professor of Medicine, Director of the Center for Clinical and Translational Science, University of Vermont College of Medicine.



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to preliminary results from the AAMC's 2012 Faculty Personnel Policies Survey, about 27 percent of institutions responding to the survey have made changes to their promotion and tenure policies to include an emphasis on interdisciplinary team science in the past four years. In addition, 15 percent of responding institutions reported having such a change under active consideration.³⁰

4.8.3. Create a system that engenders respect for the translational science career path and recognizes high performance in team science in promotion and tenure review.

In considering how to execute on this recommendation examples from other institutions may be informative. At the University of Florida College of Medicine, the promotion and tenure committee recently started looking at how to revise its guidelines to fit in with a broader definition of scholarship—one that may allow flexibility for team-based work. The Director of the Clinical and Translational Science Doctorate program reflected: *"It is happening, but I think it's very slow," ... "It might be one of those things that will take a top-down approach. I know there is a lot of faculty interest."*

The traditional benchmarks for academic promotion and advancement – public, peer-reviewed research funding and teaching – need to be revised and harmonized with new benchmarks that value team-based efforts and collaborative approaches to translational science. Success in translational science will require multidisciplinary and in many cases, multi-organizational teams.

NCATS CTSA Working Group Report, page 4

At Jefferson Medical College, the Office of Faculty Affairs established an award for team-based collaboration, incorporated language that "values" team-based science into its promotion and tenure policy, and revised its reward system to recognize team contributions. Leadership noted the difficulty in shifting a system that rewards faculty on largely individualized accomplishments to one that values contributions to team discoveries. "Faculty who have a mixed portfolio of individualized and team work will be easier to evaluate than faculty who focus exclusively on team work."

At the Medical University of South Carolina (MUSC), faculty members on a research track have different promotion and tenure criteria than those on a clinical track. When research faculty at MUSC apply for promotion or tenure, in addition to a faculty member's publications and presentations, the committee considers the individual's contributions to team-based science and whether he or she led or initiated a team-based project.³¹

³⁰ Team Based Science Increases, but Promotion and Tenure Policies Lag Behind. AAMC reporter: January 2013. Sarah Mann. <https://www.aamc.org/newsroom/reporter/jan2013/325940/team-based-science.html>

³¹ S. Mann. AAMC. Team-based Science. <https://www.aamc.org/newsroom/reporter/jan2013/325940/team-based-science.html>



4.9. By 2015 bring a competitive revenue stream into the Office of the Dean and/or Institute to support development of strategic programmatic development and recruitment

As discussed in Section 4.10 below, the President should form a President's CURE² Institute Working Group to advise on the launch of an integrated CTS architecture at WSU. This Working Group will be especially critical to advise and support the organization through the politically charged waters that must be navigated to move funds into the office of the Dean of SOM and/or into the CURE² Institute to support this new architecture. As a bottom line: **Greater consolidated authority with the power of the purse will be needed to focus, recruit, build and distinguish this new translational research emphasis at Wayne State.**

Interviews with faculty and administration, coupled with analyses prepared internally, paint this picture: The SOM has endured \$11 M of cuts to the general fund from 2011 to 2014.³² There remains a perception that the physician practice plan will cover the finances of the SOM and can support the cuts. While this shifting of costs to the practice plan – by increased support to the Fund for Medical Research and Education (FMRE) – has been possible in previous years, it appears not to be working in the current environment. Reduced Medicaid Enhance Payments and the eroding hospital support for residency and clinical programs contribute to this bind.³³

Many are discussing the need for an overhaul of the current system. Notably, Bruce Alberts, Harold Varmus, Marc Kirshner and Shirley Tilghman have co-authored an article appearing in the current edition of PNAS, entitled, *Rescuing US biomedical research from its systemic flaws*. The premise for this article is stated as:

The long-held but erroneous assumption of never-ending rapid growth in biomedical science has created an unsustainable hypercompetitive system that is discouraging even the most outstanding prospective students from entering our profession—and making it difficult for seasoned investigators to produce their best work. This is a recipe for long-term decline, and the problems cannot be solved with simplistic approaches. Instead, it is time to confront the dangers at hand and rethink some fundamental features of the US biomedical research ecosystem.”³⁴

Relevant to this discussion, the authors unpeel the growing reliance on indirects and offer strong criticism:

The assumption that the biomedical research enterprise will expand continuously at a high rate has powerfully motivated the behavior of large academic medical centers (7–9). Salaries paid by grants are subject to indirect cost reimbursement, creating a strong incentive for universities to enlarge their faculties by seeking as much faculty salary support as possible on government grants. This has led to an enormous growth in “soft money” positions, with stagnation in the ranks of faculty who have institutional support. The government is also

³² 2013 Report to the President by the Dean of the School of Medicine

³³ The sequelae from this shrinking revenue base are delineated in the 2013 Report prepared by the Dean of the School of Medicine. Her observations are consistent with the challenges outlined in this report.

³⁴ <http://www.pnas.org/content/111/16/5773>



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indirectly paying for the new buildings to house these scientists by allowing debt service on new construction to be included in its calculations of indirect cost recovery. These are perverse incentives because they encourage grantee institutions to grow without making sufficient investments in their own faculty and facilities. As a result, thousands of US faculty members now compete intensely not only for research funds but also for their own salaries within a shrinking pool of dollars.

In her 2013 Report to the President, Dean Parisi references an NSF study that examines how other institutions are responding to the national downward trends in national funding for biomedical research and points to the comparative rise investments being made directly by many institutions. This NSF report illustrates that while R&D expenditures across higher education remained flat in 2012, nongovernmental funding sources showed increases between 2011 and 2012. Of these non-governmental sources, *“Institution-funded R&D – including institutionally financed research, cost sharing on sponsored research, and unrecovered indirect costs on sponsored research – showed the most significant growth across sectors.”* As she notes, the reverse has been the case at WSU.

This funding gap must be tackled.

As a first step in meeting this challenge, the various funding sources that may be in play should be confirmed. These sources, as described in interviews, include:

- **Salary support:** Consider increasing salary support recovered from grants, moving from 11% salary support “tax” to closer to the national norm at 50%.
- **Indirect Costs (ICDs):** Consider a bold move analogous to that taken at Northwestern to move a greater portion of the indirects into the office of the dean (or into the Institute) for support retention and recruitment across the translational research priority clusters.
- **IGTs:** Intergovernmental transfers (IGTs) for Medicaid population. With respect to IGTs:
 - IGTs come through the University Physicians Group (UPG) Practice Plans. These have dropped from \$15M to 8M in 2.5 years.
 - There is a sense that some departments are favored by UPG while others are “punished.” Pediatrics has its own Practice Plan. All other departments are part of a single Practice Plan at UPG. The health of the various practice plans seems to vary widely.
 - There is a perceived opportunity with Tenet to “redesign the relationship and integrate the plans into a system with WSU that returns greater dollars into the clinical enterprise.”

Tenet leadership advises that an emphasis on clinical research to improve the health in urban populations is very important to Tenet. There is potential interest in Tenet becoming a recognized leader and corporate citizen in this realm.



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Preliminary conversations with leaders within the Tenet system outside of Detroit confirm that discussions with leadership at DMC should be pursued as part of advancing CTS at WSU.

- **FMRE:** The Fund for Medical Research and Education (FMRE) (or a “Dean’s tax”), today, goes to the individual department rather than to the school, where it could be used centrally.
- **RVUs:** Relative Value Units: Tenet pays RVUs based on clinical revenues produced by WSU faculty physicians. Tenet incentive compensation plans will be based on productivity as measured by RVUs.

A range of opinions inform whether and how to re-allocate scarce revenues to support a new focus and investment in translational science. The full flavor of these opinions is included below in a series of direct observations for the WSU Department Chairs:

- *We must have financial stability to attract and recruit. We can generate ideas and data, but with no dollars for collaboration it goes nowhere.*
- *We can generate ideas and data but there are no dollars to support collaboration.*
- *We need to look at how the departments are configured. We need the ability to leverage clinical dollars between departments. The day is here to break the departmental walls. As an example, we need a cross institution bio-repository. We can’t expect a department that is struggling to produce clinical income to shoulder alone the costs of developing this needed resource.*
- *We can’t become competitive in clinical research when our people have only 10 to 15% of their time to conduct research. Today the person whose time is 100% in the clinic and the person who divides his/her time 50/50 between the clinic and research are not viewed as equals.*
- *We need to recruit mid-level faculty with funding as they will serve as magnets*
- *Research needs require vision from the top – without clear vision from the top, may be harder for basic science departments to participate in clinical-translational science.*

The Associate Deans for Research saw the problem through this lens:

- *The SOM has a small operating budget. Dollars for medical research and education from clinical dollars: a 9 % tax on clinical revenues, with 6 % going to the Department and 3% going to the Dean.*
- *With philanthropic dollars, there is a big variation at the department level. The Pediatric Department enjoys a funding line through the Children’s’ Hospital Foundation that supports fellow and trainees, preliminary research, grant administration and IRB submissions.*
- *Regarding indirects, 40 % come to the school, with the Dean, Depart Chair and the PI each taking 1/3.*
- *We recognize that the Practice Plan does not fund research.*



Other observation:

- *Chairs can be the real obstacles to getting work done. Chairs must see this as in their interest.*

These conversations confirm the challenge and the pressing need to examine sources for enhanced financial support for the *CURE² Institute* and to assert leadership in ultimately assuring that modest but essential revenues are brought forward into the Institute in order for the larger enterprise to take shape and thrive.

FaegreBD will be pleased to discuss this challenge in even greater detail following receipt of this report.

4.10. Consider Examples of Restructured Schools of Medicine, but accept incremental, step-wise change

As noted in the 2012 School of Medicine Research Strategic Planning Report, *“The current departmental structure of the basic science departments should be re-evaluated to determine if it best compliments research initiatives and support educational objectives.”*

Again, there exists a range of opinions:

- *“The structure of basic science research in the SOM is based on the 1970-1990’s model of research in wet bench labs.”*
- *“Today, research should be responsive to the community WSU is living in. The community must be viewed as a template for our research enterprise. Achieving this future state is highly dependent on how we reorganize our departmental structure. Today we have a traditional, rigid structure that encourages the PI as the driver of research. We need to make changes that allow us to look at translational disciplines and contemporary science.” (Senior Administration. Department of Pediatrics)*
- *“We need fluid thematic approach versus the traditional departmental structure. This takes strong political will.”*

The Assessment of Graduate Programs and Proposed Actions, produced in May 2013, suggested the combination of molecular and cellular biology and the introduction of a systems biology course. Success of the focus on systems biology at an institution such as Harvard, where an entire department was formed in 2003 to respond to the growing understanding of the complexity of disease pathways and mechanisms and the lack of the current tools to respond to this understanding, has been recognized widely:

This complexity is forcing biologists to turn to the intellectual tools of other disciplines, such as physics, mathematics, and computational science. Harvard Medical School's bold step was to create a full Department of Systems Biology—the first in the world—within the intense biomedical research environment of the Longwood Medical Area. Thanks to initial



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*key hires of outstanding theoreticians with a genuine commitment to biomedical research, the department has become a magnet for the very best young researchers in this area, and the related field of synthetic biology. The department's alumni, students and post-doctoral fellows who trained in the department, are now leading the development of systems biology and synthetic biology across the globe.*³⁵ (See **ADDENDUM F** for more detail on the program at Harvard.)

The University of Rochester Medical Center, in its 2007 – 2012 Strategic Plan, created four innovation science programs, each representing strong opportunities for commercialization and cross campus collaboration, with three of the new centers being joint ventures between the Medical Center and the University's College of Arts, Sciences and Engineering:

- ▶ Stem Cell and Regenerative Medicine
- ▶ Biomedical Imaging and Biomarkers (Joint with the College)
- ▶ Nanomedicine (Joint with the College)
- ▶ Genomics and Systems Biology (Joint with the College)

Reshaping the WSU School of Medicine to meet the needs of 21st Century science clinical practice and translational discovery, while remaining true to the School's core mission, should be undertaken in a strategic, step-wise fashion. This is a discussion that should be held as a follow on to this report, the Battelle Report and the completion of the Strategic Plan.

4.11. Use Affiliation Agreements as a Vehicle for Shared Vision and Measurement of Community Health Impact

4.11.1. Leverage relationships with partner institutions to drive the CURE² Translational Research Priority Platforms

As a campus without a university hospital, WSU has a long history of collaboration and cooperation with key local hospitals and health systems, large and small. Beyond the traditional function of being a locus for training medical students, the WSU must rely on the researchers, clinicians, patients, infrastructure and community relationships of these partner hospitals and medical systems to execute on its urban research excellence and equity agenda. The connection with such local institutions is essential to achieve the vision anticipated for the CURE² Institute.

"If we are going to improve health care and health outcomes, we must have a different level of collaboration and cooperation among the entities – KCI, DCI and HFHS - that are invested in the health of the community."

"Urban translation science is a national need and we need to be ready to seize the opportunity including seeking collaboration with other groups investing in Detroit."

(Dept. Chair)

³⁵ <https://sysbio.med.harvard.edu/>



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WSU has a number of affiliation or master research services agreements now existing and in various stages of revision. The principal purpose of these agreements is to describe the legal conditions underpinning cooperative research projects involving both WSU and hospital researchers and services. These affiliation agreements define the relationship between WSU and the hospitals in, e.g., training, faculty appointments, research contracts and grants, and mutual IRB responsibilities.

“There is no formal university collaboration with our hospital partner that could provide us with a wealth of resources, patient data, and foster translational work. Tenet health care is based out of 11 states and can be a major platform for translational work. Again individuals are doing it at their own level without any programmatic approach at the university level.”

The creation of a new platform for coordinating and promoting translational science at WSU presents an opportunity to define a shared vision for Detroit regional community health with these affiliate institutions and to establish a clear set of cross-dependencies to achieve this shared vision.

Either within the affiliation agreements or as a separate Memorandum of Understanding (MOU), WSU should confirm with each affiliate institution this platform for engagement and partnership with the CURE² Institute. Items for this MOU would include:

- Coordinated efforts to expand clinical trials
- Participation in the CURE² CORES Collaborative, including mechanisms for utilization, coordination and cross institution service user fees for CURE² Cores and for participation in the CURE² CORES Collaborative
- Confirmation of access to EHRs as an essential tool for all areas of the CURE² Priority Research Platforms
- A broadened and robust feedback and education loop of seminars and symposia bringing together research teams across the institutions whose work falls within one of the CURE² Translational Research Priority Platforms or is central to an urban translational science competency. The March 2014 “First Annual Retreat of the WSU, KCI and HFHS Immunology Focus Group” is an excellent example of the kind of activity that the CURE² Institute will be designed to support and replicate.
- Shared mechanisms to measure community health impact

“The traditional benchmarks for academic promotion and advancement – public, peer-reviewed research funding and teaching – need to be revised and harmonized with new benchmarks that value team-based efforts and collaborative approaches to translational science. Success in translational science will require multidisciplinary and, in many cases, multi-organizational teams.”

NCATS CTSA Working Group Report

WSU has historically strong ties with the area health care systems and research institutions. A robust translational science platform must build on these and leverage the bottom line interests of regional affiliates in demonstrating investments that will improve the health status of the



citizens of the region. Observations pertinent to each of the regional health system partners and Wayne County health authorities are included in ADDENDUM G.

4.12. Develop a CURE² Institute Design Roadmap

4.12.1. Appoint a President's CURE² Institute Working Group

The President's CURE² Institute Working Group should have a carefully crafted charge to advise the President on how (not whether) to accomplish the vision, design and launch for the Institute. It would have a small set (ten to twelve?) of recognized leaders across each of the components of the Institute. Those chosen should be faculty and administrative members who have demonstrated the interest and ability to think "system-wide" and who represent both today's and tomorrow's basic science and translational research leaders at WSU. Consideration should be given to participation by key influencers, such as a member of the City Council or member of the Board of Regents who will become informed champions in their respective venues.

The Working Group will develop an 18 month roadmap for the launch of a CURE² Institute. This plan with should have significant milestones in place by the beginning of the 4th quarter of 2014. This will position the Institute to be part of any response to the NIH CTSA FY 2015 RFP that is anticipated for the Fall 2014, should this direction be elected.

4.12.2. Conduct a series of outreach and engagement meetings

The President and/or the Working Group should lead a series of engagements with key stakeholders, systems, and enterprises that will be critical to both the design of the Institute, identification of sources for sustainable funding, and assurances of national prominence. These engagements will be internal, regional and national. As examples only, input sessions might include:

- **Internal and Community Shared Value Sessions**
 - The Faculty Committee
 - Leaders of key programs that will be linked and leveraged under the CURE² Translational Priority Research Platforms and the suite of urban translational research competencies
 - Leaders of CORES that will become part of the umbrella CURE² CORES Collaborative
 - Political leaders, including the Mayor, the City Council
 - Regional Health System Affiliates: Preparatory meetings held one-on-one in which the President shares and gains input from senior leadership in each regional system on a series of key questions relating to the design and shared value of the Institute. These meetings will be followed by a convening of the regional affiliates collectively to present and further refine the framework for this shared value across the region. The CORES Collaborative, metrics for community health impact, the impact on their operations of the new connections between public health and clinical medicine, and the shared commitment to urban research excellence and equity will be part of this agenda



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- Community Foundations and public health agencies: Kresge and others to establish a shared vision and investment in the urban research excellence and equity agenda.
- **External Exposure and Engagement Meetings**

This outreach can be informal through introductory conference calls or in person. Again, based on the audience, the outreach should be conducted by the President and/or by the Working Group

 - **NIH** – Series of in person meetings for the President at the NIH
 - Yvonne Maddox, new acting director of the NIMHD
 - NICHD
 - Chris Austin, Director of NCATS
 - Francis Collins, Director NIH
 - Maria Freire, Executive Director, Foundation for NIH
 - Others, to be determined
 - **AAMC** – to leverage the President’s current leadership within the Urban Universities for Health initiative
 - **CROs**, such as Covance, Quintiles, with a goal toward funding the **Center for Urban Community Engagement and Research Partnership** as a platform to study minority recruitment
 - **National Minority Quality Forum**: Gary Puckrein, President and Executive Director
 - **PhRMA**: Bill Chin, Senior VP for Scientific and Regulatory Affairs and previously head of translational science at Harvard, to brief him on the Institute and consider direct engagement with the “*I’m In*” minority recruitment initiative that is underway in collaboration with the National Minority Quality Forum
 - **Industry**: conduct a series of conversations with potential industry partners who perceive a new opportunity for conduct of trials in Detroit with special skill in minority recruitment and engagement. Consider Lilly.
 - **ResearchMatch**: to advised on the minority recruitment platform. This program out of Vanderbilt works with 83 academic research institutions and will bring high value to the consideration of the creation of **Center for Urban Community Engagement and Research Partnership**
 - **Rapid Science**: this is an interesting enterprise that has developed mechanisms to track in real time faculty collaboration
 - Others, to be determined and recommended by the Working Group.

4.12.3. Hold two major meetings to position the Institute for regional and national prominence: A CURE² Institute Design Symposium and a National Conference on Community-based Urban Research Excellence and Equity

CURE² Institute Design Symposium

Consider an externally facilitated design symposium. Invite regional affiliates, public health agencies, foundations and political leaders to a ½- ¾ day design session where the President lays



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out his vision for translational science at WSU and each component of the institute is presented, structured input is received and the sense of shared value is cemented.

National Conference on Community-based Urban Research Excellence and Equity

Consider hosting national conference to be held in 2015 on *Community-based Urban Research Excellence and Equity*. Consider potential co-sponsorship with:

- a. NIH: FNIH and/or NCATS, NHLBI, NIEHS, NICHD, NCMHD, and others
- b. PhRMA
- c. ACRO – or a member
- d. Industry
- e. Community Foundations
- f. Affiliate Institutions

FBDC is prepared to help to develop this roadmap for design in further detail, if requested.



5. CONCLUSION

This report, *Transforming Clinical and Translational Sciences – A Roadmap to Lead the Nation in Urban Research Excellence*, presents an aggressive, system-wide roadmap for transformation. These transformations are within reach. The commitment to and process to achieve these results will be invigorating for a large array of Wayne State leaders who are ready for and committed to be part of this positive movement forward.

FaegreBD Consulting looks forward to responding to questions and assisting the institutes as it moves toward this stronger, effective platform for research, teaching, and practice of urban translational science.



ADDENDUM A

Roster of Interviews

Wednesday, October 30, 2013 @ 5057 Woodward, 6th Floor, Conference Room B

9:00 – 9:45 AM	Margot LaPointe, Ph.D., Vice President for Research Ben Rybicki, Ph.D., Division Head, Public Health Sciences Henry Ford Health System	5057 Woodward 6 th Floor, Conf. C
10:00 – 10:45 AM	Stephen Krawetz, Ph.D., Associate Director C.S. Mott Center for Human Growth & Development Wayne State University	5057 Woodward 6 th Floor, Conf. C
1:00 – 1:45 PM	Larry Matherly, Ph.D., Director, Cancer Biology Graduate Program, Karmanos Cancer Institute	5057 Woodward 6 th Floor, Conf. C
2:00 – 2:45 PM	Kendra Schwartz, M.D., MSPH Professor, Department Family Medicine & PHS Wayne State University School of Medicine	5057 Woodward 6 th Floor, Conf. C
3:00 – 3:45 PM	Hilary Ratner, Ph.D., Vice President for Research Gloria Heppner, Ph.D., Associate Vice President for Research Joseph Dunbar, Ph.D., Associate Vice President for Research	5057 Woodward 6 th Floor, Conf. C
4:00 – 4:45 PM	Gerold Bepler, M.D., Center Director Ann Schwartz, Ph.D., Deputy Center Director Anthony Shields, M.D., Ph.D, Associate Center Director Karmanos Cancer Institute	5057 Woodward 6 th Floor, Conf. C

Thursday, October 31, 2013, 5057 Woodward, 6th Floor, Conference Room C

9:30 – 10:00 AM	Valerie Parisi, Dean Wayne State University, School of Medicine	4100 F/AB
10:00 – 10:45 AM	Farshad Fotouhi, Ph.D., Dean, College of Engineering Wayne State University	5057 Woodward 6 th Floor, Conf. C
11:00 – 11:45 AM	Robert Sokol, MD, Director C.S. Mott Center for Human Growth & Development Founding Chair, Department of CTSA	5057 Woodward 6 th Floor, Conf. C



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1:00 – 1:45 PM	Bonita Stanton, Ph.D., Vice Dean for Research, SOM By phone: 888.363.4734 Access Code 1779617 Sylvie Naar-King, Ph.D., Department of Pediatrics SOM Wayne State University	5057 Woodward 6 th Floor, Conf. C
2:00 – 2:45 PM	Margaret Winters, Ph.D., Provost & Sr. Vice President Wayne State University	5057 Woodward 6 th Floor, Conf. C
4:00 – 4:45 PM	Sonia Hassan, Ph.D., Associate Dean, Perinatology Research Sorin Draghici, Ph.D., Professor, College of Engineering Wayne State University	5057 Woodward 6 th Floor, Conf. C

Monday, December 9, 2013	Faculty Member
1:00 – 2:00 PM	Melissa Runge-Morris, MD Professor and Director, Academic Department of Environmental Health Sciences
2:00 – 3:00 PM	Shijie Sheng, PhD Professor Department of Pathology WSU School of Medicine
Tuesday, December 10, 2013	
9:00 – 10:00 AM	Dawn Misra, PhD Associate Department Chair Department of Family Medicine WSU School of Medicine
10:00 – 11:00 AM	Jinsheng Zhang, PhD Professor & Research Director Otolaryngology Head and Neck Surgery Communication Sciences & Disorders WSU School of Medicine
Wednesday, December 11, 2013	
2:00 – 3:00 PM	Alana Conti, PhD Assistant Professor Department of Neurosurgery WSU School of Medicine Maik Huttemann, PhD Associate Professor Center for Molecular Medicine/Genetics WSU School of Medicine



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Thursday, December 12, 2013	
10:00 – 11:00 AM	Timothy Stemmler, PhD Professor Department of Pharmaceutical Sciences WSU School of Medicine
11:00 – 12:00 PM	Bengt Arnetz, PhD Professor Department of Family Medicine WSU School of Medicine

CTSA meeting w/ WSU/SoM, Frank Swain and Debra Lappin January 24, 2014 1140 Scott Hall	
8:30-9:45	Paul Giblin, Ph.D., Professor and Vice Chief of Carmen and Ann Adams Department of Pediatrics, Wayne State University School of Medicine
9:45-10:30	Associate Chairs for Research
11:00-1:00	CTSA Committee: Bonita Stanton, M.D., Vice Dean of Research and Graduate Programs Philip Levy, M.D., Assoc. Professor, Emergency Medicine Juri Gelovani, Ph.D., Department Chair, Biomedical Engineering, College of Engineering Noreen Rossi, M.D., Professor, Internal Medicine Dawn Misra, Ph.D, Associate Department Chair, Family Medicine Rodger MacArthur, Professor, Internal Medicine Shijie Sheng, Ph.D., Professor, Pathology Steven Firestine, Associate Professor, Pharmaceutical Sciences Nancy Artinian, Ph.D., R.N.,SAAN, Interim Dean, College of Nursing
1:15-2:15	Chairs-Basic and Clinical Sciences
2:30-3:15	Daniel Walz, Ph.D., Associate Dean for Research and Graduate Programs Stanley Terlecky, Ph.D., Associate Dean for Graduate Programs Thomas Holland, Ph.D., Director of Masters of Science in Basic Medical Sciences and medical Research



ADDENDUM B

Methodology

Wayne State is an urban university with a strong teaching and research record. It has attempted within the past eight years to further strengthen its health research by competing for NIH CTSA recognition, which brings funding and prestige. Three CTSA applications have been unsuccessful.

Dr. Roy Wilson, a distinguished medical researcher, with C level experience at NIH and leading research institutions, upon becoming President of Wayne State, signaled his strong intent to change this course by transforming WSU's clinical and translation research capacities. This report was commissioned to inform the strategic plan to accomplish this vision.

Soon after commissioning this effort, it became clear that the report should reform not only strategies to pursue a NIH CTSA, but more importantly strategies to transform the CTS enterprise at Wayne State University. The charge for this report evolved to include three primary elements:

1. Analyze NIH's evolving perspective on supporting CTS research and in particular the CTSA grant program and provide observations on the larger changing landscape for CTS
2. Examine the strengths of CTS against the changing backdrop at Wayne State
3. Recommend actions the President and University to take to transform the CTS infrastructure and collaboration to position Wayne State University to become a competitive force in the decade ahead

FaegreBD Consulting made three onsite visits to the WSU campus. During these visits or by conference call, FaegreBD met with 39 members of faculty and administration. Through follow on email communications with certain members of the faculty, opinions and advice were clarified and expanded. On two visits, FaegreBD met with the formally appointed Faculty Committee, first as composed to address the CTS enterprise, and then on a second visit as expanded to consider the larger research system to inform the report being undertaken by the Battelle Memorial Institute (Battelle). FaegreBD has had multiple follow on conversations with leaders in the administration. Addendum B contains a full listing of the individuals involved in those meetings.

To provide further context, FaegreBD spoke with a small set of external stakeholders, including Chris Allen, the Director of the Wayne County Health Authority; Ron Kauffman, Chief Medical Officer, Tenet Health System, California Region; Roland Chang, Director of the Institute of Public Health and Medicine, Northwestern University, and Malika Fair, Director of the AAMC Urban Universities for Health initiative.

FaegreBD Consulting reviewed an expansive set of materials and data supplied by the Vice President for Research and the Chair of the Faculty Committee. These materials included: overviews of the current and recent funded research record at the University; internal reports to the President;



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previous assessments and reports concerning biomedical research at Wayne State; each previous CTSA proposal and NIH comments on the proposals, and draft research services agreement with DMC. Further, this report is informed by external literature review including publications on team science; publications of the AAMC on changing expectation for academic health centers, and sources on structures of Schools of Medicine. The IOM report evaluating the NIH CTSA program and the Report of the NIH NCATS CTSA Working Group, delivered on May 16, 2014, were carefully considered.

The recommendation in this report are informed and enhanced by the Draft report presented to the President in April 2014 by the Battelle Memorial Institute.



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ADDENDUM C

FaegreBD Consulting Translational research presentation January 2014

Wayne State University
Responding to the Changing
Landscape for Clinical and
Translational Science



Confidential
January 2014

Debra Lappin and Frank Swain

debra.lappin@faegrebd.com frank.swain@faegrebd.com

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**"It's easier to act your way into a new way of thinking,
than think your way into a new way of acting."**

— Jerry Steiner, *The Power of Positive Deviance: How Unlikely Innovators Solve the World's Toughest Problems*

Our observation:

Change in CTS performance at WSU will require new structures and incentives (carrots and sticks) that encourage and instill a new way of acting. Without this, WSU will not keep pace with transformations in how science is conducted.

This is about more than the CTSA.



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**Timing and opportunity-
take advantage of a changing image**

Old headline:

**From Motown to Ghost Town -
How the once mighty Detroit is
heading down a long, slow road to
ruin**

Daily Mail
Peter Hitchens In Detroit
July 2011

Today's headline:

**Hope surfaces as bankrupt
Detroit eyes rebirth**



Retroit: A watchmaker examines her materials at Shinola's Detroit factory on Oct 2 | AFP/JUI

**The Japan Times
Oct 2013**

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A glimpse into what we have heard....

- "There is no central core resource that assures that scientists at WSU can compete with modern science."
- "Leadership needs to understand the depth of the challenges. Hard to appreciate the gaps. Significant research profile, but MUCH erosion since 2010."
- "Inability to recruit people to do this kind of work -- must have something to come to -- Detroit is the amazing clinical laboratory plus great physiology groups at WSU. We must break the mold by looking at problems, working with the community to understand root causes, then moving these back to bench to develop interventions..."
- "Can the President get rid of high priced professors who are doing nothing?"
- "We must address the forces that work against inter-disciplinary work at WSU."
- "WSU MIRRORS DETROIT -- you expect the worst and then you blame ... this is a Detroit mentality.... Retrench back to your cocoon and say we were right and they are wrong."

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Against this backdrop: *Our discussion today*

- I. Evolution of the CTSA
 - ▶ From GRCs to today's CTSA
- II. State of Play Today
 - ▶ Congressional Signals
 - ▶ IOM Report
 - ▶ Blue Ribbon Panel
 - ▶ Insights and Intel from NCATS
- III. Applying the State of Play to WSU
- IV. Proposed Next Steps



I. Evolution of the current CTSA Program

1960

- VISION: To foster POR (patient oriented research) in universities across the country the National Institutes of Health (NIH) instituted 5-year renewable competitive grants for the establishment of General Clinical Research Centers (GRCs).
- 5 funded sites

2004

- Described by Congress as "critical" resources for providing optimal venues and essential infrastructure for patient-oriented research.
- The GRCs are expected to be a driving force for future biomedical research, technologies and resources, and are in the forefront of clinical research training. They may also play a prominent part in implementation of the NIH Roadmap on translational research.
- 80 GRC's

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I. Evolution of the NIH CTSA

II. State of Play today

C Austin, Director, NCATS



2004:
The NIH Roadmap



2005:
Conceiving the program



2007:
Anticipating the new era



Clinical and Translational Science Awards
Led by NCATS Division of Clinical Innovation

CTSA's:

- Support a national consortium of medical research institutions
- Work together to improve the way clinical and translational research is conducted nationwide
- Accelerate the research translation process
- Provide innovative training for clinical and translation researchers



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II. State of Play: The Challenges for Translational Research Grow



Fundamental science advanced, but:

Poor transition of basic or clinical observations into interventions that tangibly improve human health



- Drug/device/diagnostic development system in crisis
- Clinical trials system in crisis
- Poor adoption of demonstrably useful interventions



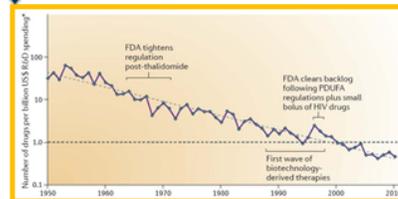
People unhealthier and funders of biomedical research enterprise (public and private) impatient

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Source: NCATS: C Austin

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Eroom's Law & the looming public question



The number of new drugs approved by the FDA per billion US dollars (inflation-adjusted) spent on research and development (R&D) has halved roughly every 9 years since 1950.

Scannell et al., Nature Reviews Drug Discovery 11:191, 2012

Source: NCATS: C Austin

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Congress/
Public:
What are
we getting
for our
nation's
investment
in the NIH?

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II. State of Play: Subtle restatement of the NCATS MISSION



To catalyze the generation of innovative methods and technologies that will enhance the development, testing and implementation of **diagnostics and therapeutics** across a wide range of human diseases and conditions.



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To catalyze the generation of innovative methods and technologies that will enhance the development, testing and implementation of **interventions that tangibly improve human health** across a wide range of human diseases and conditions.

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What NCATS wants to see in an application

The Standard Model
MOVING RESEARCH INTO HUMAN HEALTH IMPACT



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Source: NCATS: C Austin

The New Model the way it should work



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II. State of Play: Congress FY 14 Omnibus Appropriations Bill

FY 14 Omnibus Bill – other themes relating to CTS

Clinical and Translational Science Awards (CTSA)

- The agreement provides a specific funding level (\$ 474 mm) for the core CTSA program within the NCATS statutory language. This change removes the funding flexibility provided during the establishment years of NCATS.
- The ICs are expected to continue to use and provide support to the CTSA infrastructure for clinical trials and other scientifically appropriate activity. In addition, NCATS should continue to collaborate with all ICs on the overall CTSA program.
 - The 2013 Institute of Medicine (IOM) report recommends the development of a **comprehensive strategic plan with measurable objectives**. The NCATS is expected to move forward with implementing the IOM recommendations in consultation with the CTSA community.
 - Any significant changes to the program should be done with transparent and ongoing consultation with the CTSA community and NIH ICs. NCATS shall provide an update in the fiscal year 2015 budget request of all planned and expected changes since the release of the IOM report through fiscal year 2015 to include a **specific plan on how NCATS will communicate and coordinate with the CTSA community**.

Clinical Trials Patient Enrollment – NIH Workshop. Focus on increasing participation of underrepresented and uninsured populations in CTs.

Big Data: report from NIH Director on core techniques and technologies for advancing big data.

Accelerating Commercialization of Therapies to Patients: Charge to examine ways to work with industry to foster private sector drug development.

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II. Current State of Play: Insights

II. State of Play: Insights

Limitations on the Current Model

Anticipated characteristics of evolving CTSA foci

- ▶ 2008 – 2012 RFPs: invited well-crafted promises to cover the CTS landscape
- ▶ Observations on the evolution of this "model"
 - Tantamount to a "Block Grant"
 - Analogous to having a single mainframe computer with no internet
 - Lack of definition of the purpose of the program
 - Need for new focus on metrics: measuring outcomes that move beyond traditional investigator "productivity" and measure demonstrated impacts on human health
 - Grantees (and NIH) are seeking greater flexibility with the funding

- ▶ Fund research priorities rather than lab or organizational infrastructure
- ▶ Fund more sites with smaller grants – recognize that more than 63 communities need to be touched by CTSA
- ▶ Support teams with distributed talent (versus a team of quarterbacks)
- ▶ Recognize value of the non-traditional, the unique contribution
- ▶ Patient-oriented clinical research a high priority: finding and working with the people most affected by a disease?
- ▶ The infrastructure must enable the proposed science, not infrastructure that exists for its own sake

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II. State of Play: Insights

Anticipated metrics and measures

- ▶ Metrics
 - ▶ CTSA must express clearer expectations of short and longer term scientific and organizational outcomes
 - ▶ Evaluation measures should comport with academic advancement but move beyond papers and grants
 - ▶ Development of a novel interventions must show a path for moving the intervention into the community with demonstrated public health impact

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II. State of Play: Insights

Top and Bottom lines

- ▶ Multiple future RFAs (beginning in FY 2015)
 - ▶ IOM Innovation Fund multisite pilots addressing specific problems in translational context may be an early focus
- ▶ Winning strategies
 - ▶ Focus on solving daunting clinical problems in the translational space
 - ▶ Develop novel strategies for academic incentives to promote and encourage excellence in CTS
 - ▶ Deploy health systems in context of translation into the community
 - ▶ Apply empirical scientific thinking to solving major translational research challenges; strive to advance the "science" of the CTS process itself
 - ▶ Team-based projects across different disciplines will be sought

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II. State of Play: NCATS CTSA Steering Committee and Working Group on IOM Report

Streamlining the CTSA Consensus

In December 2013, prior Steering Committee & Executive Committee were disbanded, and the new NCATS Steering Committee was established.

Chair: [Name]

Members: [List of names and titles]

Advisory Council WG on the IOM CTSA Report

Established December 2013
Report expected to be presented to Council in 2014

Chair: [Name]

Members: [List of names and titles]

REPORT DUE MAY 14 2014

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II. State of Play: the IOM Report

Changing research ecosystem

- ▶ Enhanced collaborations
- ▶ Emerging (big) data and technology
- ▶ Streamlined IRB review processes and enhanced patient protections
- ▶ Broader research participant recruitment
- ▶ Development of a dynamic research workforce at several levels – undergrad through post-doc

Opportunities for Action

- ▶ Adopt and sustain more active program leadership
- ▶ Engage in additional substantive and productive collaboration and measure it
- ▶ Develop and disseminate innovative research resources beyond WSU
- ▶ Build on initial success in training and education, community engagement and child health research

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IOM Report - Recommendations

1. Strengthen NCATS Leadership of the CTSA Program
2. Reconfigure and streamline the CTSA Consortium
3. Build on strengths of individual CTSA's across the spectrum of clinical and translational research
4. Formalize and standardize evaluation processes for individual CTSA's and CTSA Program
5. Advance innovation in education and training
6. Ensure community engagement in all phases of research
7. Strengthen clinical and translational research relevant to child health



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1. Strengthened leadership

- Ensure program supports full spectrum of CTS while encouraging flexibility for each institution to build on its unique strengths
- Form strategic partnerships – across WSU, NIH, research networks, community groups, health systems, and industry
- Establish an innovations fund through a set aside mechanisms that would be used for collaborative pilot studies and other initiatives

2. Reconfigure and streamline

- Establish new multi-stakeholder NCATS – CTSA Steering Committee

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3. Build on the strengths of the CTSA's across the spectrum of CTS

- Individual CTSA's should emphasize their strengths
 - Innovation and collaboration in methodologies, processes, tools and resources
 - Interdisciplinary team-based approaches to training, education and research
 - Engagement: patient, HC workers, community partners
 - Collaborations across schools and disciplines
 - Partnership with industry, community groups, stakeholders
 - Share resources across the CTSA Program

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4. Formalize and standardize evaluation processes for CTSA's and the Program

- Metrics should align with the programs mission and goals
- Go beyond standard academic benchmarks (publications/grants) to assess impact

5. Advance innovation in education and training

- Train next generation of CTS workforce
- Innovative education and training models and methodologies
- Focus on Team Science, Community Engagement and Entrepreneurship
- Online offerings, flexible and personalized training experiences that offer advanced degrees

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- Online offerings, flexible and personalized training experiences that offer advanced degrees

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6. Ensure Community Engagement in all phases

- Define community engagement broadly
- Active and substantive community participation in priority setting and decision making across all phases of CTR and in leadership and governance of the CTSA Program
- Explore opportunities and incentives to engage a more diverse community

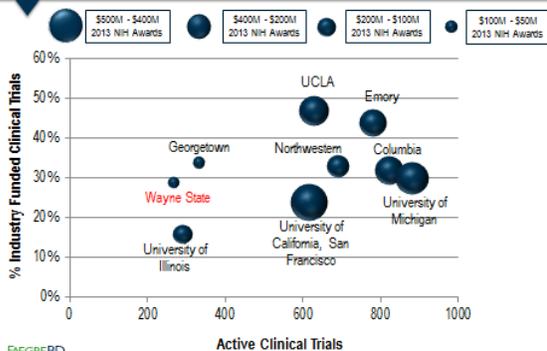
7. Strengthen CTR relevant to child health

- Identify and designate CTSA's with expertise in child health research as leaders and coordinators for the CTSA program wide effort
- Promote and increase community engagement specific to child health

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III. WSU: Industry Funded Clinical Trial Comparison



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WSU: What will the future state begin to look like?

- ▶ **Center for Urban Research (CURES) in CTS**
 - ▶ Affiliation with UM to train urban-focused students
 - ▶ Integrated programs with undergrad Arts and Sciences
 - ▶ Public health within SoM
- ▶ **Career Development and Training for the Urban Translational Scientist**
 - ▶ Network of hospitals becomes constellation of community-based training opportunities
 - ▶ ER as a site for CTS research
- ▶ **Central CTS Wheelhouse with core CTS tools and resources**
 - ▶ Trial design, ethics, biostats, regulatory support
 - ▶ ONCORE, SCIVAL, LABS
- ▶ **Team science and inter-disciplinary collaboration:** P&T incentives
- ▶ **Community Engagement**
 - ▶ Closed loop from bench to community and back
 - ▶ Community Board
 - ▶ Metrics to measure changes in community health
 - ▶ Health system reform: Accountable Care Community
- ▶ **Child health**
 - ▶ Leveraging PRB
- ▶ **Industry collaboration**
- ▶ **Systems strategies**
- ▶ **Shared data; Big Data**
 - ▶ Affiliation Agreements: networked EHRs
 - ▶ Shared Biospecimen repositories
- ▶ **Academic home with clear authorities**

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What is needed to get to this required future state?

- ✓ Evolution in the culture of the WSU CTS research community defined by
 - ▶ Ability to see around the corner, beyond the single lab or individual program, to co-create, become team players engaged in team science
 - ▶ Enthusiasm for "trans"-disciplinary research, supported by new infrastructure and renewed institutional commitment
- ✓ A new CTS structure that
 - ▶ Taps into the entire institution,
 - ▶ Encourages and support traditional projects,
 - ▶ Breaks rules and traditions to identify new projects and set the course for institutional distinction
- ✓ CTS Leadership with
 - ▶ Ability to inspire
 - ▶ Actions that are rapid, energizing and aligning
 - ▶ Authority to reward/compel academic and clinical performance that leads to new results



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DISCUSSION: WSU CTS -- the path forward



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ADDENDUM D

Strategic Planning

Signaling Shifts in Schools of Medicine

University of North Carolina at Chapel Hill (UNC).

As a background to its 2012 Strategic Plan for the School of Medicine, the UNC committee commented on the changing environment for CTS:

We must achieve this goal (to become the nation's leading public school of medicine) within a rapidly changing extramural funding landscape. Constrained federal and state budgets are expected to make competition for research dollars ever more challenging. Additionally, agencies such as the NIH are increasingly directing these limited dollars away from more traditional, single-investigator awards (e.g., R01s), to larger, team-based projects spanning multiple basic and clinical disciplines (e.g., U01 mechanisms and Clinical and Translational Science Awards, or CTSAs).

.....we and all medical schools must face the challenge of fostering translational research by bridging basic science with clinical care. Meeting this formidable challenge will require continued investment in curiosity-driven basic research to drive the novel discoveries that form the foundation for advancements in clinical care as well as the establishment of an efficient communication framework between basic and clinical scientists necessary to achieve effective translational research

Our proposals are aspirational, representing what we believe we need to put into place in order to become the nation's leading public medical school. We understand that we, and all others in American health care, are entering a time of transformative rather than usual change; we, and all academic health centers, face many fiscal and regulatory threats. We believe, however, that these conditions will also provide opportunities for leadership and innovative solutions as the new health system is created. It is through this leadership that we will become the nation's leading public school of medicine. We believe that this strategic plan — with its emphasis on meaningful innovation, teamwork, accountability and careful integration — is the right roadmap to guide us through the coming years.

The UNC Strategic Plan for the SOM has four components, built out as follows:

Research: We will build on existing strengths in basic mechanistic, model system and clinical research to position UNC as a leader in translational and multidisciplinary team science at the forefront of applying discovery science to human health. Key to



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this effort will be providing the tools needed at all stages along the translational continuum (from basic to clinical to population research) by making targeted investments in research infrastructure while streamlining and strengthening current assets.

Education: We will restructure the medical school curriculum to prepare students for 21st century medicine. A foundation of this effort will be to invest in the necessary infrastructure at UNC and across the state and to optimize student recruitment and admissions to provide needed physicians for North Carolina and beyond.

Clinical care: We will design and implement a comprehensive program to improve quality of care across the UNC health care system, enabled by an integrated SOM-HCS informatics strategy. Recognizing the unique role that UNC can play as a fount of innovation in the emerging health care system, we will establish a Center for Health Care Innovation.

Faculty: Faculty are our most precious asset. We will improve tracking of individual and institutional performance on key dimensions, ensuring that faculty expectations, evaluations and rewards are aligned. By providing targeted benefits, promoting career development opportunities and addressing the needs of specific subgroups, we will create conditions in which as many of our faculty as possible succeed — our overall goal.

And, even an institution with the level of NIH funding enjoyed by UNC, notes the following:

Faculty Accountability: Interestingly, although our overall level of extramural research funding is high, with UNC ranking 15th in total NIH funding for FY2011, on a closer look we found wide variations in research productivity across the faculty, with a small proportion of faculty generating the vast majority of research dollars. This is both a strength (reflecting tremendous achievement by some of our best investigators) and a weakness (reflecting a lack of depth across the spectrum of investigators at UNC).

DUKE.

In building its plan for its SOM, Duke stressed its effort to look beyond “the traditional model of universities. That model, with its emphasis on specialization and tightly bounded disciplines, has served us well for more than a century, yielding intellectual breakthroughs in many fields. But its limits are increasingly clear for the challenges that lie ahead.” The plan notes:

The important problems of the contemporary world exceed the scope of any single discipline. Health challenges require the understanding of medical diagnosis, management economics, cultural differences and ethical values. Dealing with global



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climate issues requires a mix of expertise including physical and biological sciences, engineering, business, policy and law.

While Duke will continue to embrace the essential aspects of specialized research, teaching and learning, the university will build on its special strengths in collaboration and connection of knowledge to real-world problems. More than ever, we will prepare students to approach issues with creativity, flexibility and a curious mind. Engagement across lines of race, ethnicity, religion and national culture will become more important as training for an increasingly interconnected world.

North Western University (NWU).

NWU has created within the Feinberg School of Medicine an *Institute for Public Health and Medicine (IPHAM)*. As WSU seeks to determine where to locate its public health effort and whether to expand this into a School of Public Health, the process and end result achieved at NWU will be instructive. It assures that public health and medicine work together, not as separate siloed departments. This is reflective of the national emphasis on the intersection of clinical care and public health. This same kind of intersection will be critical if WSU is to become a national leader in urban translational science.

The stated goal of the IPHAM is to accelerate innovation at the interface of medicine and public health and achieve measurable improvements in health for patients and populations. The Institute includes the following Centers, all brought together for the first time as this Institute was created:

- [Centers](#)
 - [Behavior and Health](#)
 - [Buehler Center on Aging, Health and Society](#)
 - [Community Health](#)
 - [Engineering and Health](#)
 - [Global Health](#)
 - [Healthcare Studies](#)
 - [Patient-Centered Outcomes](#)
 - [Population Health Sciences](#)

Whereas at NWU Departments are recognized as the major organizational entities for activities pertaining to medicine, IPHAM Centers will operate at the interface of medicine and public health. IPHAM Centers provide a home for membership in the Institute where academic scholars from different disciplines can join in coordinated activities. This can only occur through strong leadership and careful orchestration of the Institute's organizational structure, combined with new resources and policies to incent new collaboration. Some examples of how the Institute serves Feinberg SOM include:



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- Leveraging space, communication strategies, and novel networking resources to enhance the probability and success of new research partnerships among centers, academic units, and non-academic collaborators.
- Using highly accessible and efficient processes to make new seed monies available for new partnerships and innovative strategies.
- Making additional resources and technical assistance easier to access, particularly in shared areas of high-priority needs, including multi-disciplinary team building; grant and protocol development, peer-review, and refinement; population data collection; data management; analysis; and communication of results to colleagues, communities, and policymakers.
- Promoting and sharing novel "core" resources in innovative new areas, such as the use of expanding technologies to support health behaviors and novel approaches to measure and analyze the impact of environment on health through geospatial analysis.
- Supporting collaborative new enrichment activities to create unique opportunities to prepare trainees to work at the boundaries of traditional disciplines, generating new insights and innovative research programs. This includes opportunities for mentorship, education, and training of oneself, partners, and a pipeline of more junior professionals dedicated to research, education and service at the interface of public health and medicine.
- Uniting Institute, Center, and Core leadership under a shared vision and strategy and with new resources for growth. This enables the Institute to leverage win-win resource commitments with academic divisions and departments, which will, in turn, benefit from the Institute's rich environment for mentorship and efficient, high-yield research operations.

This approach is highly instructive. NWU took assets it possessed and brought these under a central unified structure to assure the use and optimization of shared resources and the synergies between medicine and public health – all critical to success in today's environment. Significantly, the Dean made the decision to move a larger percentage of the institution's indirect costs recovery away from the departments into the office of the Dean in order to provide resources to support the new center.



ADDENDUM E

The Emerging Intersection of Clinical Medicine and Public Health

The Problem

In 2006, when serving as the Commissioner for the New York City Department of Health and mental Hygiene, Tom Frieden (now Director of the CDC), launched a program to promote use of essential clinical preventive services; the program had members of the public health department effectively ‘detailed’ to primary care offices. This was one of a handful of early efforts to bring the formerly siloed enterprises of clinical medicine and community health together.

Frieden’s language, captured in the publication of this intervention, reflects themes he advances today across many public settings:

The leading causes of illness, disability, and death in New York City are largely preventable. While disease prevention has generally been a longstanding focus of public health agencies, relatively little effort has been directed at supporting the delivery of preventive services in the clinical setting. Working with community providers to enhance the provision of preventive services could both strengthen the relationship between the public health and health care communities and contribute significantly to the attainment of Healthy People 2010 goals, such as increasing the proportion of persons appropriately counseled about health behaviors and reducing hospitalization rates for three ambulatory-care-sensitive conditions—pediatric asthma, uncontrolled diabetes, and immunization-preventable pneumonia and influenza.

Evolution in Concept

Frieden’s thinking on this critical nexus between clinical care and population health continued to evolve. By 2010 he presented his observations on the limitations in the current ‘four-tiered’ health where the bottom level represented population-wide interventions that have the greatest impact and ascending levels, each with decreasing impact, that represent primary, secondary, and tertiary care. In beginning to discuss the components of a health “system” as opposed to health “care,” he noted:

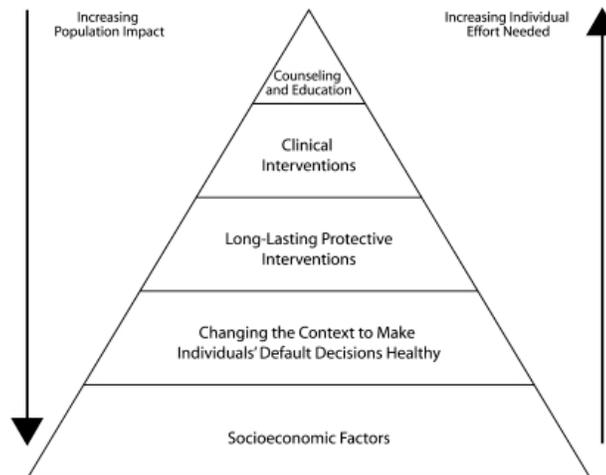
All of these models, however, focus most of their attention on various aspects of clinical health services and their delivery and, to a lesser extent, health system infrastructure. Although these are of critical importance, public health involves far more than health care. The fundamental composition, organization, and operation of society form the underpinnings of the determinants of health, yet they are often overlooked in the development frameworks to describe health system structures. As a result, existing



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frameworks accurately describe neither the constituent elements nor the role of public health.

Frieden presented in the following figure his sense of the five tiers of a health system:



Frieden sees the five tiers as linked in the following way:

The health impact pyramid, a framework for public health action, postulates that addressing socioeconomic factors (tier 1, or the base of the pyramid) has the greatest potential to improve health. Interventions that change the context for individual behavior (tier 2) are generally the most effective public health actions; 1-time clinical interventions (tier 3), such as immunizations, can be more effectively applied than those requiring ongoing care; and clinical interventions (tier 4) are generally, although not inevitably, more effective than counseling and education (tier 5).

Speaking in 2012, Reed Tuckson, then Executive Vice President and Chief of Medical Affairs at the UnitedHealth Group, captured the growing understanding the ability to couple public health capacities with clinical care delivery as a critical lever to address the lagging health status of Americans against international norms: *“We’re spending a lot on health care yet not getting the best health. What can public health do to partner more closely with health care to get us to a better health destination?”* He expanded on this observation:

One of the really exciting movements that is now gaining momentum and energy is this realization that we’ve got to stitch together the preventive and population health movement with the medical care delivery movement. These are two worlds that have unfortunately operated in silos. And so now we’re beginning to have a shared realization that we have to be able to address the needs of each individual across the continuum of their needs, from prevention, early identification of disease, all the way through to management of disease



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and the restoration of function. It's putting the pieces of the puzzle together, which is very exciting and this is an interesting moment when the incentives to encourage that are beginning to become aligned.

In 2012, following the passage of the ACA, the CDC, under Frieden's leadership, together with HRSA, commissioned an IOM Study on: **Primary Care and Public Health: Exploring Integration to Improve Population Health (2012)**. The report notes

Ensuring that members of society are healthy and reaching their full potential requires the prevention of disease and injury; the promotion of health and well-being; the assurance of conditions in which people can be healthy; and the provision of timely, effective, and coordinated health care. Achieving substantial and lasting improvements in population health will require a concerted effort from all these entities, aligned with a common goal. ...

Primary Care and Public Health identifies the best examples of effective public health and primary care integration and the factors that promote and sustain these efforts, examines ways by which HRSA and CDC can use provisions of the Patient Protection and Affordable Care Act to promote the integration of primary care and public health, and discusses how HRSA-supported primary care systems and state and local public health departments can effectively integrate and coordinate to improve efforts directed at disease prevention.

This report is essential for all health care centers and providers, state and local policy makers, educators, government agencies, and the public for learning how to integrate and improve population health.

Significantly, the IOM report notes the critical role of academic health centers in driving this new level of integration:

Academic health centers often are well positioned to facilitate the integration of primary care and public health and the development of improved means of engagement and integration, as they are often located in communities of need and draw both their patients and their employees from these communities. As illustrated by several of the examples highlighted in Chapter 2, academic health centers can serve as effective partners with both health centers and local health departments in sharing data; aligning clinical, research, and educational programs; and sustaining integrated operations aimed at improving the health of the entire community.... The evidence in this area is sparse, but the committee believes that creating an interface for the Health Resources and Services Administration (HRSA) and the Centers for Disease Control and Prevention (CDC) to work with academic health centers, their primary care programs, and their local health departments to promote the integration of primary care and public health is an opportunity that should be explored.

Recommendation 4 of the IOM Report, as an example, sets out a sweeping national policy strategy to support the integration of primary care and public health:



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Recommendation 4. To improve the integration of primary care and public health through existing HHS programs, as well as newly legislated initiatives, the Secretary of HHS should direct:

- CMMI to use its focus on improving community health to support pilots that better integrate primary care and public health and programs in other sectors affecting the broader determinants of health
- the National Institutes of Health to use the Clinical and Translational Science Awards to encourage the development and diffusion of research advances to applications in the community through primary care and public health
- the National Committee on Vital and Health Statistics to advise the secretary on integrating policy and incentives for the capture of data that would promote the integration of clinical and public health information
- the Office of the National Coordinator to consider the development of population measures that would support the integration of community-level clinical and public health data
- AHRQ to encourage its Primary Care Extension Program to create linkages between primary care providers and their local health departments.



ADDENDUM F

Harvard Systems Biology Department

Scientific Contributions

The department has published **1,508** papers over the last 10 years, using mathematical and computational approaches to offer novel insights into cancer, infectious disease, aging, human physiology, genetic diseases, and vertebrate development. Key contributions include:

- Computer-enabled methods for measuring cell growth, aging, gene expression, and cell movement in model organisms;
- A new perspective on how antibiotic resistance evolves, and how to slow or reverse the spread of resistance;
- Profound revisions to the textbook models of spinal cord development and the behavior of adult stem cells;
- New models of the behavior of signaling pathways in cancer that help predict and explain how these pathways behave;
- Dramatic progress in engineering biological materials to make precise shapes, engineering improved carbon fixation and making useful molecules such as hydrogen, sugar, and other products;
- New theoretical and experimental approaches to the problem of variation, or “noise”, in biology. Noise is important in clinical problems, such as “fractional kill” in cancer therapy and the persistence of bacterial infections after antibiotic treatment;
- A new level of understanding of the mitochondrion, the powerhouse of the cell, and its role in disease;
- Novel ways to detect diseases, such as anemia, colon cancer, kidney injury, diabetes, and tuberculosis, as well as engineered cells that record antibiotic treatments;
- Methods for predicting protein structure from DNA sequence information, solving a decades-old problem of great importance;
- Ways to understand drug action at a new level, contributing to the founding of the Harvard Program in Therapeutic Science (HiTS).

A Pioneering Interdisciplinary Effort

- All laboratories in the department include an interdisciplinary mix of biologists, mathematicians, physicists, computational scientists, and engineers. Because of the interdisciplinary training we offer, many individual scientists are able to span multiple disciplines in their own research.
- Department faculty and trainees come from many different backgrounds, but are all entirely committed to biomedical research. This commitment has led to an unusual degree of focus on real medical problems, compared to other systems biology efforts.



ADDENDUM G

Leveraging Relationships with Regional Health Systems and Public Health Entities

Henry Ford Hospital System

Leaders from HFHS note that the Affiliation Agreements today are written in general, non-specific terms. They endorse strengthening the WSU HFHS cooperative record by expanding these agreements to cement specific tools and resources, such as seminars, symposia, collaborative research projects, joint pilot project funding that will provide real incentives for new behaviors.

HFHS leadership note that, today, WSU researchers cannot “look into medical records at HFHS. While this existed in the past, today with the installation of EPIC this is no longer achievable. “

Today the HFHS affiliation is heavily focused on medical education. Leadership at HFHS stressed that, given the leadership in basic cancer research at KCI and the strong clinical oncology program at HFHS, the opportunity for collaborative clinical oncology research efforts among HFHS, KCI and WSU is significant. Such a translational oncology program that drives trans-institutional collaborations among the three institutions thus stands as a sixth translational research platform.

Karmanos/McLaren

Interviews suggested that the ongoing redefinition of the WSU relationship with Karmanos is viewed through dramatically different lenses, depending upon whether the observer is grounded at Karmanos or at WSU. Karmanos leadership with deep expertise in population health expressed “shock” that Karmanos was not at the “center” of previous WSU CTSA submissions. On the other hand, a leading translational scientist at WSU was clear to recognize KCI as “very productive” but then cautioned that in the bigger WSU CTS picture they “should not be part of the CTSA.” While one would like to see this comment as an artifact of a less inclusive less partnered era, it came from one of the institution’s emerging leaders in translational science

The asset of a thriving and resourceful cancer center must be related to the WSU CTS CURE² Institute. CTSA reviewers have clearly signaled, as they should, that strong ties between an institution’s cancer center and the CTSA platform are essential. The basic cancer biology program at Karmanos has housed a T 32 grant for 32 years. 17 percent of the trainees are minorities. KCI brings the second largest Phase 1 program after MD Anderson.

In fact the evolution of the KCI corporate identity coupled with the new WSU commitment to CTS is an opportunity for both parties to constructively and practically redefine and expand shared commitment to CTS. The CURE² focus on cancer, unlike some of the other cluster focuses, would rely heavily if not in primary part on execution through KCI and HFHS.



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The process for redefining the WSU KCI collaboration could be an opportunity to provide Karmanos with greater access to biospecimens housed in the WSU Department of Pathology or even possibly at HFHS.

DMC/Tenet

DMC has been a principle venue for WSU SOM clinical education and training. The recent ownership change to Tenet is an opportunity to redefine the relationship between the institutions to strengthen and expand the level of collaborative CTS activity and support. As a matter of national policy, Tenet advises it is strongly committed to research, especially in the context of community population health opportunities. FBDC is prepared to facilitate a discussion on this shared research mission and how it should factor into the design of the CURE² Institute.

Partner Agreements with Detroit or Wayne County Medical agencies

The WSU SOM is identified with, directly linked to, and mission-driven to serve the communities in Detroit. To strengthen CTS, the community must be involved. While involvement can come through local health systems, and through historic or ad hoc arrangements with particular community organizations, the obvious opportunity for the CURE² Institute is to conduct a purposeful roadmap for outreach and engagement with Wayne County and City of Detroit public officials with public health responsibilities.

As discussed above, the interconnections of translational and clinical medicine and clinical practice are becoming linked through healthcare reform with the public health enterprise. The goal of becoming a nationally recognized force in urban research excellence and equity is dependent on relationships with the public agencies who share a responsibility for the health of the area's citizens. The focus of any such relationship would fall within the remits of the **Center for Urban Medicine and Population Health** and the **Center for Urban Community Engagement and Research Partnership**.