

## Translational Research Institute for Space Health (TRISH)



# Remote Biomarker Measurements in Microphysiological Systems

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#### A. About TRISH



The <u>Translational Research Institute for Space Health</u> (TRISH) is an applied space health research catalyst supported by the <u>NASA Human Research Program</u> (HRP) that funds disruptive, high-impact scientific studies and technologies to equip astronauts for space exploration. TRISH relentlessly pursues and funds novel research to deliver high-impact scientific and technological solutions that advance space health and help humans thrive wherever they explore, in space or on Earth.

TRISH support focuses on maintaining and improving human health in space. Since its inception, TRISH has funded over 150 projects that have advanced medical science for both our world and the worlds that lay beyond. As the only institute dedicated to promoting space health discoveries and technologies, TRISH is accelerating research that will benefit all people with a future in deep space and here on Earth.

Founded on October 1, 2016, TRISH works in partnership with NASA's HRP through Cooperative Agreement NNX16AO69A. Led by Baylor College of Medicine's Center for Space Medicine, TRISH's consortium leverages partnerships with the California Institute of Technology (Caltech) and the Massachusetts Institute of Technology (MIT). More details on TRISH, its mission and funding opportunities can be found at <a href="https://www.bcm.edu/spacehealth">https://www.bcm.edu/spacehealth</a>.

TRISH recognizes the need to encourage innovation among the space health community, to attract cutting-edge technologies and high-risk, high-reward ideas, and to translate existing technologies for use in space flight. Our primary goal is to help mitigate <a href="NASA HRP's Human Research Roadmap">NASA HRP's Human Research Roadmap (HRR)</a> Risks and enable future Artemis missions and deep space exploration.

## **B.** Opportunity

#### **Background:**

NASA's Artemis missions will place astronauts in lunar orbit and on the moon's surface, where they will experience deep space exposure on par with the Apollo missions. As the mission profiles progress, the Artemis exposure durations will greatly exceed the prior Apollo experience. Therefore, it is imperative that the space life science community has the tools to study the effects of long-duration and deep space exposure and test ways to prevent and mitigate its potential negative effects. The upcoming Artemis missions provide an unprecedented opportunity to understand the risks of deep space exploration and advance new approaches to managing those risks.

Enabling study of microphysiological systems (MPS; also known as tissue chips, advanced biological systems, 3D tissue, or organ chips) in space have been a recent scientific endeavor in the last decade, beginning with the "Microphysiological Systems Program for Translational Research in Space funding opportunity" from National Institute of Health (NIH)'s National Center for Advancing Translational Sciences (NCATS) institute's partnership solicitation with the Center for the Advancement of Science in Space (CASIS). These systems have made significant advancements during this time and focused on a demonstration of capability. Following this work, TRISH funded several projects focused on exploring the capability of using MPS to understand radiation risks in human constructs and test potential countermeasures. Currently, ongoing work

outside of TRISH in tissue chips is focused on improving the <u>longevity of these constructs</u> and their <u>utility in understanding aging</u> and other disease constructs.

TRISH's ongoing initiative, Science ENterprise to INform Exploration Limits (SENTINEL), is an effort to build automated MPS that also have in-line sensing capabilities to self-regulate and provide data to the astronaut crew as well as scientists on the ground, thus overcoming the need to return samples to Earth for analysis. These constructs have the potential to address several knowledge gaps in the impacts of the deep space environment. They also have the potential to greatly improve upon current methods of characterizing space exploration risks that use ground analogs and the International Space Station (ISS) which provide limited or incomplete translatability and require sample return to Earth for analysis for ISS research.

By using automated and self-reporting MPS, the lunar surface and vicinity can enable critical health and performance studies. These systems can also be built as single organs or as systems of organs allowing for interactions to simulate responses that might occur within the human body in space. Successful research and technology development in this area would enhance the capability to test the effects of the realistic, deep space radiation environment on a tissue as well as the impacts of medications or other interventions on said tissue.

On Earth, these systems are being matured and validated with the goal of facilitating personalized and precision medicine. In the future physicians on Earth may use cells acquired from a patient to diagnose and test treatments on that individual's engineered tissues and organs before ever having to introduce more risk to the patient since as responses to medications may differ from person to person.

TRISH has the same vision for the future of health prevention of space explorers. Since astronauts are already working and living in the remote, hostile, and austere environment of space, rather than introduce risk through new pharmaceuticals or interventions, tissue chips can be utilized to ensure that negative health outcomes are avoided prior to start of treatment.

In the shorter term, this approach during the Artemis missions and emerging opportunities in commercial spaceflight will allow the MPS payloads to experience deep space exposures similar to those anticipated for exploration class missions and return that data autonomously during the entire deep space exposure. Thus, these MPS would enable researchers to conduct time-course, mechanistic and countermeasure development studies while the MPS remain in space.

In the longer term, these tissue chips could be utilized for personalized medicine: with a customized tissue chip of each individual space explorer sent into deep space before or together with the same space explorer, thus assisting in the overall assessment of the risks of the space environment on that individual's physiology.

The end goal of the SENTINEL initiative is to provide the space life science research community and, ultimately, NASA space medicine with effective and reliable tools to preserve astronauts' health span and ensure a performance-ready state during and after the mission. TRISH is also supporting research and development to automate a multi-organ tissue chip platform that will operate without human intervention. This solicitation focuses on the second part of the SENTINEL effort, namely, advancing automated analysis capabilities in MPS.

#### **Goal of the Request For Proposals (RFP):**

As discussed above, MPS have the potential not only to (1) define new countermeasures and (2) improve personalized healthcare but also to (3) explore biological effects in new environments. Currently, most MPS studies conducted in space have primarily relied on post-flight analysis. Future exploration class missions beyond Low Earth Orbit (LEO) are unlikely to provide a fully capable wet lab environment nor be able to easily transport samples back to the ground, so new methods are needed to measure biomarkers to support research and advance human health in space. To enable biological research for these exploration class missions, advancements in current technologies are needed to support *in-situ* analysis and monitoring capabilities during missions and for precision health in preparation for future missions. This solicitation focuses on improving analysis capabilities for research advancements in biomarker, bioindicator, or biosignature measurement capabilities within or connected to an MPS that could be done during space flight and do not require sample return.

Ideal methods would be non-invasive and non-sample destructive, allowing for data collection over multiple time points separated by days or weeks, especially considering that the field is moving toward MPS that can survive for six months. In addition to biomarkers, proposers may also address environmental factors, cell function, and tissue function that would impact the overall health of the advanced biological construct.

Priority will be given to technologies or methods that can measure a broader range of usable markers. For example, we are looking for measurement systems or technologies that can measure multiple biomarkers rather than bespoke systems for each potential marker. The ideal measurement system would be usable in any advanced biological construct and thus should not be specialized for a particular laboratory group's MPS.

No particular biomarkers are specified for this solicitation. Proposers must make a case for their biomarker choices or targets. Proposers are expected to provide information on how the method of analysis is expected to impact an MPS' function as well as how they would handle potential decrements to the health of the advanced biological construct that might result from the use of the method of analysis. Preliminary data supporting the feasibility of the proposed method of measurement is required.

#### **Deliverables:**

Expected deliverables by the end of the grant are to demonstrate both the functionality of the measurement tool and the robustness of the measurement system.

- 1. Demonstrate the tool's ability to measure the specific biomarkers of choice.
- 2. Showcase the measurement system's robustness and highlight its capability to function effectively across various MPS.

#### **Required Characteristics:**

The following characteristics are required.

- The proposed method must be capable of use within or connected to an MPS.
- The proposed method must provide data without the need for sample return.
- The proposed method must collect data autonomously without the need for human intervention.
- Preliminary data supporting the feasibility of the proposed method is required within the proposal.

- The choice of biomarker, bioindicator, biosignature or marker of MPS environment, cell function, or tissue function must be clearly justified.
- The proposal must address the potential impact of the proposed method on the health of the MPS.
- The proposed method must be innovative.
- The proposed method must be robust and function effectively across various MPS.

#### **Preferred Characteristics:**

The following characteristics would strengthen an application but are not required.

- The proposed method should be capable of being used within multiple kinds of MPS.
- The proposed method should be non-invasive to the MPS.
- The proposed method should be non-sample destructive.
- The proposed method should allow for data collection over multiple time points separated by days or weeks.
- The proposed method should be capable of measuring more than one marker.
- The proposed method should avoid the use of genetic modification because future uses
  of these measurement tools may include cells from individual patients for personalized
  medical approaches.

#### **Decline Characteristics:**

Inclusion of the following characteristics will result in a declined application.

- Methods that are <u>not</u> capable of use within or connected to an MPS.
- Methods that require sample return.
- Methods that require human intervention for sample/data collection.
- Methods that are **not** supported by preliminary data.
- Methods that are **not** innovative in the field (for example, imaging of cardiac contractility).

## C. Award Information

**Projects** can reach a total amount of \$400K for one year. Awards can begin as early as June 2025 and must initiate by August 2025. **All direct and indirect costs must be included in the total cost of the award.** Selected proposals will be funded as research grants.

## **D.** Eligibility

All categories of United States (U.S.) institutions and companies are eligible to submit proposals. Principal Investigators (PIs) may collaborate with universities, the private sector, and federal, state, and local government laboratories. In all such arrangements, the applying entity is expected to be responsible for administering the project according to the management approach presented in the proposal. For our policy on international proposers and institutions, please refer to the <u>FAQ</u> and <u>FAR Supplement</u>.

## **E. Application and Submission Information**

Proposers considering applying must register in the system for award management (SAM) database (<a href="www.sam.gov">www.sam.gov</a>) to ensure ability to receive funds if selected. It is recommended that new registrations on SAM are started as soon as possible (at least 15 business days) in advance of any due dates to allow sufficient time to complete SAM registration before registering in the

TRISH Grant Research Integrated Dashboard (GRID - <a href="https://spacehealth.bcm.edu/">https://spacehealth.bcm.edu/</a>). A Unique Entity Identifier (UEI) will be issued as part of the SAM.gov registration process. An entity must provide its unique entity identifier (UEI) in each application it submits to TRISH.

Any proposals not submitted through the TRISH GRID and sent directly to TRISH by email, fax, or other means will not be considered. Format and template will be available on GRID and are detailed below.

#### 1. TRISH Proposal Submission Website

The deadline for proposals submission is March 6, 2025 by 11:59 PM Eastern Time (ET). Proposals received after the deadline will not be reviewed.

#### To register on TRISH GRID:

- Go to <a href="https://spacehealth.bcm.edu/">https://spacehealth.bcm.edu/</a> and follow these <a href="instructions">instructions</a>.
- Fill in the requested information and click the "Create Account" button at the bottom of the page.
- Verify your email via the "Send verification link" button at the top right. Email verification is required to submit an application. You will receive an email from <a href="mailto:noreply@smapply.io">noreply@smapply.io</a> to "Confirm Your Email Address." The website will state that your email address has been verified.
- Click the "Continue" button.

#### To submit an application:

- After you have registered and verified your email, login to your GRID account.
- Click "Programs" in the top navigation bar.
- Select "Remote Biomarkers" and click "Apply."
- Complete the tasks listed under "Your tasks." When all sections are marked as complete, you will be able to review and submit your proposal.

Requests for assistance in accessing and/or using this website may be sent to TRISH's Cosmic Concierge by selecting "Open Solicitation" from the drop-down menu. Any emails from the GRID will come from <a href="mailto:noreply@smapply.io">noreply@smapply.io</a>. Please check your Spam folder if you are not receiving emails from the GRID.

#### 2. Pre-Proposal Briefing

A pre-proposal virtual briefing will be held on Monday, January 13, 2025, at 1:00 PM Central Time.

The pre-proposal briefing will provide interested proposers with the opportunity to ask presubmitted questions in order to better understand the intent, scope of work, and selection criteria. This meeting will be open to the public and accessible with an internet connection.

Questions submitted in writing to TRISH at least 24 hours in advance of the scheduled virtual meeting will be addressed. Please submit a question by visiting <u>TRISH's Cosmic Concierge</u> and selecting "Open Solicitation" from the drop-down menu. Please see the link to register for the preproposal virtual briefing via <u>Zoom</u>.

#### 3. Proposal Requirements

Proposals that do not conform to these requirements may be declared noncompliant and declined without review.

#### a) Application Form

All proposals **must be** in the format given below. Key project information must include:

- Principal investigator (PI)
- Contact information (email, phone, mailing address)
- Proposing institution
- Team members and/or Collaborating Institutions (if any)
- Project title
- Proposed start/end dates
- Technical point of contact
- Authorized organizational representative, with contact information
- Total funds requested
- Cost-sharing

Proposals are prepared by the PI and submitted by the PI or an authorized representative from the PI's institution. TRISH does not require institutional sign-off at the time of proposal submission, but PIs must follow their home organization's institutional policies. **Proposals will not be accepted after the listed due dates.** 

#### b) Project Description

The maximum page limit for the Project Description is 10 pages, using 8  $\frac{1}{2}$  by 11-inch pages, a standard 12-point font and one-inch margins. The page limit for full proposals includes all figures, tables, and charts (references are not included in the page limit). Figure and Table captions can use a 10-point font. The submission of appendices along with the proposal is strongly discouraged and reviewers will not be required to review any extraneous materials. **The Project Description should include the following <u>required</u> sections:** 

- Background and Proposed Methods: This should include state of the art for the proposed area, specific aims, preliminary data, and a clear description of methods/technologies. Proposals should clearly explain why the proposed method is innovative compared to existing, commonly used, tools. Proposals should include a well-defined rationale for selected biomarkers or environmental factors, assess the anticipated impact of the analysis method on the MPS, and outline how they will manage any potential health decrements of the biological constructs. Be succinct and articulate in the description of the proposed methods and the background and data supporting the proposed research. Proposals should explain the potential challenges for the project and mitigation strategies.
- <u>Timeline and Milestones</u>: Proposers should describe the project timeline along with milestones.
- <u>Deliverables:</u> In this section, proposers should outline their plans for demonstrating both the functionality of the measurement tool and the robustness of the measurement system.
   1) Proposers should detail how they will demonstrate the tool's ability to measure the specific biomarkers they have defined; and 2) they should also describe how they will

showcase the measurement system's robustness, highlighting its capability to function effectively across various MPS.

**References must be included** and support the scientific and technical validity of the proposed research (no page limit).

#### c) Biosketches

The proposal should describe the participants who will have critical management or technical roles including their qualifications, capabilities, and experience. These team members, defined as devoting ≥10% of their effort, must provide a biographical sketch or track record. Although TRISH does not require a specific biosketch format, we recommend using the NIH biosketch template found <a href="https://example.com/here">here</a>.

#### d) Description of Institution/Organization, Resources, and Equipment

This section must describe the organization's current activities or projects, relevant partnerships and collaborations, and any features that differentiate the organization. It must also describe any existing facilities and equipment that are required for the proposed project and whether the team already has access or how they plan to gain access (no page limit).

#### e) Current and Pending Support

Pls must provide all ongoing projects and pending proposals (regardless of salary support) in which they are performing or will perform any part of the work. Co-investigators devoting >10% of their time to the proposed effort must provide ongoing projects and pending proposals (regardless of salary support) that require a significant share (more than 10%) of their time. For those investigators for whom it is required, this section must provide the following for each current and pending project:

- Title of funded project or proposal title;
- Name of PI on award or proposal;
- Program name (if applicable) and sponsoring agency or organization, including a point of contact with their telephone number and email address;
- Performance period;
- Total amount received by that investigator (including indirect costs) or the amount per year if uniform (e.g., \$50K/year); and
- Time commitment by the investigator for each year of the period of performance.

There is no page limit for this section. The proposing PI must notify TRISH (<a href="https://trish.my.site.com/s/concierge">https://trish.my.site.com/s/concierge</a>) immediately of any successful proposals that are awarded for substantially the same research as proposed from any time after the proposal due date and until the time that selections are announced.

#### f) Management Approach

The management structure for the proposal personnel should be provided. In particular, plans for distribution of responsibilities and arrangements for ensuring a coordinated effort should be described. The plan should include:

- A project schedule that identifies anticipated key milestones for accomplishments and dependencies between tasks;
- The management structure for the proposal personnel;

- Any substantial collaboration(s);
- Any proposed use of consultant(s); and
- A description of the expected contribution to the proposed effort, by task and sub-task, by the PI and each person identified in one of the additional categories.

#### g) Data Management Plan

Each proposal must include a Data Management Plan (DMP) including a Software Sharing Plan (if appropriate) that describes how data generated by the proposed research will be shared and preserved as well as how data collected will be made available to the public, in a reusable deidentified format, on completion of experiments. The DMP should include justification if data sharing or preservation is not appropriate or possible. DMPs must provide a plan for making all research data underlying results and findings in publications digitally accessible at the time of publication. DMPs are expected to include publication in peer-reviewed journals as well as plans to deposit study data in NASA data archives, as requested. The DMP is limited to 2 pages and proposers must use the template provided.

TRISH has plans to store research-related data sets, and these data sets must be stored in a secure manner and for potential delivery of TRISH products to NASA. The data and information obtained from this program will be used to generate a knowledge base that will inform a unified human physiologic response to risks in spaceflight. Participation in the sharing of data will be expected from awardees.

Applicants must commit to sharing and making protocols and methodologies, data, biomaterials, models, reagents, tools, and resources available to TRISH as appropriate and consistent with achieving the goals of the program. Adjustments for coordination of research plans, validation of models, materials, methods, and data; and sharing with the research community will be established by TRISH and applicable NASA policies.

#### h) Budget Form and Budget Justification

Please fill out the TRISH budget form posted alongside the solicitation.

The proposal budget is made up of two parts: the budget details and the budget justification. Each proposal shall provide a proposal budget for the proposed effort that is supported by an appropriate budget justification. There must be a direct parallel between the items described in the budget justification (*e.g.*, written description of planned purchase), those given in the budget details (actual estimates of costs, in whole dollars, for the purchase) and the figures entered in the proposal cover page and TRISH GRID forms. The budget details are the actual or estimated costs, in whole dollars, that correspond with the budget narrative. In this section, the proposer must break out the costs, as needed, for the items listed in the general budget found on the proposal cover page. Cost sharing of 10% is expected to be included.

The proposer must break out the cost for each team member's efforts individually.

- All proposers are required to submit a thoroughly detailed cost breakdown.
- All proposed costs must be directly related to the proposed project and scope of work.
- All proposed costs must be allowable, allocable, and reasonable.

The budget justification must **not** include any information that belongs in the Project Description.

#### It must:

- Cite the basis of estimate and rationale for each proposed component of cost, including direct labor, subcontracts/subawards, consultants, other direct costs (including travel), and facilities and equipment;
- Include costs to travel to annual NASA Human Research Program Investigators Workshop for each year.

The Budget and Budget Justification section length is as needed to properly understand the expected costs for the funded work.

TRISH awards are total costs (direct + indirect costs). TRISH caps indirect rates at negotiated federal rates.

A minimum of 10% cost sharing is required on all TRISH award amounts (direct and indirect costs). Cost sharing may be contributed in cash or in-kind (non-cash contributions) provided by non-Federal third parties. The 10% cost-sharing minimum must be added on top of the budget per year. Please refer to the <u>FAQ</u> for more details.

Do <u>not</u> include cost-sharing amounts in the TRISH Budget Form. Amounts (direct and indirect costs) entered in the budget should only be costs requested from the TRISH-funded award amount. The sample cost table (see example below) is a required element of the budget justification section. Details on how cost-sharing will be achieved are not required at the time of proposal submission.

#### **Cost Table**

Total Amount Requested from TRISH for Year 1 (direct and indirect costs)	\$400,000
Total Anticipated Cost-share for Year 1 (at least 10%; see above for examples;)	\$40,000
Total Value for Year 1 (sum of the two rows above)	\$440,000

Example of sample cost table

#### i) Letters of Collaboration and Resource Support

Every person who is expected to have a significant role (*i.e.*, assigned responsibilities appropriate to a defined category of personnel), regardless of their organizational affiliation, in the execution of the proposed effort, or who will be receiving payment for their contributions, should be identified by being added as a Collaborator on the proposal.

In GRID, PIs should click on the "Add Collaborator" button on the application's first page. Adding a collaborator within the GRID application will generate an invitation to the individual who has been identified, facilitating account creation in GRID. Creation and verification of a GRID account from this email invitation will indicate collaborator acceptance.

Letters of resource support are only required if there is a facility or resource essential to the proposal not under the control of a Proposal Team member. Submitting the statement of commitment, the team member confirms that any facilities or resources needed for the proposal

are readily available for the proposal team members(s) requiring its use. Appropriate institutional commitment to the program includes the provision of adequate staff, facilities, and educational resources that can contribute to the planned program.

TRISH funding through this TRISH Research Announcement may not be used to support research efforts by non-U.S. organizations at any level; however, the direct purchase of supplies and/or services that do not constitute research from non-U.S. sources by U.S. award recipients is permitted. Additional information on international participation can be referenced in the <a href="NASA FAR Supplement">NASA FAR Supplement</a>. If the proposal involves a non-U.S. organization, signed letter(s) of certification must be included that verifies that funding for their portion of the project will be provided by a responsible organization(s) or government agency(ies) should the proposal be selected by TRISH. Letters must be signed by an official at the organization or agency authorized to make such a commitment.

#### j) Instructions for Preparation of Proposals

Section	Required?	Page Limit	Location
Table of Contents	Optional	As needed	
Project Description	Yes	10 pages	<u>E.3.b</u>
References and Citations	Yes	As needed	
Biosketches	Yes	As needed	<u>E.3.c</u>
Description of Institution/Organization, Resources, and Equipment	Yes	As needed	<u>E.3.d</u>
Current and Pending Support	Yes	As needed	<u>E.3.e</u>
Management Approach	Yes	As needed	<u>E.3.f</u>
Data Management Plan	Yes (including Software Sharing Plan if experiment produces any software or code, including high-level languages)	2 pages	<u>E.3.g</u>
Budget Form and Budget Justification	Yes	As needed	<u>E.3.h</u>
Letters of Collaboration and Resource Support	Yes, if resources or facilities are not directly under PI control	As needed	<u>E.3.i</u>

Instructions for Preparation of Proposals

## F. Review and Selection

#### 1. Compliance Matrix

All proposals must comply with the general requirements described below. Upon receipt, proposals will be reviewed for compliance with these requirements including:

o Proposals will not be accepted after the due dates and times listed in this solicitation.

- o The proposal project description must be no more than 10 pages in length (including all tables and figures).
- o Submission of an appropriate and justified budget including the cost-sharing table on the first page of the budget justification section. The total for a funding period requested from TRISH should not exceed the total described in this document.
- o A description that provides track record of delivering research products and outcomes from previously supported research.
- o Submission of all other appropriate information as required in this document.

Note: At TRISH's discretion, non-compliant proposals may be withdrawn from the review process and declined without further review. Excess material beyond the page limits specified in this document will be redacted and the PI notified. Compliant proposals submitted in response to this solicitation will undergo an intrinsic scientific or technical merit review. Only those proposals most highly rated in the merit review process will undergo additional reviews for programmatic alignment and cost; however, at the TRISH science management's discretion, proposals with lower scores may also undergo additional reviews if they can be re-scoped and meet specific programmatic needs.

#### 2. TRISH Initial Screening

All compliant proposals will be initially screened by the TRISH Science Office for availability of funds, programmatic relevance, and compliance with this solicitation for the following attributes:

- o Alignment to the topic;
- o Inclusion of preliminary data to support the use of the method;
- o Appropriateness of budget, timeline, and technical feasibility;
- o Alignment of the proposed method with the TRISH mission; and
- o Eligibility for federal funding support (see Eligibility Criteria for details).

For proposals declined during initial review the proposer will receive a notification by email indicating the proposal is not going to be reviewed.

#### 3. Scientific and Programmatic Review

Proposals that are within scope of the TRISH mission and have programmatic relevance will be considered for technical and scientific merit review. It is the policy of TRISH to ensure impartial, equitable, and comprehensive proposal evaluations based on the evaluation criteria for scientific and technical merit, potential contribution, relevance to TRISH mission, and cost.

The overall evaluation process for proposals submitted in response to this solicitation will include a First-Tier scientific merit review and a Second-Tier programmatic alignment and operational relevance review. The **First-Tier Review** will be a merit review conducted by a panel composed of scientific or technical subject matter experts. Proposals that are highly rated in the merit review process will undergo a **Second-Tier Review** for programmatic alignment and operational alignment. The Second-Tier review will be conducted by TRISH science management and overseen by TRISH's Acting Chief Scientific Officer.

#### All of the following criteria will be used in determining the merit score:

#### Significance:

Does the proposed analysis method meet the specific needs outlined in the RFP? Does it fit with TRISH's overall mission and goals? Does it support future deep space exploration and enable a future of more autonomous research? Does the proposal provide significant justification for their choice of biomarkers or bioindicators?

#### Innovation:

Does the study include ideas or hypotheses that, if successful, would propel the field of space health forward in a significant leap? Does the study use innovative techniques or use a technique in a way that is new compared to what is commonly used in the field?

#### Approach:

Does the proposed approach have the potential to meet the needs as specified in the RFP? Is the proposed approach likely to work in a variety of MPS? Does the approach realistically address whether the proposed analysis method will impact the health of the MPS? Does the proposed approach address potential problems and alternative solutions? Is preliminary data or evidence provided? Does the group plan to validate their analysis capability in a way that would give confidence of the method working in another setting (e.g., laboratory outside of their direct control)?

#### **Biomarker Choice:**

Is there sufficient justification provided for the choice of biomarker(s)? Would the measurement of the chosen biomarker(s) be important or beneficial for assessing spaceflight changes or precision health?

#### **Deliverables and Value:**

Are the deliverables well-defined and aligned with TRISH's requested deliverables? Are there appropriate milestones that ensure timely completion?

#### **Proposing Team and Management:**

Have the proposing company or institution and individuals assigned to the effort demonstrated experience in completing similar projects on time and within budget?

#### Non-merit:

Is the budget appropriate? Are the plans for data management acceptable?

#### 4. Selection

Award(s) will be made to proposers whose proposals are determined to be the most programmatically relevant to TRISH, as determined through internal and/or external review and consistent with instructions and evaluation criteria specified in this document, and availability of funding. Proposals may be partially funded. Proposers may be asked to modify sections of the research plan based on the review process, or to work with other experts to ensure the feasibility of the project.

## **G.** Award Information

#### 1. Availability of Funds for Award

TRISH's obligation to make awards is contingent upon the availability of funds from which payment can be made and the receipt of proposals that are deemed acceptable for award in response to this solicitation. It is possible that no award will be made; it is also possible that multiple awards may be awarded. Proposals may also be partially funded.

#### 2. Award Notices

At the end of the selection process, each proposing organization will be notified of its selection or non-selection status. Selection notification will be made by a letter signed by the TRISH Selection Official. Selection letters are not an authorization to begin performance. The selected organization's business office will be contacted by a TRISH representative to negotiate an award. Any costs incurred by the investigator in anticipation of an award are at their own risk until contacted by TRISH. TRISH will determine the type of award instrument, request further business data, and negotiate the resultant action. TRISH awards will be issued and funded by TRISH.

TRISH reserves the right to offer selection of only a portion of a proposal. In these instances, the investigator will be given the opportunity to accept or decline the award.

Once an award is made, TRISH typically directly funds each collaborating institution participating in a joint project, as opposed to sending all funds through a prime awardee. Separate budgets will then be required from each participating institution.

Award recipients will be reimbursed for expenses incurred during the performance period. TRISH may, at its sole discretion, withhold payment of any expenditure that appears questionable or for which additional information or support is required. Final invoices will not be paid until the final annual project report has been submitted, reviewed by the institute's science management and deemed acceptable to TRISH in its sole discretion.

#### 3. Administrative and National Policy Requirements

All grant awards are subject to the provisions detailed in 2 CFR Parts 200 and 1800 (*i.e.*, for higher education, hospital, and non-profit entities) and 14 CFR 1274 (*i.e.*, for commercial firms).

#### 4. Investigator Requirements

Awarded PIs will be expected to follow a number of reporting procedures, as delineated below:

#### a) Publications

For TRISH funded research, please clearly identify support received from TRISH in all publications, invention disclosures, copyrights, and patents, using the following phrase: "This work is supported by the Translational Research Institute for Space Health through NASA Cooperative Agreement NNX16AO69A."

#### b) Intellectual Property (IP) Reporting

Institutions awarded TRISH funding must report each invention disclosure or patent application resulting from their TRISH research grant to **both** TRISH and NASA within 60 days of investigator disclosure to the home institution.

For NASA: Both the electronic and paper version of the NASA Form 1679 may be accessed at the electronic New Technology Reporting website at <a href="http://invention.nasa.gov">http://invention.nasa.gov</a>. In the field designating contract number, please cite NNX16AO69A. See 2 CFR 1800.908 and 14 CFR 401.14 for additional information.

For TRISH: In addition to reporting on intellectual property on the annual project report, please also send copies of the institutional invention disclosure AND NASA Form 1679 or the summary from the online disclosure at <a href="NASA's New Technology Reporting System">NASA's New Technology Reporting System</a> via email to <a href="mailto:spacehealth-info@bcm.edu">spacehealth-info@bcm.edu</a>.

#### c) Deliverables

The purpose of these awards is to advance in situ capabilities for remote advanced biological construct monitoring without sample return.

#### d) Final Report

A final report must be provided to TRISH at the end of the funding period, including a detailed listing of all peer-reviewed publications and IP. The final report is a requirement for eligibility for future TRISH solicitations as well as for the payment of final invoices.

The information in the final report will consist primarily of:

- 1. A statement of the specific objectives;
- 2. The significance of the work;
- 3. The background;
- 4. An overall progress during the performance period;
- 5. A narrative discussion of technical approaches, including problems encountered;
- 6. The accomplishments and impacts related to approach, including any quantitative and qualitative metrics collected; and
- 7. An appendix with bibliography, copies of all publications and reports, and intellectual property disclosures. Any publications or other public materials containing data are particularly important to include in this section.

TRISH encourages interface between the awardee and TRISH to ensure timely completion of the work, as needed. TRISH reserves the right to terminate projects deemed to have missed key aims, deliverables, timelines after TRISH review, as per NASA regulations, <u>Section § 1260.161</u>.

Resolution of concerns during the pre-award and post-award phases is under the purview of the TRISH Science Office at <a href="https://trish.my.site.com/s/concierge">https://trish.my.site.com/s/concierge</a>.

## H. Section VII. Summary of Key Information

Review considerations	TRISH will consider competitive and efficient cost during programmatic review.
Duration	1 year
Last day for submission of proposals	March 6, 2025 at 11:59 pm ET
Selection Announcement	June 2025
Submission Medium	Electronic proposal submission through the TRISH GRID is required.
Web site for submission of proposal via TRISH GRID	https://spacehealth.bcm.edu/
TRISH point of contact concerning this call for proposals	Contact TRISH's Acting Chief Scientific Officer, Rihana Bokhari, Ph.D., by selecting "Open Solicitation" from the drop-down menu at TRISH's Cosmic Concierge website:  https://trish.my.site.com/s/concierge