

BIO – Nanomaterials for Biomedical Sensors and Devices

Problem Statement

The mission of the National Institute of Biomedical Imaging and Bioengineering (NIBIB) is to improve health by leading the development and accelerating the application of biomedical technologies. The Institute is committed to integrating the physical and engineering sciences with the life sciences to advance basic research and medical care. This is achieved through: research and development of new biomedical imaging and bioengineering techniques and devices to fundamentally improve the detection, treatment, and prevention of disease; enhancing existing imaging and bioengineering modalities; supporting related research in the physical and mathematical sciences; encouraging research and development in multidisciplinary areas; supporting studies to assess the effectiveness and outcomes of new biologics, materials, processes, devices, and procedures; developing technologies for early disease detection and assessment of health status; and developing advanced imaging and engineering techniques for conducting biomedical research at multiple scales. For this exam we are interested in nanoscale and microscale solutions.

Nanotechnology Focus

This topic is focused on research and development of new enabling technologies for the fabrication and use of nanoscale components and systems in diagnostic and therapeutic applications. *Of specific interest are new approaches to the sensing and quantification of biologically important molecules using nanoscale specific properties.*

In regards to using emerging nanotechnology for biological sensing and/or treatment capability, the list of diseases and etiological agents of operational concern are listed below. The strongest need will be for the detection and/or treatment of undifferentiated febrile illnesses. *You may choose one of the following infectious agents to aid in defining the scope of your proposal.*

- Influenza
- Pneumonic Plague
- Dengue
- Endemic typhus
- Scrub typhus
- Leptospirosis
- Chikungunya
- Lassa Fever
- Crimean-Congo Hemorrhagic Fever

You are the Chief Technology Officer of a company that has specialized in creating low volume customized high reliability electronic systems for specific applications in a wide range of operating environments (clinic, hospital, field, etc.). Your CEO believes that the company's expertise in micro to nanoscale materials, processing, and devices could provide a research and development path to meet NIH's objectives in their solicitation. Your job is to define the research and development needed for new base technologies that would provide the platform for many future biodetection systems and biosafe treatment (infectious agent detection and treatment, drug delivery, etc.), and perhaps even expansion into other bioengineering markets.

While meeting the NIH performance requirements are your priority, the cost of customized systems for NIH biosensors, implantable devices, etc. will always be very high as compared to off the shelf commercial systems. In order to have potential to be competitive in other market applications which value compact, high-performance biosensing (point of care facility, remote medical facilities, small clinics, etc.), it is desirable if your approach can be easily modified or adapted for lower price-point markets.

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 Monday morning, January 13th deadline.

YOUR DELIVERABLE

Your task is to write an internal proposal 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 and 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 be selected by NIH? Address scientific *and* engineering aspects of these questions. Where relevant, consider: device size, weight and power (SWAP) requirements; materials of construction; critical components and considerations that comprise the complete device-level or subsystem-level solution; and what are the required prototyping and/or production methods, tools and costs? ***Even if you are not an expert in all of the technological areas required to bring the end-product to fruition, you should at least be able to intelligently discuss the other critical components, considerations and R&D requirements.***

Research & Development Plan - Describe a set of tasks and/or tests you will complete to demonstrate that your approach is effective and that your implementation of the solution is meritorious of further R&D. ***This is essentially your design of experiments. What are your objectives? What are the tasks required to achieve those objectives?*** Where applicable answer the following:

- i) What are the key product specifications that you are targeting and how do they compare to the specifications of the existing solution(s) if any exist?
- ii) What mathematical models and/or simulation constructs will you use to validate your approach, especially if prototyping and test trials are costly?
- iii) What are the key dependent and independent variables that you must utilize and evaluate to confirm the proposed solution works?

Above all, be specific and detailed about the key tasks to confirm feasibility and validity of what you are proposing.

Cost Analysis – Identify cost and market issues that will impact the pricing strategy of the solution you have proposed. Identify Strengths, Weaknesses, Opportunities and Threats (SWOT) in the market place. If you are unfamiliar with the typical SWOT marketing analysis, I encourage you to ‘google it’. 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 for the total system as the technology reaches mature stage, so the marketing

team can determine potential for penetrating other markets. Avoid subcontracting design, 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 2020 PhD Candidacy Exam Guidelines document for general instructions.