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RE: Request for Proposals in 2015

Background

Insurance companies are key stakeholders in the health care industry but they have not generally participated in proactive research and innovation in order to simultaneously increase the affordability, simplicity, and accessibility of healthcare. In 2013, CMU announced the formation of the Disruptive Health Technology Institute (DHTI) that has been launched with support from Highmark and the Heinz Endowments. DHTI is in place to facilitate research that lies at the intersection of science, engineering, business and healthcare delivery. DHTI's link to Highmark Health Services and the Allegheny Health Network, which is defined within a Master Research Agreement, will foster innovation in healthcare that can be tested in a clinical setting, rapidly translated and delivered to patients.

Over the first three years approximately \$4 million was made available to teams of researchers that were awarded seed funding for projects that might reasonably be expected to show significant results within 1-2 years. In this round of funding, we expect to be in a position to fund 5-10 projects. Through a series of on-going research retreats we have identified areas of particular interest that serve as focus areas for project submissions. DHTI areas of focus have expanded beyond the initial identified areas as we continue to monitor and examine issues and unmet clinical needs as they pertain to the delivery of healthcare solutions.

The DHTI Joint Research Committee (JRC) is requesting brief proposals that will be peer reviewed for both technical and business relevance. Individual projects will be funded through this mechanism and each project will proceed with project-specific deliverables. The JRC is charged with focusing on science and engineering that is not subject to exclusive licenses with third parties. There is a real desire to use DHTI funding to stimulate interdisciplinary collaborations between clinicians who are part of the Allegheny Health Network and CMU faculty. The JRC meets quarterly to assess progress in each of the projects requiring input from the project PI's on a quarterly basis.

Proposal Process: Funds are available immediately to support research. The deadline for receipt of proposals is **Monday March 9, 2015**. Discussions with PIs will be initiated in April and funding decisions made at the beginning of June for a June 30, 2015 start date. DHTI will be delighted to discuss details and field any questions prior to the investigator's submission. Please contact cemig@cmu.edu (x85214) and visit www.dhti.cmu.edu to review the online submission forms.

Request for Proposals

DHTI is seeking proposals from CMU faculty directed at addressing pressing issues in health care and improving community health and wellness. Proposals will be competitively reviewed based upon the following factors:

- Impact to the population and appropriate leverage of benefit to the individual and the population as a whole with cost consideration.
- The likelihood that success would improve quality of life and/or safety for patients
- Inclusion of tangible work products / deliverables that represent meaningful (further fundable) milestones if successful
- Science/Engineering
- PI experience
- Novelty of approach
- Technical risk (moderate risk is acceptable)

Awards are intended to support research that identifies disruptive health care innovations which can be clinically tested and rapidly delivered to a clinical setting or practice in the field. The research team for the project must be in place and details about the team should be included in the proposal submission. Fully funded projects are expected to have a 1-2 year duration and generally range in cost between \$100-300k (Total cost including full indirect costs). Proposal budgets that reflect an effort to minimize costs while delivering high impact have an increased chance of being funded. **Preference will be given to projects that offer near-term deployment potential.**

Based on the results of several years of strategic horizon-mapping and subject matter retreats, key areas have been identified in each funding cycle as areas of focus for the institute. Since 2013, DHTI has reviewed 97 project proposals and awarded nearly \$4M to 29 projects.

2015 proposals shall consist of the following:

- Completed proposal template with budget form (included in this document)
- White paper not to exceed 8 pages including brief description of background and technical approach
- Work experience of the team and the value proposition for the innovation
- Quad chart (template available at www.dhti.cmu.edu)
- Budget (CMU costs only) (template available at www.dhti.cmu.edu)

We have identified technical focus areas in which we believe innovation is likely to lead to rapid gains in healthcare quality and affordability. DHTI specifically seeks proposals in the technical focus areas listed below but we are open to any proposals that the faculty deems relevant, provided they meet the criteria for leading to measurable, short term, impact on healthcare quality and affordability.

Technical Focus Areas

I. Medical Diagnostics: Medical diagnostics continue to improve in their ability to detect biomarkers for diseases and the symptoms brought on by such diseases. This focus area seeks the development of diagnostic tests that are simple and inexpensive to administer, are widely accessible to the general population, and may identify conditions that will alert a patient to a significant health risk. The tests need not be definitive but should have sufficient sensitivity and specificity to generate a referral to a medical specialist without imposing a financial burden on the patient and payer.

One area of rapid growth is in the use of “omics” to target therapies to patients. The advent of affordable human whole genome sequencing opens the door to combining sequence data with claims and health data in order to predict wellness. This would enable preventative personalized medicine to become a reality. We are particularly interested in proposals that use advanced data analytics to extract meaning from genomic and claims data.

Advanced imaging is a powerful diagnostic aide, but has become dramatically over-utilized and expensive. We remain very interested in proposals that increase the quality of simple imaging techniques such as ultrasound.

Medical diagnostics in the home are increasing in number and effectiveness. We are interested in proposals that develop in home diagnostic tests to promote wellness.

II. Transforming Care Delivery:

Tele-medicine and tele-health: For most of the 1800’s US healthcare was provided in the homes of its citizens. Hospitals and physician offices became popular in the late 1800’s because a) centralization facilitated medical education, b) the development of specialist medical providers, and c) technical innovation led to the development of large, complicated, and expensive instruments and diagnostic equipment that required central location. Citizens began to become accustomed to traveling for their care.

Recent technical innovations have initiated a reversal of this phenomenon. The proliferation of high resolution video systems, smart phones, easy-to use peripherals, and information routing capabilities has enabled ‘virtual’ visits. Such visits may be done patient to provider in real or near-real time as well as via provider-provider consults. Even more recently, payers have begun to recognize the value and convenience of these virtual visits and have instituted mechanisms by which they may be reimbursed in the same manner as a conventional visit. Furthermore, payers are beginning to flex their reimbursement policies when business cases are presented that utilize telemedicine technologies that not only

improve patient access to care and quality of care, but minimize the overall cost of providing care by reducing unnecessary readmissions and decreasing length of stay.

Issues around payment, effectiveness and whether patients will trust telemedicine consults are emerging but the drive toward tele-medicine and tele-health is in full movement. Many large and small companies are investing \$billions in the underlying technology and the opportunity space for translational research must be carefully refined. Our interest would be in research that can be piloted rapidly in order to measure success.

We are interested in technology that will facilitate virtual visits. This might be technology that sits with a patient and makes it easier for a provider to manage a real-time virtual visit. It could also be a peripheral that would enable the home-based collection of data not otherwise possible today. It is important to note that this is a particularly active area of technology development across the globe. We are interested in novel systems or ones that can integrate multiple existing capabilities to generate a truly unique system. Provider reimbursement is oftentimes a limiting factor when considering innovative concepts in this arena. It should not be when considering ideas for this topic. We are particularly interested in how human computer interaction can be optimized to deliver tele-psychiatry in which trust building is critical.

Operating Room Efficiency: Operating room services are highly complex entities within the health care environment. Each day hospital staff is required to orchestrate a highly complex sequence of efforts to provide complex care. We are seeking proposals that aim to improve operating room efficiency in the arenas of patient flow, communication, scheduling, equipment and instrument processing, operating room organizational structure, turn-over times, and perioperative services. Proposals should center on specific and quantifiable challenges. Proposals that present the potential for extrapolation to other aspects of operative services are encouraged.

III. Chronic Disease Management: Chronic diseases and conditions such as heart disease (chronic heart failure), COPD, stroke, cancer, and diabetes are among the most common, costly, and preventable of all health problems.

- As of 2012, about half of all adults (117 million) have one or more chronic health conditions. One of four adults has two or more chronic health conditions.¹
- Seven of the top 10 causes of death in 2010 were chronic diseases. Two of these chronic diseases, heart disease and cancer, together accounted for nearly 48% of all deaths.²

The cost of chronic diseases and health risk behaviors associated account for the majority of all US health care and economic costs.

- Eighty-four percent of all health care spending in 2006 was for the 50% of the population who have one or more chronic medical conditions.³
- The total costs of heart disease and stroke in 2010 were estimated to be \$315.4 billion. Of this amount, \$193.4 billion was for direct medical costs, not including costs of nursing home care.⁴
- Cancer care cost \$157 billion in 2010 dollars.⁵

There are many initiatives underway to educate the population on key risk factors, improve disease management and improve patient compliance with prevention and treatment programs. This topic seeks novel and innovative programs that may lead to improved outcomes and reduced system-wide costs for caring for this patient population in the following areas: heart disease, stroke, cancer, and diabetes.

1. Ward BW, Schiller JS, Goodman RA. Multiple chronic conditions among US adults: a 2012 update. *Prev Chronic Dis*. 2014;11:130389. DOI: <http://dx.doi.org/10.5888/pcd11.130389>.
2. Centers for Disease Control and Prevention. Death and Mortality. NCHS FastStats Web site. <http://www.cdc.gov/nchs/fastats/deaths.htm>.
3. Robert Wood Johnson Foundation. *Chronic Care: Making the Case for Ongoing Care*. Princeton, NJ: Robert Wood Johnson Foundation; 2010:16.
4. American Heart Association. Heart Disease and Stroke Statistics—2014 Update. AHA Statistical Update
5. National Cancer Institute. Cancer Prevalence and Cost of Care Projections www.costcareprojections.org

IV. Computational Health Care: Despite a strong commitment to delivering quality health care, persistent problems involving medical errors and ineffective treatment continue to plague the industry. **We seek proposals in the following areas:**

Data Mining and Machine Learning: Healthcare payers have medical claims data that is commonly used for member risk stratification, pricing insurance products, and financial reporting to regulatory agencies. A number of recent partnerships between data holders and analytical firms profess to make use of data for identifying healthcare trends, non-traditional disease markers, and a variety of ancillary uses. **We seek proposals for the development of automated tools that use healthcare claims data in (among others):**

- Improving the accuracy of medical claims coding
- Identifying fraudulent or errant claims
- Identifying significant outliers from commonly accepted medical practices
- Detecting trends that may identify new risk factors for future member adverse events

Wearable Devices: The influence of wearable technology has become an integral part of entertainment, communication and education. According to TECHanalysis Research, a smart wearable device is defined as a battery-powered, portable electronic device worn on a human body that offers some level of onboard processing and runs some type of integrated software.¹ Most wearables have integrated sensors of various types attached to the body that detect and monitor changes in body signatures of various areas and organs. In addition, they integrate connectivity options (either wired or wireless) to other smart devices, such as smartphones.

For the purposes of this RFP we are defining Wearable Health and Diagnostic Devices as those that:

- are meant to be worn by the person 24/7 (as opposed to discrete testing devices or monitoring systems that are not wearable)
- record measurements relating to health or sickness monitoring (as opposed to exercise)

CMU innovators, in collaboration with clinical partners, can build on the excitement in this space while also matching data analytics and machine learning expertise to disrupt the delivery of healthcare. We can develop technology and wearable devices to support doctors in the operating room, arm patients with real-time feedback and provide access to electronic health records to unleash valuable information that can bring transformational improvements in the delivery of health care solutions and patient care.

According to a market research report published in *Modern Healthcare*, the worldwide market for mobile health applications reached \$2.4 billion in revenue in 2013 and will grow to \$26 billion by the end of 2017.² Even if the apps related to fitness monitoring are currently the most popular, by 2017 this trend will change to apps involving remote monitoring and consultations gaining the highest business potential.

The PwC report, *The Wearable Future* states, “human-centered design is critical to the success of wearable devices—design thinking must be embedded in disruptive strategy and innovation, with a focus on optimizing the customer experience and use.”³ Much of what is available to users today lacks impactful user value and consistency of data. In order for the industry to advance, data from the wearable devices will need to be integrated in a broad exchangeable system, rather than acting as a standalone data point, as it does now, in a very finite experience between a one device and its supporting app or mobile interface. CMU can seize on the opportunity to create devices enabled with analytics to help users manage their health and position healthcare organizations to improve care and reduce costs.

Healthcare information has traditionally been extremely disconnected. Finding ways to integrate, aggregate and analyze incongruent data can be challenging and expensive, but is required to push healthcare toward cost-effective, evidence-based treatments and outcomes.

CMU has the opportunity to address the fundamental failing of today’s wearables. It is not enough to have more and more data and massive amounts of information for the sake of just gathering information. Instead, users need insights that are tangible and actionable. CMU innovators can disrupt and change the value and adoption of wearable technology, specifically in healthcare applications, by leveraging expertise to develop platforms that generate accurate information in real-time, sort and synthesize that information using advanced analytics and machine learning and create human-centered devices that provide insights leading to better health decisions or specific changes in behavior.

As is the case in tele-health, many companies are investing huge resources in the wearables space. DHTI must focus resources in ideas that are transformative in the context of those very large investments.

We are seeking proposals in 4 primary areas:

- influencing behavior change (high value target: hospital readmission due to non-compliance)
- movement analysis (hot area: fall prevention)
- mental health (including depression)
- improved heart monitoring

1. TECHnalysis Research. TECHnalysis Research Worldwide Smart Connected Devices Forecast Update

<http://www.technalysisresearch.com/press%20releases/2014%20Press%20Releases/november-3-2014-November-Wearable-Forecast.html>

2. Modern Healthcare. Mobile health app revenue to grow tenfold by 2017, study predicts
<http://www.modernhealthcare.com/article/20140522/blog/305229997>

3.PwC- PricewaterhouseCoopers. The Wearable Future.

<http://www.pwc.com/us/en/industry/entertainment-media/publications/consumer-intelligence-series/index.jhtml>

V. Behavioral Health: Major depression is a mental health condition defined as a mood disorder, a disabling condition in which feelings of sadness, loss, anger, or frustration interfere with daily life for weeks or longer. It negatively affects the patient, the patients' family, work or school life, sleeping and eating habits. Major depression involves the patient's body, mood and thoughts.

Without effective treatment, symptoms can last for weeks, months, or years. Depression is a common, serious illness and most people who experience it need treatment to get better.

Statistics indicate that 9.1% of adults¹ and approximately 11 percent of adolescents² suffer from depression in the United States. According to the World Health Organization, major depressive disorder is the leading cause of disability among Americans age 15 to 44.

Depression can adversely affect the course and outcome of chronic conditions, such as COPD, asthma, cardiovascular disease, cancer, diabetes, and obesity and can be accompanied by alcohol and drug use disorders and anxiety disorders. Depression also can result in increased work absenteeism, short-term disability and decreased productivity leading to estimated costs to employers of \$34 Billion per year in direct and indirect costs³. Some of the present challenges in the mental health field are due to diagnoses being heterogeneous and the lack of valid, objective, scientific diagnosis and specific biologic markers to detect mental health problems. Currently, depression is diagnosed by patients reporting their own symptoms. According to studies involving large number of patients, primary care physicians diagnose correctly less than half of patients with depression. We seek proposals that aim to improve the screening, early detection, assessment, treatment, treatment monitoring and prevention of relapses in depression. The

development of biomarkers and novel biomarker detection strategies are of special interest.

1 *CDC*

2 *(National Comorbidity Survey-Adolescent Supplement (NCS-A))*

3. *University of Michigan Depression Center*

VI. Other: This is an open ended topic for proposals that have the potential to improve the simplicity, accessibility and cost of healthcare while enhancing the overall quality of life of members and patients. Applications submitted to this area should include a clearly defined value proposition for the proposed innovation as well as estimates on the number of impacted individuals and financial savings should the effort be successful.

SUMMARY

Our technical areas of interest and suggested proposal topics are summarized below.

I. **Medical Diagnostics**

II. **Transforming Care Delivery**

III. **Chronic Disease Management**

IV. **Computational Health Care**

V. **Behavioral Health**

VI. **Other**



TECHNICAL PROPOSAL TEMPLATE

SOLICITATION #3 – 2015

Deadline: 12:00 p.m. Monday March 9th, 2015
Submit online at www.dhti.cmu.edu

INSTRUCTIONS: Please use this form to submit your proposal. Fill-in complete answers for all questions. Submit this form and a white paper (not to exceed 8 pages) along with your completed budget form and quad chart.

1. **Project Title:**
2. **Spex #**
3. **CMU Research Team:** List PI's (name, affiliation and email address) and anticipated student involvement (name, degree program, anticipated completion date, curriculum/department)

PI:
Graduate Students:
Undergraduate Students:
4. **Highmark/AHN Research Team:** List PI's (name, affiliation and email address) and anticipated involvement.
5. **External Project Participants:** List name and complete address including zip code of company or agency as well as a point of contact (name, title, and email address)

Non - University Partner:
Partner PoC:
6. **Executive Summary (Abstract) of Project:** (limit of 200 words; Executive Summary will be used for public dissemination if project is awarded)

7. Human Subjects:

Will this project involve any activities with humans or their data?

- Yes
- No

Check all project characteristics that apply:

- Conducted at CMU
- Conducted at another location
- All or part of the work carried out by CMU faculty, staff or students
- All or part of the work carried out by non-CMU individuals
- Includes interaction or intervention with a living individual
- Includes review of data derived from humans (data that may or may not be personally identifiable)
- Uses a device, algorithm, system, software, etc. developed and/or modified at CMU

8. Intellectual Property

Does the research build upon any existing IP at either CMU and/or AHN? If yes, please identify by disclosure and/or patent/patent application #s.

Was this background invention developed in collaboration with any other 3rd parties (companies, universities, etc.) or as a part of a consortium? Please state yes or no. ____

Have you used any third-party resources in the creation of your technology (i.e. material or equipment from a company or university under a Material Transfer Agreement (MTA) or other formal or informal agreement)? Please state yes or no. ____

Have you used any software, libraries, etc. from other internal (e.g., CMU) sources (ex. projects or researchers) in the development of this technology or does the technology otherwise build upon earlier work at CMU? Please state yes or no. ____

Have you used any Open Source software in the development of this technology? Please state yes or no. ____

Do you know of any other inventions which are related to this invention? Please state yes or no. ____

9. Please identify the technical focus area to which this proposal is directed:

- Medical diagnostics
- Care delivery transformation
- Chronic disease management
- Computational Health Care
- Wearable Devices
- Behavioral Health
- Other

PROPOSAL SUBMISSION

In 5-8 pages, the submission should convey the unmet clinical need, market potential, uniqueness and protectable nature of your research including path to market/clinical use.

The body of the proposal must include:

1. Summary of preliminary data.

- Current research progress that supports the proposed technology
- Information supporting the efficacy of the proposed technology

2. A description of the unmet clinical need.

- Number of patients affected
- Health care expenditures for treatment and/or diagnosis
- Future trend of the problem

3. The proposed solution and scope of work.

- The proposal must be as focused as possible on the development of an innovative technology and novel solution for the identified problem. We are focused on proposals with translational solutions as opposed to academic and those that add to the general body of knowledge.
- Comparison to standard of care and competitive marketplace. Discuss competing technologies if any.
- Include if and for how long your investigative team has worked together on the proposed solution.

4. Research and Development timeline.

- “Bench to bedside” time taking into consideration technology feasibility, proof of concept, product development, verification and validation, manufacturing and regulatory considerations.

5. Intellectual property status.

- Include invention disclosures, patent applications filed, shared IP ownership with others, patents awarded and/or technologies licensed, related to the proposed technology, including third party IP.
- DHTI is interested in proposals with unencumbered IP.

BUDGET INFORMATION AND RESTRICTIONS

- Deadline for Submission: Monday March 9th, 2015
- Period of Performance: June 30, 2015 – July 1, 2017
- No faculty salary allowed without pre-approval
- Indirect rate: 54.1%
- SPEX number required for submission
- Graduate student support: Use standard tuition/stipend rate for your department.
- Benefits rate: Please use current non-federal rate of 28.3%
- Sub-contracts: Provide budget, justification, Statement of Work, and contact info
- Budget cap: \$300,000
- Inflation rate: 3%
- No capital equipment without prior approval
- Budget Template: Download from www.dhti.cmu.edu

Questions:

For questions regarding DHTI, pre-Award and post-Award activities and requirements, and/or preparation of proposals, please contact:

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