

Request for Proposal Guidance Document

Request for Proposal (RFP) title:

Human Integrated Sensor System (HISS) Challenge

DMTC Program:

CBR Sensing Systems

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1. DISCLAIMER

DMTC is releasing this RFP to identify proposals from industrial and academic organisations who will collaborate in the development and enhancement of Defence relevant capabilities in the chemical, biological or radiological (CBR) Sensing Systems domain.

The area of interest is *Human Integrated Sensor Systems (HISS)* and the program aims to support prototyping activities around wearable or portable technologies for measurement, analysis and interpretation of human exposure to chemical and biological threats.

It is recognised that a fully realised HISS capability requires financial resourcing that is much larger than that available under this challenge. We are thus looking for focused projects that meaningfully advance the HISS in a self-contained work with measurable outcomes and that provides a launch point for follow-on research and development at larger scale.

The response to this Request for Proposal (RFP) form will be reviewed by the DMTC CBR Sensing Systems Technical Advisory Group. However, having your RFP response reviewed by the Technical Advisory Group is <u>NOT</u> a guarantee that you will be granted funding.

2. INTRODUCTION

DMTC is an independent, not-for-profit company that creates, manages, directs and delivers successful industryresearch collaborations involving multiple partners to enhance sovereign defence and national security capabilities, consistent with Government policy. Over more than a decade DMTC has been leading collaborative projects to advance technologies, as well as pursuing best practice governance and maintenance of ISO accredited quality systems.

With a historical focus on materials and manufacturing process improvements in the land, sea and air domains, DMTC has developed know-how in how to deliver innovation into Defence projects and has recently hosted programs in new technology areas such as Medical Countermeasures and High Altitude Sensing Systems on behalf of partner organisations wishing to utilise DMTC's proven project management and collaborative research expertise.

Recently, the Department of Defence through its Operating in CBRN Environments (OCE) STaR Shot approached DMTC to lead and manage a collaborative program of work which will enhance warfighter capability via the application of advanced biotechnology and data analytics to measure, interpret and mitigate damage to the human body caused by the effect of chemical and biological threats.

Over the course of a ten year innovation science and technology program, the OCE STaR Shot aims to enhance the Joint Task Force such that it will be able to operate safely and effectively in environments where chemical, biological, radiological and nuclear (CBRN) threats are present. The OCE has been launched as part of Defence's Science and Technology Strategy 2030 - "More Together" to focus more on mission driven science and technology (Focus), to engage with the wider community (Scale), and to more rapidly translate innovation into military capability (Impact).

The threat of exposure to hazardous chemical substances and biological pathogens is growing, both in conflict and in the provision of humanitarian assistance. Defence personnel are challenged to work harder and for longer periods in more difficult environments, whilst under greater physical and mental loads.

As part of an integrated approach to chemical, biological, radiological and nuclear (CBRN) defence, the objective of the Human Integrated Sensor System (HISS) Challenge is to develop novel wearable sensors and / or integrate existing in-human and on-human sensor technology into a networked system to alert warfighters of situations in which chemical or biological threats are present.



Potential theatres of operation include contested, complex and disaster-stricken environments. Given the spectrum of operations, it is envisaged that all Defence services (Army, Navy and Air Force) could use such wearable sensor systems and that there may be benefits to integrating new military wearable sensors with environmental sensor systems and commercially available civilian monitoring systems.

3. BACKGROUND

In collaboration with the DMTC, the OCE STaR Shot wishes to enhance warfighter capability via the application of advanced biotechnology and data analytics to measure and interpret indicators of chemical and biological (CB) exposure from the human body. Therefore, both organisations have partnered to seed a self-contained program of work, in the first instance, which advances the Human Integrated Sensor System (HISS) concept.

The vision is to create a HISS that:

- 1. Amalgamates outputs from wearable on/in body sensors with advanced data fusion and analytics approaches
- 2. As a system, assimilates both subtle and overt sensor derived cues of Chemical/Biological (CB) exposure/infection
- 3. <u>Identifies the threat within hours of exposure and gives the wearer warning well before</u> <u>deleterious symptoms begin to manifest.</u>

To achieve the proposed vision, a hybrid sensing approach is required where targeted biochemical analytes, rapid physiological changes and physical measurements are all considered in response to a CB exposure/infection. Analytics approaches will need to handle data of differing format, temporal resolution, and uncertainty and be required to identify patterns of exposure from the complicated baseline of normal bodily function, normal progression of infection and responses to non-CB threat external stimuli.

The HISS is scalable in its potential output – ripe for continual iteration as new understanding and technology leaps are realised. The development process is likely to generate data analytics approaches, individual sensors and an understanding of human centric measurement that will have application/s as discrete technology solutions.

The HISS will allow countermeasures to be enacted with greatest effect while also buying crucial time for key operational decision making. The theatres of useful application are broad and encompass all the tri-services. There will also be significant civilian opportunities across the health, first responder, industry occupation health and safety and law-enforcement sectors.

The following sections provide a guide to addressing this RFP and should be read carefully.

4. RESEARCH SCOPE

The available fund for this HISS Challenge is up to \$3 million (\$3M). While smaller research proposals may be considered, the preference is to fund a small number (potential only 1) of projects of scale that draw together multi-disciplinary and multi-institutional expertise. Projects are envisaged to have duration of 2-3 years. Responses to the RFP are limited to organisations possessing an Australian Business Number (ABN). While responses may include international collaboration, the \$3M funding for this program will not be sent to foreign jurisdictions.

The focus for this HISS challenge is limited to **Biological Pathogen Exposure**. It is anticipated that the physiological health measurements, that rapidly manifest early measurable indicators of exposure, may be a key component of HISS. Such approaches will require advances in artificial intelligence and data analytics to interpret the onset of measurable indicators of infection more reliably, more selectively and much earlier than currently done in the general health and enhanced human performance sectors. However, it is considered unlikely that these measurements alone will deliver the envisioned specificity for the HISS and as such, changes in



biochemistry (disruption to metabolic or signalling pathways, and specific immune responses at the molecular level) will need to be considered, new probes developed, and new sensors integrated into the system.

A HISS capability may benefit from cross-referencing with (or integration within) a network of environmental contaminant monitoring devices/sensors. However, the HISS Program is envisioned to be capable of delivering powerful "capability effect" even in isolation of other sensor systems. Project proposals that rely on environmental monitoring sensors to supplement the human integrated elements of their proposed system are misaligned with the focus of this RFP.

The following biological threats are exemplars for a proof of principle HISS system. Respondents may choose from the list provided or provide a reasoned case for a different exemplar – however there is a preference for "threats" that could be tested in relevant future clinical trials. Respondents may also/or wish to demonstrate efficacy in their project by drawing data collected in "simulated" environments or threats (ie live attenuated vaccine approaches).

• Virus

- Influenza, SARs-coronavirus, Hepatitis A, Chikungunya, Zika, Japanese encephalitis, Bunyaviruses, Flaviviruses
- Bacteria
 - Diarrheagenic E.coli, Pathogenic Vibrios, Shigella species, Salmonella, Listeria monocytogenes, Campylobacter jejuni, Yersinia enterocolitica, Bacillus anthracis, Yersinia pestis
- Toxin
 - o Botulinum toxin, Ricin, Abrin
- The HISS Challenge is not focussed on research or development of new sensors nor is the focus directly on enhancing the maturity of existing sensor prototypes:

At the heart of the HISS Challenge is the identification of the key indicators / biomarkers of exposure and establishment of analysis methods that enable causal attribution (i.e. "change is due to exposure"). In the first instance, achieving this objective and demonstrating efficacy for a proposed system may not necessarily require on/in body wearable sensor measurements. For example, manual sampling and analysis of bio-fluids is an acceptable approach for the HISS Challenge.

Respondents may wish to include proprietary, or "in development" sensor/s or commercial off the shelf sensors to enable their system approach but they should not require further research or development to do so. Sensors that are already in (or close) a format (wearable) amenable to the vision of HISS and at an advanced development stage (e.g. wearable, automated, sensitive, selective) are likely to be favourably received.

- > Data analytics and data science approaches will be central to the HISS capability.
- > Multi-institutional teams with diverse expertise are sought.
 - Successful bids will draw together a blend of deep technical expertise and ideally include access to clinical setting capabilities.
 - Single institution bids are exceedingly unlikely to attract funding under this challenge.
 - Preferential weighting may be given to active and integrated collaborations that involve both industry and academic partners,



• "Industry only" or "university only" collaborations will still be considered for award.

5. PROPOSAL GUIDANCE

The primary aim of this Request for Proposals (RFP) is to advance the HISS as concept through a self-contained project that

- Includes measurable indicators of success
- Addresses the key challenges/questions identified in this guidance document.

The available funds for this HISS Challenge is up to \$3 million (\$3M).

A systems integration approach is desired, where consideration is given to each of the component parts of a HISS. The HISS RFP promotes defence-capability based thinking, and therefore linking cause (here: exposure to biological pathogen) and effect (here: biochemical changes in the human body potential paired with physical, physiological or mental changes in the human) is important, especially given the range of factors other than exposure to chemical and biological threats that can cause biochemical, physiological and mental variations in humans.

Successful proposals will develop projects that consider each of the four key questions below and that articulate a clear vision for a self-contained demonstration system that meaningfully and measurably advance the HISS towards a product/s that is capable of being used in the field.

1. What indicators are being targeted?

- "Common across all infection" indicators useful
- "Specific to class/type of infection" indicators more useful
- "Specific to pathogen" indicators ideal
- Consideration of homeostasis and normal fluctuations in physiological function
- Possible indicators (not exhaustive):
 - Biochemical markers of exposures/infectious disease.
 - Quick to initiate physiological and cognitive change including measurement and interpretation of a family of physical parameters and vital signs.
 - \circ $\;$ Electromagnetic signals that are correlated with human health deterioration.
 - Other by-products of changes to metabolic or signalling pathways inside the human body and brought about by exposure to biological pathogens.
 - Specific immune system responses
- 2. How do we calibrate the "human as a sensor" so that we can search for early cues of infection?
 - Possible considerations:
 - "Zeroing out" responses to environmental stimuli and accounting for the transient nature of normal biological function.
 - o Data fusion, artificial intelligence and machine learning approaches.
 - "Population" vs "Individual" calibration/measurement/detection of events
- 3. Data analytics approaches will be central to realising HISS
 - Possible considerations:
 - Extraction of subtle signals of exposure from a noisy background.



- Capable/adaptable to a multitude of heterogeneous data sources.
- Fusing key outputs from sensors working at different time increments and possibly matching to known patterns of physiological/biochemical response to exposure (also working on varying time scales)
- 'Multi-omics' approaches, utilising parallel integration of datasets,
- Edge computing potential (enabling remote isolated operation) vs centralised analysis necessitated methods.
- 4. How do we test prototype systems?
 - Possible considerations:
 - Ethical requirements for clinical trial testing
 - Relevance of chosen test paradigms to envisioned capability effect

Common to all proposals:

- Should be self-contained, measurable and address each of the Key Questions (Focus)
- Should be multi-party, trans-disciplinary and ambitious (Scale)
- Should significantly advance the HISS as a potential capability (Impact)

6. **PROPOSAL THEMES**

To address the HISS Challenge, respondents should select one of the below themes. Please note this is not a sensor development project, but rather an integrated sensing systems approach.

Theme 1: Rapid onset (pre-perceived) physiological biomarkers of exposure - detect and interpret

- This will require earlier detection (within minutes/hours of exposure) and with higher specificity then currently possible.
- This may involve existing sensor/measurement technologies but is likely to require an expansion on the range of biomarkers that are followed.
- Core to this approach will be data analytics and sensor data fusion to de-convolute signals of exposure from background normal bodily function and to increase rapidity and specificity of anomaly detection.

Theme 2: Biochemistry of exposure

- This will require work to narrow the measureable and meaningful changes in biochemistry upon pathogen incursion into the body.
- Greater understanding of the progression of infection will be required from first entry into the body to the mechanisms that trigger the biomarkers of research theme 1 and inform new biomarkers that should be monitored.
- This work will reveal what sensors are already available and which still need to be realised (and possibly what research needs further investment to enable them – e.g. nanotechnology, biotechnology).

Theme 3: Hybrid system approach

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- Detection, interplay and integration of both biochemistry and physiological biomarkers
 - Amalgamation of key research elements identified in both themes 1 and 2.



7. CONFIDENTIALITY

DMTC will treat all responses confidentially. DMTC will share responses to this RFP with the DMTC CBR Sensing Systems Technical Advisory Group, as well as Australian Government stakeholders including DSTG. DMTC will not distribute responses outside of this group without the explicit permission of the originator.

8. CONTACT PERSON

The point of contact in relation to this Request for Proposal is:

Name:	Dr Felicia Pradera
Title:	General Manager – Health Security Systems Australia
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9. LODGEMENT

Please return completed responses by Friday December 17th 2021, at the latest. Earlier responses are welcomed.

Please submit responses to: email

When responding to the RFP by email, please ensure:

- "RFP -Human Integrated Sensor Systems" appears in the subject line of the email; and that
- Your submission is in a *PDF format* prior to submission.

10. RESPONSE TEMPLATE

DMTC has developed a response template for your completion. This template <u>MUST</u> be used for your response.

Within the bounds of the word limits specified, your answers may include as much or as little detail as you feel is necessary.