**BIO: Chronic monitoring of biomarker(s) for a lifestyle disease**

### **PROBLEM STATEMENT**

Disease burden in the developed world as well as many developing nations continues to shift toward so-called ‘lifestyle’ diseases like cancer, heart disease, and psychiatric disorders. At the same time, the penetration of digital mobile communications technology, i.e., smartphones, has increased to over one-fourth of the total global population. These concurrent trends create opportunities to introduce micro to nanoscale materials, processing, and/or devices that could support chronic monitoring of an individual’s biomarker(s) for a lifestyle disease. Possibilities for chronic monitoring range from ‘real-time’ readout of biomarker(s) status to a periodic assessment at a frequency sufficient to enable informed changes in personal choices that have potential to alter disease onset and/or trajectory. Selected candidate biomarker(s) must have demonstrated relevance to the lifestyle disease; support user-informed choices and/or changes in lifestyle that are demonstrated to impact the onset or progression of the disease; and be well-suited for chronic monitoring. To be viable, the envisioned material, process and/or device must be biocompatible, secure, mobile, user-friendly, accurate, and designed to encourage high user adoption rates. Glucose monitoring of diabetes offers proof of principle that chronic monitoring of biomarker(s) can affect disease progression. However, monitoring of glucose, heart rate, electrocardiogram, blood pressure, respiration rate, blood oxygen, pulse oximetry, hemoglobin, plethysmography, skin temperature, prostate specific antigen, sleep, body mass, food or drink intake, calories burned, or body movement (e.g., steps, swim strokes, sleep movement or development of accelerometry or global position system technology of any kind) are specifically excluded from consideration.

You are the Chief Technology Officer of a company that has specialized in creating innovative, wearable sensors, transceivers, and data analysis and communication systems. Your CEO believes that the company’s expertise in micro to nanoscale materials, processing, and devices could provide a research and development path for a sensor, transceiver, data analytic and/or communication element that meets the demanding needs of chronic monitoring of biomarker(s) for a lifestyle disease. Your job is to identify, design, and develop an element or suite of elements that draws from the specific expertise and resources in your organization to provide an innovative platform that contributes in a meaningful way and has significantly enhanced properties and performance relative to competitors’ state of the art capabilities. Your job as CTO is to deliver a complete proposal with your plan for the company to compete in this area to your CEO by your Tuesday morning, January 16, 2018 deadline.

### **YOUR DELIVERABLE**

Your task is to write an internalproposal for your corporate officers describing your idea for research and development. The proposal should include the following:

* Executive summary (one page)
* Risk assessment roadmap form (one page)
* Full proposal (15 pages maximum)
* Appendix A: List of references (no page limit)
* Appendix B: Ranked list of intellectual property documents examined (no page limit)

**Most Importantly** – The significance and novelty of your creative solution, one that moves the boundaries of knowledge outward, will be the primary assessment focus of your review panel. The list below is just a minimum list of issues you might consider. There may be many more. The point is that your proposal ***should contain the evidence*** needed to make an effective and compelling case to your CEO in order to insure that she/he makes the right decision.

**At a minimum, be sure you address all of the following:**

**Current Science and Technologies** - What is already being done in this area by other researchers, companies and governmental institutions? Describe the current state-of-the-art for both the science and the implementation. Use diverse resources such as science literature, journals, conference proceedings, the internet, patents or other sources of existing public knowledge. ***Cite all references you use and use quotes for any word-for-word transfer to your report.***

**Your Design Approach –** What is the basis for your design approach to the problem? Why is your technology better than existing technologies? What technology attribute(s) make it likely to penetrate the market and be selected by health-conscious users and medical professionals? Address scientific *and* engineering aspects of these questions.

**Testing and Qualification** - Describe a set of tests you will use to demonstrate that your approach is effective and that your implementation of the solution will launch successfully.

**Cost Analysis** – Identify cost and market issues that will impact the pricing strategy of the solution you have proposed. Consider such things as: the major cost items that would impact the implementation; which elements of your implementation solution would be handled in-house versus externally-sourced; major risk elements that could drive up costs if the primary path item fails; costs of IP licensing needed, etc. Provide justification and/or reasoning behind your decisions. Estimate manufacturing cost as the technology reaches mature stage, so the marketing team can determine potential for penetrating other markets. Avoid subcontracting manufacture or assembly of any proprietary component outside the company, because the CEO is concerned with potential IP leakage.

**Intellectual Property** – In Appendix B, list in rank order of importance ***all*** commercial, academic, and governmental IP sources that were consulted while formulating the answer, including reference data. For instance, include the patent number; title; inventor name; and assignee name for a patent. Discuss the 3 most significant IP documents affecting your approach to your solution in the 15-page document. Compare strengths and weaknesses of these approaches relative to your own. Recommend how these IP threats should be handled.

**Hint –** Clearly state your hypothesized solution. Identify its innovation(s) and advantages relative to state of the art. Describe both existing data, and work needed to support each aspect of the hypothetical solution. Consider theoretical, fabrication, and characterization aspects: for each, identify software/equipment and methods to use, parameters to vary, anticipated outcomes, and possible alternatives in the event of unsatisfactory results. Discuss material, process, device, and systems aspects of your solution. *Refine* your hypothesized solution as you accumulate information and prepare the manuscript. **Remember**: clearly distinguish what is known from what is hypothesized or not known. What is needed to distinguish the important things to know?

*Reference the 2018 PhD Candidacy Exam Guidelines document for general instructions.*