2019 Focused Solicitation
Request for Proposals (RFP)
Issued: 5/6/2019
White Paper Responses Due Date: May 24 2019
Full Proposals Due Date: July 3, 2019

1. NBMC Mission/Objectives

The Nano-Bio Materials Consortium (NBMC) was founded in 2013 to bring together scientists, engineers and business development professionals from industry, government and universities to collaboratively initiate research and development of electronic technologies to improve human performance monitoring and performance augmentation. Over 25 industry partners advanced the state-of-the-art in human performance monitoring over the course of the first 5 years of NBMC, executing 15 projects. The consortium-based R&D initiative, built upon this history of success, is moving to the next phase. The goal is to proactively build an ecosystem that can accelerate healthcare and medical electronics innovation towards products that serve society.

By creating a community of experts who conduct strategic gap analysis and vet the placement of public/private sector funding, NBMC focuses on specific challenges and opportunities early in the R&D process and raises the technology and manufacturing readiness levels (TRL/MRL) of nano- and bio-technologies. NBMC was formed in 2013 under a cooperative agreement with the U.S. Air Force Research Laboratory (AFRL) to SEMI-NBMC. AFRL and SEMI have partnered to focus on several key application areas for next-generation medical monitoring in the defense sector, but common enabling electronic technologies for health and wellness create an excellent example of dual-use opportunity.

Innovations in the public sector are springboards for new products in digital health and personalized medicine. Since 2013, seventeen separate programs with more than two dozen organizational participants developed materials, electronics, microfluidics, manufacturing processes and algorithms to create low cost, wearable sensors. Most of these integrated sensing systems communicate wirelessly, are flexible and incorporate high performance silicon devices that are designed to move with the individual. Previous advancements included subsystems designed for ECG, functionalized biomarker sensors and hydration sensors.

The NBMC program continues its next phase, with an emphasis on advanced electronics to develop technologies relevant not only to health monitoring but also diagnostics and performance augmentation. These innovations will lay the groundwork for new products in digital health and personalized medicine as well as for enabling new human-performance monitoring/augmentation capabilities and aeromedical-monitoring and diagnostics capabilities within the en route care mission for the US Air Force

The En Route Care (ERC) Aeromedical Evacuation (AE) system is a unique and significant part of the Department of Defense's mobility resources. Air Mobility Command is responsible for the strategic military medical evacuation of patients during peace, humanitarian, noncombatant evacuation operations, US and Joint contingency operations. Vital to this mission is the pursuit of new methods for transporting patients with increased effectiveness and efficiency. There are several challenges unique to this flight environment that may negatively impact patient health or device performance during transport which must be addressed: reduced barometric pressure, humidity, and oxygen availability, increased acceleration, vibrational forces and auditory noise, and ambient thermal instability.

The AE mission of tomorrow is to move towards autonomous and assisted care, including closed loop control systems and clinical decision support through AI. Physiological monitoring solutions in this austere environment which effectively address size, weight, power, and cost (SWaP-C) are the first step towards this longer-term vision. In addition, next-generation biochemical sensing capabilities and/or tools which provide additional context and clinical value above traditional vital signs monitoring are of interest.

Topics in this 2019 Solicitation are:

A. Wearable Device for Ambulatory Monitoring Capability
B. Wearable, Human-Biochemistry Monitoring Capability
C. Wearable, Cuffless Blood Pressure Monitoring Capability
D. Open Concepts for Wearable/Mobile Human-Monitoring/Diagnostic Capabilities

Further detail about each topic is listed the section titled Proposal Topic Detail, below.

Concept demonstrations (demos) must be part of the deliverables for consideration of an award. Clinical demonstrations are desired and partnership with end user for third party test and characterization is encouraged. End users can be defined as defense customers, commercial market segment customers, or in some cases the direct supply chain customer.

2. Proposal Process and Topics

The proposal process will start with a white paper submission. Members of the NBMC RFP Review Committee will review the white papers and recommend those for full proposal submission to the NBMC Governing Council. The point-of-contact for the submissions selected by the review committee for further consideration will be invited to submit a full proposal. Full proposals will be evaluated by the review committee based on a set of criteria that include budget, collaboration value, dual-use (commercial and military/aerospace) applicability, relevance to the ecosystem, relevance to advancing or demonstrating the role of nano-bio materials on human-monitoring, schedule & milestones, deliverables, and overall proposal quality. White paper and full proposal content requirements are listed in sections 6 and 7. Typical NBMC programs run from 9-18 months including a final report.

In soliciting these proposals, SEMI-NBMC plans to grant and administer funding which should be matched (50% of total project cost requested) with funds in the form of cash and in-kind contributions provided by the grant recipients to cover the total project cost. If all other criteria are equal, preference will be given to proposals with a higher percentage of cost share. It should be noted that historically, cost share for funded development programs has averaged greater than 60% industry funding. Project Teams of skilled technical resources from NBMC member companies will be identified to provide project oversight and direction. These Project Teams typically will be comprised of 2 to 4 experts from the consortium membership as well as members from the successful individual supplier or supplier team.

In responding to this solicitation, partnering among industrial companies or industrial company/ R&D organization/university teams is appropriate and is highly encouraged. Individual responses are appropriate where size, breadth and expertise are sufficient to cover effectively all areas (e.g., technical resources, financial stability, and market presence) critical to the successful completion of the proposal.

NBMC will support technical approaches that are novel, or game-changing thus having a more significant element of risk, as well as approaches that represent evolutionary improvements upon existing capability, which tend to be less risky and involve shorter development and delivery intervals. It is recognized that it may be desirable to include information that is considered confidential and proprietary by the submitter to fully and effectively convey the technical merits of the proposal. While a best effort will be made to restrict the proposal information to those with a need to know expressly for purposes of the review, it is

recommended that the inclusion of proprietary information be limited to the minimum necessary to convey the highlights of the technical approach.

With respect to intellectual property developed under a SEMI-NBMC contract, the following policy has been established to encourage suppliers to cooperate with SEMI-NBMC and AFRL in the accomplishment of their objectives:

> "Legal title to any technology developed under a NBMC funded research and development contract will be the property of the development partner."

Development agreements generally will be awarded on an actual cost basis, not-to exceed contracts, with payments to be made quarterly and based on milestones as presented in the proposal. If your institution has a U.S. government approved rate structure, use it. If not, the normal commercial cost accounting system used for internal R&D projects will be acceptable. The methods used to value "cost sharing" cost must be the same as those used to value the full project costs. All suppliers are expected to have a government approved or industry standard accounting system by which actual project costs are tracked and reported. This is an absolute requirement to be sure that cost share obligations are met.

A work breakdown structure should be the basis of project schedules, milestone definitions, and cost estimates. Cost estimates for each major step leading to completion of a milestone should be used as the basis for the amount from the grant to be paid. A spreadsheet showing these calculations should accompany each proposal. The same spreadsheet should also show the specifics of how you will contribute your matching share of the total costs of the development contract. Cost sharing expectations have been established in the master agreement between SEMI-NBMC and AFRL, and a minimum 50/50 cost sharing ratio between government and industry is targeted.

3. Research and Development Award Budget

Anticipation for this 2019 RFP solicitation is a cash budget range of $500k - $2M with an additional matching (or greater) cost share from the award recipient. Proposals may be from single institutions or a project team comprised of various companies and/or universities. Proposals from multi-institutional teams will be preferred.

4. TRL and MRL Entry and Exit Levels

The maturity of the proposed research effort should be assessed by a TRL or MRL definition. We seek innovations in the TRL4 through TRL6 showing clear technology maturation over the duration of the project. TRL/MRL levels are determined through the project team self-assessment as well as AFRL, or other designated end user assessment. Proposers should consider the definitions of TRL and MRL and reference specific elements within the TRL category that will enable the maturation of the technology. Primary focus by the RFP review team will be on the justification and maturation of TRL, however, reference to MRL awareness should be included.

The definition of the TRL and MRL levels are described below:

TECHNOLOGY READINESS LEVEL DEFINITIONS

TRL 4. Component and/or breadboard **validation** in laboratory environment

- Basic technological components are integrated to establish that they will work together
- Relatively "low fidelity" compared with the eventual system
- Examples include integration of "ad hoc" hardware in the laboratory

TRL 5. Component and/or breadboard **validation** in relevant environment

- Fidelity of breadboard technology increases significantly
- Basic technological components are integrated with reasonably realistic supporting elements so they can be tested in a simulated environment
- Examples include "high-fidelity" laboratory integration of components

TRL 6. System/subsystem model or prototype **demonstration** in a relevant environment

- Representative model or prototype system, well beyond TRL 5, tested in a relevant environment
- Represents a major step up in a technology's demonstrated readiness
- Examples include testing a prototype in a high-fidelity laboratory environment or in simulated operational environment

MANUFACTURING READINESS LEVEL DEFINITIONS

MRL 4. Capability to produce the technology in a laboratory environment

- Required investments, such as manufacturing technology development identified.
- Processes to ensure manufacturability, producibility and quality are in place to produce demos.
- Manufacturing risks identified for prototype build.
- Manufacturing cost drivers identified.
- Producibility assessments of design concepts have been completed.
- Key Performance Parameters (KPP) identified.
- Special needs identified for tooling, facilities, material handling and skills.

MRL 5. Capability to produce prototype components in a production relevant environment

- Mfg strategy refined and integrated with Risk Management Plan.
- Identification of enabling/critical technologies and components is complete.
- Prototype materials, tooling and test equipment demonstrated on components in a production relevant environment.
- Manufacturing technology development efforts initiated or ongoing.
- Producibility assessments of key technologies and components ongoing.
- Cost model based upon detailed end-to-end value stream map

MRL 6. Capability to produce a prototype system or subsystem in a production relevant environment

- Initial manufacturing approach developed.
- Most manufacturing processes have been defined and characterized, but there are still significant engineering/design changes
- Preliminary design of critical components completed
- Producibility assessments of key technologies complete
- Prototype materials, tooling and test equipment, as well as personnel skills have been demonstrated on subsystems/ systems in a production relevant environment
- Detailed cost analysis include design trades. Cost targets allocated.
- Producibility considerations shape system development plans.

TRL/MRL CLARIFYING DEFINITIONS

BREADBOARD: Integrated components that provide a representation of a system/subsystem and which can be used to determine concept feasibility and to develop technical data. Typically configured for laboratory use to demonstrate the technical principles of immediate interest. May resemble final system/subsystem in function only.

HIGH FIDELITY: Addresses form, fit and function. High fidelity laboratory environment would involve testing with equipment that can simulate and validate all system specifications within a laboratory setting.

LOW FIDELITY: A representative of the component or system that has limited ability to provide anything but first order information about the end product. Low fidelity assessments are used to provide trend analysis.

MODEL: A reduced scale, functional form of a system, near or at operational specification. Models will be sufficiently hardened to allow demonstration of the technical and operational capabilities required of the final system.

OPERATIONAL ENVIRONMENT: Environment that addresses all of the operational requirements and specifications required of the final system to include platform/packaging.

PROTOTYPE: The first early representation of the system which offers the expected functionality and performance expected of the final implementation. Prototypes will be sufficiently hardened to allow demonstration of the technical and operational capabilities required of the final system.

RELEVANT ENVIRONMENT: Testing environment that simulates the key aspects of the operational environment.

SIMULATED OPERATIONAL ENVIRONMENT: Environment that can simulate all of the operational requirements and specifications required of the final system or a simulated environment that allows for testing of a virtual prototype to determine whether it meets the operational requirements and specifications of the final system.

PRODUCTION RELEVANT ENVIRONMENT: An environment normally found during MRL 5 and 6 that contains key elements of production realism not normally found in the laboratory environment (e.g. uses production personnel, materials or equipment or tooling, or process steps, or work instructions, stated cycle time, etc.). May occur in a laboratory or model shop if key elements or production realism are added.

Additional Information on the Technology and Manufacturing Readiness Assessment process can be found at:

TRL Assessment: http://www.acq.osd.mil/chieftechnologist/publications/docs/TRA2011.pdf
MRL Assessment: http://dodmrl.com

5. Focused Solicitation

There are three focused solicitation and one open area:

Part A: Wearable Device for Ambulatory Monitoring Capability: The purpose of this focused solicitation is to fund a recipient, a single team, or multiple recipients and teams to conduct an R&D effort to develop and demonstrate wearable monitoring solutions (patch, glove, compression garment/sleeve, wristband, finger sleeve, etc.) for non-critical care patients from point of injury/care through to traditional clinical environments (typically 12-18 hour). Proposals of consideration will illustrate how the innovation will advance the state-of-the-art in integration, materials, system-level design and/or assembly. The AE mission provides for tens of ambulatory, non-critical patients at a time in addition to multiple critical care patients on a single large transport aircraft like a C-130 or C-17 without the infrastructure necessary to get real-time vital sign measurements on all patients. Robust physiological monitoring solutions can provide improved situational awareness, electronic medical alerts, and decision support during ERC to optimize care.

- Integrated devices will incorporate some or all of the following attributes:
- System-level integration of multiple sensors and components to enable multi-parameter physiological signal detection, identification, and classification: examples include vital sign measurements such as blood oxygen content, pulse and respiration rate, EKG, and blood pressure.
- Advanced multiplexing and data fusion of biosensor signals.
- Size, Weight, Power and Cost (SWaP-C) optimization of sensors, active electronics for form, fit, and function.
- Advanced low-power communication protocols and wireless data communication with enhanced data security.
- If regulatory action and/or IRB approval is required for demonstration of the solution, the strategy should be clearly articulated.

Part B: Wearable Human-Biochemistry Monitoring Capability: The purpose of this focused solicitation is to fund a recipient, a single team, or multiple recipients and teams to conduct an R&D effort to develop and demonstrate a monitoring system for continuously collecting human biochemistry data that can be used to inform on human-performance and the human-state as well as accelerate decision making (triage, safe-to-transport) during normal operation, point-of-injury and ambulatory care. Non-invasive to minimally invasive sample techniques are acceptable.

- For example all modality of biochemical data access that provide decision-making capability, early indication of patient decompensation, or awareness into the tissue-level chemistries present in traditional blood-gas panels (O_2, CO_2) will be considered.
- Additional analytes and biofluid matrices beyond traditional blood-gas panels are of interest.
- All analytes should be considered with appropriate justification of potential value.
- Solutions that are not cold-chain reliant (i.e. refrigerated storage) are strongly preferred.
- Systems should enable dynamic and continuous monitoring – at least 24 hours of use.
- If regulatory action and/or IRB approval is required for demonstration of the solution, the strategy should be clearly articulated.

Part C: Wearable, Cuffless Blood Pressure Monitoring Capability: The purpose of this focused solicitation is to fund a recipient, a single team, or multiple recipients and teams to conduct an R&D effort to develop and demonstrate a system capable of clinically-relevant and continuous collection of human blood pressure measurements. The device should at least provide a capability for informing on a safe-to-fly decision prior to ambulatory care. Ultimately the objective is to deliver a solution that is capable of

accurately and continuously measuring human-blood pressure prior to and during flight conditions (i.e. acceleration, thermal variability, vibration, high-noise, etc.) Other clinically relevant human-pressure monitors (especially for hypobaric environments) will be considered. Examples of non-invasive approaches include, but are not limited to:

- Flexible imaging techniques, for example ultrasound
- Strain gage techniques
- Indirect BP measurement through multi sensor correlations

Part D: Open Concepts for Wearable and/or Mobile Human-Monitoring/Diagnostic Capabilities:
Proposals that build upon topics relevant to medical wearables and human-performance monitoring. Solutions including, but not limited to, mobile support technologies or human health protection (pathogens, toxic chemistries, personal/epidemiological, etc.) will be considered. Possible topics include, but are not limited to:

- Lightweight, high-sensitivity, low-power systems to detect pathogens, toxic chemistries, and other threats.
- Machine learning for sensor fusion, event detection, and accelerated decision making demonstrated in conjunction with a system or sub-system, addressing Part A, B, or C
- Novel materials for chemical and biological sensing, microfluidics, thermal stabilization of bioreagents.
- Portable, low-power sensing systems for hypoxia and hypercapnia detection and alerting.
- Non-pharmacological interventions for acute pain management.

6. Requirements for Receiving an Award

To submit a response to this NBMC RFP and subsequently be considered for an award, several requirements must be met as detailed below.

- To receive an award from NBMC, the company or composite team of companies must have a significant presence in the United States in the form of R&D activities and/or manufacturing. At least 50% of the work activity (funds) must be spent within the U.S. operations. The primary company leading the proposal must be a U.S.-owned company. Further, for the period of award performance plus the 3 years following, the primary company plus all IP resulting from said award must remain under control of a U.S.-owned or majority-controlled company. In certain cases, where it can be demonstrated that the development is both critical to U.S. manufacturing capability and unique, this “preference for U.S. operations” requirement can be waived with AFRL approval. Any responding company requiring such a waiver must make this known in the pre-proposal document.

- The company or companies must be committed to volume manufacturing of the developed products and provision to the U.S. medical electronics industry on a right-of-first acceptance basis. Applied research conducted by universities will be considered and does not need to meet this requirement. However, in this latter case a pathway to commercialization and or licensing must be envisioned and described.

- The company or companies, including universities, must provide a matching share of the development cost in cash and in-kind contributions (e.g., labor and materials) - 50% recommended.

- Companies and organizations which are selected for an award, including all partners and/or subcontractors, must subsequently join SEMI at the appropriate membership level. Membership information is available at https://www.semi.org/en/connect/semi-membership-levels

- Companies and organizations which are selected for an award, including all partners and/or subcontractors, must agree to terms and conditions set forth in the SEMI-NBMC Development Agreement before receiving any portion of the award.

7. White Paper Instructions

White paper submissions should be 5 pages (including any cover pages, tables of contents, figures, etc.) or less and contain a description of the proposed idea, high level budget, timeline, and background/experience of the R&D team. In addition, the submission should clearly outline the problem being addressed and how the proposed idea would solve the challenge. The current state-of-the-art and the advancement the proposed idea has over that state-of -the-art and its relevance to advancing or demonstrating the role that nano-bio materials have on human-monitoring should be discussed. In addition, the value to the smart medical electronics ecosystem and potential path to commercialization should also be outlined. White paper submissions do not have to adhere to a specific format (other than maximum page length), but it may be useful to review the full proposal instructions in section 7 for suggested content.

White papers will only be accepted electronically up to 5:00 PM PT on the due date of May 24, 2019. Please submit your completed proposal via email to nbmcrfp@semi.org

8. Full Proposal Instructions

The format below will help us evaluate your proposal and ensure that the major topic areas are covered. A full proposal is typically 20 pages with a page limit of 35 pages.

Content: The proposal shall comply with the following content and structure.

Page 1: Cover Page

Date
Project Title

Company Name
Address

Project Leader Contact Information (telephone and email)
Project Team (Prime & Subs)
Project Duration

Total Project Cost
Cost Share
NBMC Funds Requested

Page 2: Table of Contents

Page 3: Executive Summary, containing a short description of the project objective and industry or supply chain impact

Pages 4-35: Proposal Content

1. Project Proposal
   1.1. Problem definition
   1.2. Project scope and objectives
   1.3. Technical approach, rationale and innovative claims with supporting data and diagrams
   1.4. Performance target metrics and/or specifications (competitive benchmark required)
   1.5. Prior work, current status, and results (if any)

2. Statement of Work
   2.1. Project management approach
      2.1.1. Roles and relationships of key personnel and institutions
      2.1.2. Lead institution and subcontract partners
   2.2. Project schedule
   2.3. Detailed task description
   2.4. Milestones, deliverables including demonstration prototypes, reports, process definition, test results, reviews etc.

3. Detailed Project Cost and Cost Share by Task or by Quarter
   3.1. Labor, materials, overhead, and capital

4. Project Risk Assessment
   4.1. Table: Analysis of Risk and Mitigation Strategy (list risk assessment tools/processes used if any)

Risk	Consequence	Mitigation Strategy	Impact (L, M, H)

5. Market Needs and Competitive Landscape
   5.1. Business justification
      5.1.1. Existing product portfolio
      5.1.2. Primary markets served and major customers
   5.2. Commercialization strategy for target markets
   5.3. Cost of ownership benefits of proposed technology in absolute terms or relative to the cost of the typical current process

6. Company Background and Capability to Meet Technical and Business Targets
   6.1. Team & key personnel
      6.1.1. Management and technical personnel experience and qualifications
   6.2. Facilities and equipment
   6.3. Relevant company information
      6.3.1. Three-year financial performance track
      6.3.2. Staff size and make-up by function
      6.3.3. IP strategy, key previous innovative developments and intellectual property (patents) held related to the proposal topic

7. Contact Information for Technical Lead, Alternative Technical Representative, and Contract Representative

8. Appendix (if needed - NOT INCLUDED IN PAGE TOTAL)
   8.1. Technical References
   8.2. Letters of Support

Full Proposals will only be accepted electronically up to 5:00 PM PDT on the due date of July 3, 2019. Please submit your completed proposal via email to nbmcrfp@semi.org

9. Proposal Evaluation

Upon receipt, proposals will be forwarded to NBMC RFP Review Committee. During the final selection process of proposals, some communication or negotiation between the potential supplier and representatives of AFRL and/or SEMI may be initiated over the terms, conditions, specifications, deliverables, schedule or other relevant factors contained in the proposal in advance of awarding of a contract. Granting of any awards to proposals submitted in response to this RFP is contingent upon the continued availability of funding from the U.S. Government.

10. 2019 RFP Schedule

The tentative schedule of activities for the NBMC 2019 RFP is as follows:

May 6, 2019	RFP Issued
May 9, 2019	Webinar
May 24, 2019	White Paper Due
June 3-7, 2019	Notification of White Paper Acceptance and Full Proposal Request
July 3, 2019	Full Proposals Due
Aug 4-9, 2019	Notification of Award (each full proposal point of contact will be notified)

RFP Schedule subject to change based on availability of review personnel, commitment of federal funds, and other factors.

11. Resources

Additional information can be found at http://nbmc.org

Additional information and guidance on prospective proposal partners may be available and should be requested at nbmcrfp@semi.org. Please include a brief description of your institutions competencies/contribution and highlight the type of institution/partner that would increase the quality, maturity, or commercial viability of your ideas.

A webinar will be held on May 9, 2019 (tentative) to review white paper requirements and answer any questions from the public. A recording of the webinar will be available at http://nbmc.org.

12. Contact Information

Communication and questions during the proposal period should be directed to nbmcrfp@semi.org.