Title of proposed program: *Mobile Health (mHealth) Technologies for Medical Diagnostics in NIH Mission Areas (SBIR/STTR)*

Note to Council of Councils members: The Common Fund does not have an SBIR/STTR pool of funds, so if this program were implemented through the Common Fund, it would not be an SBIR/STTR program.

What is the major obstacle/challenge/opportunity that this concept should address?

Mobile health (mHealth), defined as "mobile computing, medical sensor, and communication technologies for healthcare," refers to a new approach to health care based on mobile communication devices such as cell phones and tablets. mHealth is an emerging field of medical technology, where in the last few years many new software applications (apps) have been developed to do things such as assist the public in making healthy dining choices and monitoring physical activity while on the go. However, there have been very few devices developed of the type that can monitor health vital signs in the field, capture medically actionable physiologic measurements (such as an individual's combined blood count), and that are regulated as a medical diagnostic device by the FDA. A recent publication from the IMS Institute for Healthcare Informatics listed approximately 24,000 mHealth apps that are genuinely health care-related. While 16,000 of these apps are focused on an individual's health only a small subset of 159 apps require sensors and make clinical measurements. In 2012, the total industry investment for mHealth was only ~$12 million for diagnostics out of a ~$907 million total for mHealth-related technologies. These data suggest that industry investments in mHealth-based diagnostic technologies have been limited. However, the potential impact of mHealth diagnostics on public health is great due to the rapid development and proliferation of mobile devices with significant computing power and the ability to equip these devices with useful sensors. These sensors have broad potential applications ranging from utilizing phone accelerometers to quantify Parkinson's disease, to phone-based EEG, ECG, ultrasound, cytometers, and microscopes, to devices for environmental exposure analysis and microbial analysis. Thus far, the limited industry investment in mHealth diagnostic devices has been focused on "low hanging fruit" in terms of relatively simple instrumentation. With the notable exceptions of a microendoscopy tool for cervical cancer detection (funded by NIH) and a device for skin lesion imaging, the fields of cancer and other complex diseases are lagging in the development of mHealth diagnostic technologies. This is in spite of the many potential applications for mHealth including cancer screening, early detection, diagnosis and treatment monitoring. mHealth is especially important for low- resource settings, and underserved areas and populations. This is because of the potential of simple, portable devices to provide health capabilities that are otherwise not feasible and that can reduce health disparities.

Challenges: One of the main challenges in developing mHealth technologies for complex diseases is the limited number of developers working on technologies for these diseases (see above). Current mHealth technologies were developed for simple measurements and do not have the capabilities to address the challenges of complex diseases which require multifactorial analysis. While many current mHealth technologies were developed by independent entrepreneurs targeting well-defined medical devices (e.g. the stethoscope, EEG, ECG, microscope etc.), the multidisciplinary nature of complex diseases research requires broad expertise and medical infrastructure. For example, there are a large number of detection and diagnostic modalities (imaging, elastography, cell-based assays, *in vitro* assays etc.) which when combined with the complexity of diseases such as cancer, infectious disease, cardiovascular disease, and diabetes, require high-level and broad expertise which cannot be easily accomplished by independent entrepreneurs. Another challenge is to bring technology to clinics especially in low-resource settings.

Opportunities: There are great opportunities for mHealth with the high computing power and inherent connectivity of low-cost mobile devices. In addition, high quality imaging and electronic interface capabilities, along with great portability offer opportunities to develop cutting-edge, 21st century medical technologies. For example, a recent publication described the use of a smartphone as a low-cost flow cytometer; this may allow future development of simple mHealth analyzers to detect Circulating Tumor Cells (CTCs) on the go. Another possibility is that this device could be adapted to CD4/CD8/CD3 T cell counting. Both applications require multiplex fluorescence-based blood analysis. This would extend access to clinical cytometry measurements well beyond the urban areas where they are used today, to smaller practices and clinics anywhere. Similarly, a recently developed

mHealth ultrasound device could be adapted (e.g. with the appropriate probe and software) to aid breast cancer screening or gynecologic care. The revolution in mobile communication technology and "big data" analysis also offers tremendous opportunities to actively prevent or manage many other diseases such as infectious disease, cardiovascular disease, diabetes, neurodegenerative disease, or stroke. Broad access to tests in community settings, especially remote areas, will empower patients to gain faster access to diagnosis and treatment.

What would the goals of the program be?

The aim of this program is to use the SBIR and STTR mechanisms to fund mHealth medical device projects. The projects would include those focused on cancer, infectious disease, cardiovascular disease, diabetes, neurodegenerative disease, or stroke, etc. The teams should include research groups with strong engineering, clinical, and translational capabilities to develop and deploy new mHealth devices. The SBIR and STTR mechanisms will require the formation of teams that will include the small business as well as scientists from academia who will provide scientific and clinical infrastructure (hospitals, clinics, cancer or cardiovascular centers, access to patients, medical expertise, etc.) that are lacking in many small business environments. Small businesses will bring the expertise on the developer side which may include new device technology development, adaptation and integration of existing technology with mobile technologies as well as the development of the operator/user experience. These teams would focus on developing mHealth technologies for screening, early detection, risk assessment, exposure analysis, diagnosis, treatment monitoring or other medical applications. They would also test the utility and effectiveness of these devices, and bring the technologies to clinics and users.

This program is intended to stimulate the sharing of ideas and technologies between innovative small business concerns and non-profit research institutions. The program will also enable and promote collaboration among, engineers, clinicians, and public health scientists needed for the development and commercialization of the next generation of mHealth technologies.

Proposed research organization and scope: All regular SBIR/STTR mechanisms (R41-R44) will be used. The research proposals will be reviewed by a special *ad hoc* panel through the Center for Scientific Review. The funded projects will be managed as standard SBIR or STTR grants. The Phase I SBIR or STTR grant will be for feasibility testing of the technology, with a project duration of up to 1 year in order to demonstrate technical functionality, proof-of-principal data, and clinical potential in disease-specific applications covering the entire NIH mission areas. The primary focus of the Phase II SBIR or STTR grant is to conduct appropriate validation trials in animal models and/or human subjects. Each applicant team will have four required areas of expertise, as listed below. Additional activities for behavioral or health disparities research are optional but encouraged in the application.

Description of Needed Multidisciplinary Expertise to be Successful in this Program:

1. **Technology**– engineering expertise needed to develop the hardware, including sensors, transducers, and the mobile device interface.
2. **Clinical** - expertise in the disease or medical specialty of focus (e.g. oncology, cardiology, kidney diseases, medical diagnosis and treatment), as well as in public health is needed to ensure clinical effectiveness and utility.
3. **Translation -** expertise in regulatory affairs, clinical trials, and training, with a focus on developing and implementing strategies for bringing the technologies to the clinics and users.
4. **Computation, communication and remote analysis** – expertise in software, user-friendly interfaces, data management and analysis, communications, networks, cloud and telemedicine features.
5. **Health disparities (optional) -** expertise in health disparities and health care delivery (clinical and community-based settings) in underserved populations is required to deploy mHealth devices in underserved areas in the United States.
6. **Behavioral (optional)** – expertise in behavioral monitoring, health behavior change, and communications for project-related disease prevention or management targets (e.g. remote care plan management).

Why is a trans-NIH strategy needed to achieve these goals?

A trans-NIH strategy is valuable because mHealth diagnostics have applications in many NIH mission areas, and furthermore one mHealth smart phone device could be used as a common platform for the analysis of several diseases. For example, a mHealth microarray reader developed for cancer biomarkers could be modified/adapted for the analysis of microbial pathogen DNA, cardiovascular protein markers, or for early

detection of kidney diseases. A trans-NIH strategy with input from various ICs (with medical/translational/behavioral expertise in those disease areas) will ensure that the needs for such adaptation will be met, and that the resources and benefits of investment by one institute can be shared across NIH to address the missions of many other ICs.

What initiatives might form the strategic plan for this topic?

This topic could include additional follow on IC-specific technology development FOAs to develop mHealth devices and applications for individual diseases, leveraging the work supported by the first, NIH-wide FOA. For example, mHealth devices for early cancer detection using protein blood markers could be adapted for early detection of protein markers associated with myocardial infarction. mHealth DNA-based analysis devices for cancer screening could be adapted for HIV screening. For analysis of neurological disorders and stroke, new mHealth carotid ultrasound, mobile EMG and improved EEG devices could be developed. Due to the versatility of the mHealth platform, the strategic plan will include the clinical and analytical needs of the various NIH ICs. Additional follow on FOAs could target later stages of product commercialization, such as translation and adoption of developed mHealth technologies in the marketplace, with an ultimate goal of self-sustainment (with no need for further federal support).

If this topic is funded and achieved its objectives, what would be the impact?

The impact of the program will be broad, with new business opportunities developed, new businesses created, and new jobs created. The new low-cost mHealth technologies created will have the potential to change management and care practices throughout the health care arena, and to reduce the cost of health care. Importantly, the program will significantly improve access to medical diagnostics devices for disease screening, detection/diagnosis, and monitoring. This is especially true for low-resource areas where access to such devices is currently limited, affording an opportunity to significantly reduce health disparities.