



The Catalyst Grants Program

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You must read and understand this solicitation in its entirety to prepare a competitive proposal. Key requirements are identified here:

- Proposals for funding are accepted at any time.
- Proposals that do not conform to the requirements in this solicitation may be declared noncompliant and declined without review.
- This solicitation uses a two-step proposal process. The Step-1 and Step-2 phases correspond to the two-step proposal submission and review process. A Step-1 submission serves as a preliminary proposal, similar to a letter or notice of intent. The Step-2 proposal is a full submission, by invitation only, based on the evaluation of the Step-1 proposal. A visual overview of the submission and review process is provided in this document.
- Catalyst Program proposal Tiers 1 and 2 refer to the requested budget amount and proposed project duration. Proposers must select either Tier 1 or Tier 2 when submitting a proposal. Refer to the specific budget and duration parameters listed in this solicitation.
- The Flight Definition and Flight Implementation Phases apply exclusively to flight-based research proposals. These phases are described in greater detail in Section E of the solicitation. Proposals involving flight studies must include two separate budget files, namely one for the Flight Definition Phase and one for the Flight Implementation Phase.

A. Background Information



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) to fund 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 supports programs in physical and behavioral health surveillance, prevention, countermeasures, and medical treatments. 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 https://www.bcm.edu/spacehealth.

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 spaceflight. All proposals should be sure to clearly justify how the project will reduce risks to human health and performance in space.

The Catalyst Grant Program offers a streamlined method for carrying out proof-of-concept projects, directed technology development(s) for space health that address a critical need(s), maturation of promising concepts with strong preliminary findings, and innovative projects that present opportunities outside of regularly scheduled solicitation cycles.

In keeping with the TRISH mission of translating and maturing novel approaches, TRISH may identify specific project(s) for deeper investigation or collaboration opportunities with other funded researchers.

Our primary goal is to help mitigate <u>NASA HRP's Human Research Roadmap (HRR)</u> Risks and enable future deep space missions.

B. 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>.

The applying entity must have in place a documented base of ongoing high-quality research and development in science, healthcare, and technology, or in those areas of science, medicine, and engineering clearly relevant to the specific programmatic objectives and research emphases indicated in this document.

For more information on TRISH and NASA procurement mechanisms, please refer to NASA FAR Supplement https://www.hq.nasa.gov/office/procurement/regs/NFS.pdf.

C. Award Information

We recognize the significant amount of effort it takes to apply for federal funding. This open call for proposals has been carefully crafted to reflect new priorities as a result of new direction from NASA. However, applicants should be made aware of the risk that all funding is subject to the availability of funds provided to TRISH by NASA. Accordingly, the disbursement of any awards under this solicitation is not guaranteed and may be delayed, reduced, or canceled in the event of changes to NASA's budgetary allocations. Projects are anticipated to begin in Spring/Summer 2026 and all projects must be completed within the 12-18 month timeline.

Please note that the Catalyst Program solicitation refers to Tiers 1 and 2, Step-1 and Step-2 proposals, and Flight Definition and Flight Implementation Phases.

- Catalyst proposal **Tiers 1 and 2** refer to the budget amount and project duration of a proposal. Proposers will select to submit a proposal for either Tier 1 or Tier 2 funding. See table below for details.
- The **Step-1 and Step-2** phases refer to the proposal submission and review process. A Step-1 proposal is simlar to a letter or notice of intent. The Step-2 proposal refers to an invited, full proposal submission. Below is a figure of the review and submission phases.
- The **Flight Definition and Flight Implementation Phases** refer to flight-based studies only. The Flight Definition and Flight Implementation phases are described in more detail in <u>Section E</u>. Flight-based studies must have two budget files broken out by Flight Definition and Flight Implementation Phases.



Tier 1 projects are a maximum total amount <\$150K for up to 12 months. **Tier 2 projects** can reach a total amount ≥ \$150K for up to 18 months.

All direct and indirect costs required by an institution must be included in the total cost of the award.

TRISH seeks research that enables and enhances human exploration of space beyond low-Earth orbit. Catalyst Projects MUST:

- Have a focus that falls outside of a currently open or recently-closed TRISH solicitation.
- Address a critical human system risk challenge for NASA HRP and TRISH.
- Represent unique and high-impact ideas, technologies, or countermeasures to spaceflight hazards.

Selected proposals will be funded as research grants. Tier 2 proposals will be funded as a one-year increment with a six-month extension. Additional funding allocations to participating investigators will be based on the submitted budget, available funds, programmatic alignment, and project review.

D. Catalyst Priority Topics

Proposals that fall outside the topics below will be scored as **significantly lower priority** with regard to programmatic relevance. It is anticipated that most award(s) will go to proposals that address a priority research area.

Ground-Based Research:

- Develop a ground-based analog of internal jugular venous flow reversal and test countermeasures and/or preventatives.
- Develop and test novel countermeasures for decompression sickness; methods should focus on nitrogen bubble reduction.
- Test the feasibility and acceptability of streamlined ways to implement validated protocols and clinical guidelines for managing behavioral emergencies of typically high-performing individuals in remote extreme environments.
- Test the feasibility and acceptability of methods to autonomously and unobtrusively detect early signs of behavioral health decline (e.g., depression, anxiety, conflict).
- Validate methods to predict potential behavioral emergencies in high-performing individuals or teams.

Flight-Based Research: Please refer to the Section E for details about flight-based research

- Characterize continuous internal jugular venous flow during orbital and suborbital spaceflight to quantify frequency and variability of abnormal venous flow. While operatorassisted monitoring is possible for orbital flights, a response to this topic must also include a passive, non-invasive method for monitoring venous flow, for use in suborbital spaceflight.
- A comparison of the feasibility, acceptability, and efficacy of known and/or potential venous thromboembolism (VTE) countermeasures. This can include hardware, procedures, and/or training in orbital spaceflight. Since VTE events are unlikely to occur in short orbital spaceflight missions, the endpoint of interest should be measurements of abnormal venous flow.
- Determine predictive markers of abnormal venous flow in orbital and/or suborbital spaceflight.
- Characterize and evaluate countermeasures for the changes in post-flight ambulation and in-flight motor control function and adaptation in commercial fliers before, during, and immediately after orbital flights. This may include testing during the descent/landing phase of flight, and potentially biosample collection. Countermeasures must be evaluated for feasibility, acceptability, and efficacy.

TRISH **discourages** the following types of proposals:

- TRISH discourages projects that provide a single-point solution (see above).
- TRISH discourages work that is primarily in animal models with no translation toward human cells, tissue chips, organs, or human subjects.
- TRISH will not consider Catalyst proposals on topics that are the same as NASA or TRISH solicitations that are currently open.

E. Flight-Based Research Considerations

a. Flight Details

Flight opportunities are dependent upon the schedule from the flight providers. Two types of private spaceflight missions are currently available, namely (1) orbital, free flyer missions and (2) Private Astronaut Missions to the International Space Station (ISS).

Orbital, free flyer missions orbit the Earth for approximately three days nominally and up to five days in a contingency. These missions do not dock with the ISS. TRISH anticipates 1-2 such flights could occur within the period of the grant. Proposers can approximate that each orbital flight will have four individuals. Subject numbers are contingent upon individuals consenting to the study.

Private Astronaut Missions (PAMs) dock with the ISS and have an approximate 10-day duration. TRISH anticipates up to two PAM missions within the period of the grant. Proposers can approximate that each PAM flight will have four individuals. Subject numbers are contingent upon individuals consenting to the study.

TRISH will accept proposals for three kinds of studies that are described in this section. The first type of study includes studies performed only during pre- and post-flight phases of a mission. These studies may access a larger number of subjects through access to both (1) orbital, free flyer missions, and (2) PAM to the ISS. As stated above, TRISH anticipates 1-2 orbital and up to two PAM missions during the duration of the grant each of which will have four individuals.

The second type of study includes studies performed in spaceflight. These studies would primarily be done on orbital, free flyer missions only that do not dock with the ISS.

The third type of study includes projects that do not require any kind of hardware, such as surveys, which are also possible to conduct on PAM missions to the ISS during undocked phases of flight (*i.e.*, the phases of flight after launch to before docking with ISS and after undocking from ISS to before landing back on Earth).

The closer a project is to flight readiness, the longer it will remain in the queue and may be more likely to fly on an orbital flight or PAM.

The Catalyst solicitation invites scientific studies that could be considered for manifest in a commercial space mission. Funded projects that involve flight-based research work will go through two consecutive phases. The first phase, the "Flight Definition Phase," will consist of preparation for a potential flight. The second phase, the "Flight Implementation Phase," will provide support before, during, and after flight. Based on the dynamic nature of commercial space missions, it is possible that only a small subset of selected projects will proceed to the Flight Implementation Phase.

PROPOSED ICP STUDY

BUDGET PHASE 1 FLIGHT DEFINITION

Prepare for flight

Example activities: pre-flight safety and validation studies, purchase of materials, hardware readiness, delivery to flight provider Progression to flight implementation is dependent on flight availability, crew consent, and other parameters. Flight Implementation is NOT guaranteed.

BUDGET PHASE 2 FLIGHT IMPLEMENTATION

Spaceflight execution

Example activities: support for hardware certification, personnel training, data analysis

Each proposed project is expected to provide two budget narratives and two budgets details: one for the Flight Definition Phase and the other for the Flight Implementation Phase. The amount of the total funding allocated to each phase is at the proposer's discretion. Each phase will be funded separately and sequentially. **All direct and indirect costs must be included in the total cost of the award.**

b. Flight Definition Phase

This phase should encompass all activities that are needed prior to the flight itself. This includes purchase of materials, hardware readiness, and delivery support to the flight provider. Proposals must clarify what activities will be included in the Flight Definition Phase. By the end of the Flight Definition Phase the project should be "flight ready" to be added to a flight manifest on short notice.

This phase may last up to one year; however, a shorter Flight Definition Phase may provide more opportunities for flight. Flight opportunities are outside of TRISH's control, thus flexibility may be required depending on the availability of flight opportunities. During this phase all data sharing and use agreements must be signed and institutional review board (IRB) approvals obtained in order to complete the Flight Definition Phase. Even if an awarded project were never selected to fly, having completed the Flight Definition Phase puts a project in a position to be flown if an appropriate flight is scheduled in the future.

c. Flight Implementation Phase

Proposers must understand that the occurrence of commercial space missions is outside of TRISH's control. While commercial spaceflight has become more common in recent years they may reduce in frequency at any time and often have limited lead time prior to flight. Thus, TRISH and any funded investigator team must organize around these dynamic parameters.

Projects must be selected by TRISH to advance to the Flight Implementation Phase. To be eligible for selection a project must:

- 1. Successfully complete the "Flight Definition Phase" as determined by TRISH;
- 2. Have their project and hardware (if applicable) accepted by the flight provider; and
- 3. Comply with all TRISH investigator requirements (see Section J).

If a project is selected for flight, then the Flight Implementation Phase budget will be awarded. It is possible that some projects may be funded in the Flight Definition Phase and not the Flight Implementation Phase. The Flight Implementation Phase is not guaranteed.

The Flight Implementation Phase begins after a mission is announced that has a subject pool with the opportunity to consent to the project. This phase includes Principal Investigator (PI) support for hardware certification, training TRISH or flight provider personnel as necessary for study implementation, and data analysis after the flight, if applicable.

F. Step-1 Proposals

Proposals for funding are accepted at any time. This solicitation uses a two-step proposal process.

All proposing organizations must register (or already be registered) with the <u>System for Award Management (SAM)</u> to ensure ability to receive funds if selected. Proposals must be submitted through the TRISH Grant Research Integrated Dashboard (GRID) at https://spacehealth.bcm.edu/. The proposal submission format and template are available on GRID and are detailed below. Proposals that do not conform to these requirements may be declared noncompliant and declined without review.

To initiate a Step-1 proposal:

- Create or login to your GRID account.
- Click "Programs" in the top navigation bar.
- Select "The Catalyst Grants Program" 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.

Step-1 proposals submitted to this solicitation should include a synopsis of the intended research, with the total length of the Step-1 proposal not to exceed two 8 ½ by 11-inch pages using a standard 12-point font and one-inch margins.

All Step-1 proposals must include:

- 1. Clearly identified specific aims and relevant approach information for the research plan;
- 2. Clearly defined deliverables or expected outcomes. A deliverable is the end result of a research project. It could be a report, protocol, new approach, recommendation, technology, software, device, product, *etc.*;
- 3. Clearly defined a path to implementation. This is required for all proposals. Implementation is defined as the ability for a solution or tool to become operationally usable in spaceflight. This section should include a well-articulated roadmap that outlines the steps required to reach implementation, including technical milestones, integration processes, and any necessary testing or validation phases. A timeline must be provided, clearly indicating progress to date, completed phases, and future development stages. This timeline should demonstrate a realistic and achievable progression from the current status to full implementation, ensuring feasibility within the context of spaceflight operations;
- 4. An explanation of alignment with the TRISH Catalyst Priorities; and
- 5. A summary of how the work will meet a need for human health and performance in spaceflight. The proposer should note the HRP HRR risk(s) they are addressing and clearly describe how the proposed work would benefit human health and performance in space.

No additional documents should be uploaded with the Step-1 proposal. Project personnel are **not** considered binding for Step-1 and can be adjusted later in an invited Step-2 proposal.

Step-1 proposals are prepared by the PI or a designated representative of the PI. TRISH does not require institutional sign-off at the Step-1 level. The proposer must follow their institution's policy regarding institutional sign-off; GRID allows for an authorized organizational representative to sign-off, if applicable.

Proposals that do not conform to these requirements may be declared noncompliant and declined without review. Following the successful submission of a Step-1 proposal, TRISH may invite a proposer to submit a Step-2 proposal. Proposers will be notified via email from GRID (noreply@mail.smapply.net) regarding Step-1 proposal status.

G. Step-2 Proposals

Proposers will be notified via email from GRID (<u>noreply@mail.smapply.net</u>) regarding Step-1 proposal status. If invited to submit a Step-2 proposal, click on the link within the email to initiate the Step-2 proposal. The system will guide proposers through submission of all required proposal information.

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

Each section of the proposal listed below should conform to the stated page limits (if no page limit is given, use space as needed). Excess pages in a section (and proposal sections not clearly identified and included in the list below) will be redacted and the proposer notified.

a. Application Form

All full 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 co-investigators
- Collaborating institutions (if any)
- Project title
- Proposed start/end dates
- Authorized organizational representative, with contact information
- Total funds requested
- 10% Cost-sharing

b. Project Description

The maximum page limit for the Project Description for Tier 1 is 8 pages and Tier 2 is 15 pages, using 8 ½ 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, Specific Aims and Hypothesis, Preliminary Data, Innovation, Relevance to Spaceflight, Deliverables, and Timeline. Furthermore, we provide below a few points to consider including:

- Background should include state of the art for the research topic, and how the proposal will contribute to it or spaceflight crew health;
- Specific Aims must be clearly stated and outlined;
- Preliminary, or supporting data (preliminary data is encouraged, if applicable);
- Clearly state the advantage of new capability over current gold standard and what will be learned by using this technique;
- How the proposed work will reduce a significant space health challenge;
- Clearly detail the team and their strengths;
- Explain the potential challenges for the project and mitigation strategies;
- A description of deliverables and a clearly defined path to implementation along with timeline. This section should include a well-articulated roadmap that outlines the steps required to reach implementation, including technical milestones, integration processes, and any necessary testing or validation phases; and
- Explain the Countermeasure Readiness Level (CRL) or Technology Readiness Level (TRL).

| TRL Definition | CRL Definition | TRL/C RL Score | CRL Category |
|--|--|----------------------|----------------------------------|
| Basic principles observed and reported | Phenomenon observed and reported. Problem defined | 1 | Basic Research |
| Technology concept and/or application formulated | Hypothesis formed, preliminary studies to define parameters. Demonstrate feasibility | 2 | Research to Prove Feasibility |
| Analytical and experimental proof-of-concept of critical function and/or characteristics | Validated hypothesis. Understanding of scientific processes underlying problem | 3 | |
| Component and/or breadboard validation in a laboratory environment | Formulation of countermeasures concept based on understanding of phenomenon | 4 | Countermeasure Development |
| Component and/or breadboard validated in a relevant environment | Proof of concept testing and initial demonstration of feasibility and efficacy | 5 | |
| System/sub-system model or prototype demonstration in a relevant environment | Laboratory/clinical testing of potential countermeasure in human subjects to demonstrate efficacy of concept | 6 | |

| System prototype demonstration in an operational environment | Evaluation with human subjects in controlled laboratory conditions simulating operational spaceflight environments | 7 | Countermeasure Demonstration |
|---|--|---|---------------------------------|
| Actual system completed and "flight qualified" through test and demonstration | Validation with human subjects in actual operational spaceflight to demonstrate efficacy and operational feasibility | 8 | Countermeasure Operations |
| Actual system flight proven through successful mission operations | Countermeasure fully flight tested and ready for operational implementation | 9 | |

References <u>must be included</u> and support the scientific/technical validity of the proposed research (no page limit).

If your proposal is a resubmission, you should identify it as such in your Step-1 submission. Resubmitted proposals that were previously externally reviewed are required to address prior reviews if invited to submit a Step-2 full proposal.

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. See the "Categories of Proposal Personnel" section on page 25 of the NASA Grant and Cooperative Agreement Manual (GCAM) for more details on team members. Although TRISH does not require a specific biosketch format, we recommend using the NIH biosketch template found here.

d. Description of Institution/Organization, Resources, and Equipment

This section must describe any existing facilities and equipment that are required for the proposed investigation and whether the team already has access to them or how they plan to gain access (2 pages maximum).

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.

The proposing PI must notify TRISH (https://trish.my.site.com/s/concierge) 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 subtask, 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. Statistical Approach

A thorough **one-page statistical section** must be included which includes a power analysis for the estimate of sample size. If a statistical section is not applicable, a justification statement must

be included. Please see the Guidelines for Statistical Evaluation of NASA Human Research Studies posted alongside this document for additional information concerning sample size calculations.

i. Budget Form and Budget Justification

The proposal budget is made up of two parts: the budget justification and the budget details. The budget details are the actual or estimated costs, in whole dollars, that correspond with the budget justification.

- TRISH caps indirect rates at negotiated federal rates.
- Proposals must include at least 10% cost sharing in the budget. Please refer to FAQ for more details. Cost sharing may be contributed in cash or in-kind (non-cash contributions) provided by non-Federal third parties.
- A travel allowance should be included in the proposal budget to attend the annual NASA Human Research Program Investigators' Workshop in the Houston/Galveston area. This meeting typically occurs in late January or early February.
- TRISH awards are total costs (Direct plus indirect).

Proposers planning a flight-based project must submit two separate budget narratives and detailed budgets: one for the Flight Definition Phase and one for the Flight Implementation Phase.

j. 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 whom 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 member(s) requiring its use.

If the proposal involves the conduct of research by a non-U.S. organization, signed letter(s) of certification must be included that verifies that funding for their research 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 for agency authorized to make such a commitment.

k. Special Matters (specific information on required animal or human subjects protocol approval, if applicable)

For proposals using human subjects and/or animals, assurance of compliance with human subjects and/or animal care and use provisions is required.

TRISH utilizes just-in-time practices for approval of the use of human subjects or animals. For proposals employing human subjects and/or animals, assurance of compliance with human subjects and/or animal care and use provisions is required within 90 days of notice of award. For such proposals, please state whether for the Institutional Review Board (IRB)/Animal Care and Use Committee (IACUC) is "pending," "approved," or explain why it is not required. If the IRB/IACUC certification is already approved at proposal submission, attach a copy of the certification as part of the proposal upload. This will not be considered part of the Project Description.

After award, a statement must be provided to TRISH from the proposing institution that identifies the selected proposal by name and certifies that the proposed work will meet all federal and local requirements for human subjects and/or animal care and use. This includes relevant documentation of IRB approval and/or approval by the IACUC.

TRISH will require current IRB or IACUC certification prior to each year's award, including commencement of the first year of funding.

Policies for the protection of human subjects in NASA-sponsored research projects are described in the NASA Policy Directive (NPD) 7100.8G "Protection of Human Research Subjects".

Animal use and care requirements are described in <u>14 CFR 1232</u> and <u>NASA Procedural</u> Requirements (NPR) 8910.1D "Care and Use of Animals".

TRISH will require current IRB and IACUC certification prior to each year's start date of award.

Each response to this solicitation that requires Vertebrate Animals and/or higher order Cephalopods Section (VACS) must address the five points outlined in the VACS instructional document posted alongside this document. This response should be presented as part of the main proposal upload and is limited to two pages. These two pages are not considered part of the project description. A sample VACS is provided in the VACS instructional document posted alongside this document.

I. <u>Instructions for Preparation of Invited Step-2 Proposals</u>

| Section | Required? | Page Limit | Location |
|--------------------------|-----------|--|-------------|
| Table of Contents | Optional | As needed | |
| Project Description | Yes | 8 pages for Tier 1 and 15 pages for Tier 2 | G.b. |
| References and Citations | Yes | As needed | |
| Biosketches | Yes | As needed | <u>G.c.</u> |

| Description of Institution/Organization, Resources, and Equipment | Yes | As needed | G.d. |
|---|---|-----------|-------------|
| Current and Pending Support | Yes | As needed | <u>G.e.</u> |
| Management Approach | Yes | As needed | <u>G.f.</u> |
| Data Management Plan | Yes (including Software Sharing Plan if experiment produces any software or code, including high-level languages) | 2 | <u>G.g.</u> |
| Statistical Approach | Yes | 1 | <u>G.h.</u> |
| Budget Form and Budget Justification | Yes | As needed | <u>G.i.</u> |
| Statement of Commitment and Letters of Resource Support | Yes, if resources or facilities are not directly under PI control | As needed | <u>G.j.</u> |
| Animal Care or Human Subjects certifications | Yes, if applicable/available | As needed | G.k. |
| Vertebrate Animals and/or higher order Cephalopods Section | Yes, if applicable | 2 | G.k. |

H. NASA Safety Policy

TRISH has chosen to adopt NASA's safety policy. Safety is NASA's highest priority. Safety is the freedom from those conditions that can cause death, injury, occupational illness, damage to or loss of equipment or property, or damage to the environment. NASA's safety priority is to protect: (1) the public; (2) astronauts and pilots; (3) the NASA workforce (including employees working under NASA instruments); and (4) high-value equipment and property. All research conducted with TRISH funding shall conform to this policy.

I. Review and selection

a. Step-1 Relevancy Review

Each Step-1 proposal will be reviewed by members of the TRISH Science Office. TRISH will review Step-1 proposals based on whether the proposal:

- a. aligns with TRISH's Catalyst Priorities and the Institute's mission;
- b. is not already being addressed by NASA or TRISH;
- c. has appropriate budget, timeline, and feasibility;
- d. is eligible for federal funding support (see Eligibility Criteria for details).

TRISH encourages proposers to review the Catalyst Priorities listed in <u>Section D</u>.

For proposals declined at the Step-1 phase, the proposer will receive an email from GRID (<u>noreply@mail.smapply.net</u>). Please note that proposals declined at this phase will not receive specific feedback regarding their proposal.

b. Step-2 Programmatic and External Scientific & Technical Merit Review

Step-2 proposals will be initially screened by the TRISH Science Office for availability of funds, programmatic relevance, and assessment of the following criteria:

- a. How the proposed work would meet a clear need for human health and performance in spaceflight;
- b. How the research approach is state-of-the-art or is considered innovative;
- c. Programmatic alignment with the TRISH portfolio;
- d. Appropriateness of the budget, timeline, and feasibility;
- e. Eligibility for federal funding support (see Eligibility Criteria for details).

For proposals declined at the programmatic review phase or for compliance reasons, the proposer will receive an email from GRID (noreply@mail.smapply.net) indicating the proposal is not going to be reviewed. Please note that proposals declined at this phase will not receive specific feedback regarding their proposal.

Step-2 Proposals that are within scope of the TRISH mission and have programmatic relevance with a budget above the Simplified Acquisition Threshold (\$250K) will then be considered for technical and scientific merit review (external peer review). Proposals under the \$250K simplified acquisition threshold will be sent to at least 2 internal reviewers. TRISH also reserves the right to send Step-2 proposals below the Simplified Acquisition Threshold for external review if deemed appropriate. 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.

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

Innovation:

Does the study use innovative techniques or methods? Are the techniques, approaches, or methods new to spaceflight research or applied in a way that is novel? Will the study meet the expectations of TRISH that studies go beyond merely taking an incremental step following prior studies? Would maturation of this project lead to new or improved approaches for space health?

Significance:

If the aims of the application are achieved, how will it affect TRISH's mission of enhancing spaceflight research and space health? Would negative data provide valuable information? Meaningful results can also include identification of technologies or countermeasures not worthy of further study; that is, evidence-based exclusion of possibilities.

Approach:

Are the conceptual framework, design, methods, and analyses adequately developed, well integrated, and appropriate to the aims of the project? Is the proposed approach likely to yield the desired results? Does the applicant acknowledge potential problem areas and consider alternative tactics?

Environment and Team:

Are the investigators, collaborators, and other researchers well suited to the project? If the project is collaborative, do the investigators have complementary and integrated expertise? Does the scientific environment in which the work will be performed contribute to the probability of success? Do the proposed experiments take advantage of unique features of

the scientific environment or employ useful collaborative arrangements? Is there evidence of institutional support?

The following criteria will be used in for **non-merit comments**:

Is the budget appropriate? Is the project feasible in the proposed timeline? Is the vertebrate animal and higher order cephalopod section (if corrections would not significantly affect the experimental design) appropriate? Are the plans for data management acceptable?

Step-2 Proposals that have undergone peer review will be presented to TRISH Executive Council for award recommendation. Final selection of awards is made by the TRISH Executive Director and Selection Official. TRISH may allow for one resubmission of the proposal, if programmatically relevant. The resubmission will also undergo peer review.

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 requested 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. TRISH will notify the proposer of the final decision, approximately 3-4 months after submission. If sent for external review, anonymized reviews will be provided to the proposer regardless of outcome.

J. Award Requirements

Institutions must be registered in the <u>SAM database</u> prior to receipt of funds. SAM registration usually takes around 30-60 business days to complete, though new policies may temporarily lengthen the registration time.

a. Award Notification

Selected investigators **must** respond to reviewer comments before funding commences. Changes to aspects of the proposal detailed in the response will be considered as part of the proposal when TRISH evaluates milestones and deliverables. Proposals may be partially funded. Proposers may be requested to modify sections of the research plan or to work with other experts to ensure the feasibility or to align the project with TRISH's science programs. The principal investigator may elect to accept or decline the award at the award notification phase.

In the award letter, TRISH will specify a start date for the proposed project. The start date may be delayed by 3-12 months based on budget availability. As a result, the principal investigator may accept or decline the award at the award notification phase.

b. Reporting

As previously stated, the Catalyst Program supports investigators working on innovative and disruptive projects that are higher risk than traditional proposals. Therefore, reporting will be required on a regular basis. The awardees are responsible for day-to-day operations related to the research supported by the award. However, to carry out these tasks as required by TRISH, a Science Office representative will monitor the progress to help identify potential problems and areas where technical assistance may be needed. This monitoring will be achieved through half-year reports and other virtual meetings on an as-needed basis. TRISH will discuss progress being

made on aims, timelines, and deliverables, while also providing feedback to help mitigate obstacles.

Recipients from the Catalyst Grants should expect the following reporting schedule and guidelines:

- As-needed virtual meetings to ensure progress is being made on aims, timelines, and deliverables while providing feedback and advice to help mitigate obstacles.
- Interim half-year reports that will present a summary of work and research completed, and aims achieved (or if not achieved, provide justification). This report should also discuss any problems encountered, update the project schedule, present financial status, and discuss planned work.
- One annual written report including a list of publications, invention disclosures, a
 description of progress including a comparison with the originally proposed work schedule,
 and results of periodic data reviews. The final report is required no later than 60 days after
 the project end date as well as a close-out webinar with NASA and TRISH stakeholders.
 If the project is an 18-month project, the report is due 30 days before year 2 renewal.
- Project data will be expected to be archived with TRISH and NASA, along with metadata and any other information required for subsequent use or interpretation within one year of project completion.
- TRISH-funded authors and co-authors will be required to 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."
- TRISH-funded authors and co-authors will also be required to send TRISH copies of their peer-reviewed scientific publications and to deposit all publications and associated data into NASA's publication repository NASA PubSpace (https://www.ncbi.nlm.nih.gov/pmc/funder/nasa/) managed by the NIH's Pubmed Central.

TRISH encourages interface between the awardee and the TRISH Science Office to foster translational relevance for deep space biomedical needs, as needed. TRISH reserves the right to terminate projects deemed to have missed key aims, deliverables, timelines after scientific TRISH review, as per NASA regulations, Section § 1260.161.

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