



The Catalyst Grants Program

Contents

Α.	Background Information			
В.	Eligibility			
C.	Award information			
D.	Submitting information			
	a.	Application form	3	
	b.	Project Description	4	
	C.	Biosketches	5	
	d.	Description of institution/organization, resources and equipment	5	
	e.	Current and Pending Support	5	
	f.	Budget form and budget justification	5	
	g.	Letters of Collaboration and Resource Support	5	
	h.	IRB, IACUC approval, and VASR	6	
E.	NASA Safety Policy		6	
F.	Review and selection			
G.	Reporting 8			

Funding Summary

Tiers	Type of Proposal	Funding/year	Timeline
Tier 1	Proof of Concept (POC)	< \$150K, Total Cost	1 year
Tier 2	Development	> \$150K, Total Cost	Up to 2 years

A. Background Information

The Translational Research Institute for Space Health (TRISH) is tasked with identifying and supporting disruptive, high-risk approaches for deep-spaceflight. Realizing that these cutting-edge programs require time and investment to be successful, the Catalyst Grant permit funding for innovative, focused research that pertains to the TRISH mission of translating **radically novel** approaches to reduce health risk and optimize physical and/or behavioral performance during deep space exploration. TRISH recognizes the need to encourage innovation among the space health community, to attract companies with cutting-edge technologies and high-risk high-reward ideas, and to translate existing technologies for use in space flight. 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), and innovative projects that present opportunities outside of regularly scheduled solicitation cycles.

In keeping with the TRISH mission of translating radically novel approaches, TRISH science leadership may identify one or more aspects of the Catalyst Grants project(s) for further review, deeper investigation, or collaboration opportunities with other funded researchers.

Our primary goal is to help mitigate <u>NASA Human Research Program's (HRP) risks for long</u> <u>duration spaceflight missions</u>. For more information, refer to the <u>NASA Human Research</u> <u>Roadmap</u> website. For more information on TRISH and NASA procurement mechanisms, please refer to NASA FAR Supplement <u>https://www.hg.nasa.gov/office/procurement/regs/NFS.pdf</u>

**This prioritization of the human health and performance risks may be subject to change according to planned space exploration missions.

B. Eligibility

All categories of United States (U.S.) institutions and companies are eligible to submit proposals. Principal Investigators 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 in international proposers and institutions, please refer to https://spacehealth.bcm.edu/res/p/applicantfaq/.

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. Start-up companies should highlight their track record from previous positions in detail in the Team Member's Biosketch.

C. Award information

Tier 1 projects consist of prototype or proof of concept (POC) projects, of maximum total amount <\$150K and limited to 1-year.

Tier 2 projects consist of development, or capability building projects, of total amount of > \$150K for up to two years.

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

Catalyst Projects will **INCLUDE** projects:

- whose focus fall outside a currently-open, or recently-closed TRISH solicitation;
- that augment a new area of research to address a critical challenge for NASA HRP and TRISH.
- with disruptive/paradigm shifting technologies or approaches (incremental projects will not be considered).
- Unique, high-impact countermeasures to spaceflight hazards, such as galactic cosmic radiation.

TRISH seeks research that enables and enhances human exploration of space beyond low-Earth orbit. Important considerations when applying:

- TRISH encourages methods that are out-of-the-box, challenge assumptions, and could lead to extraordinary outcomes;
- TRISH seeks new ways to partner with stakeholders, new ways to find promising technologies, or new ways to extend TRISH's reach into emerging areas with the potential to reduce health risk **AND/OR** to optimize human (physical/behavioral) performance during deep space missions;
- Catalyst proposals should not be deemed appropriate to be funded directly by NASA or through other TRISH open solicitations;
- TRISH does not encourage proposals that emphasize incremental advances to existing approaches or methods.

Selected proposals will be funded as research grants; with Tier 2 proposals being funded in oneyear increments. Additional funding allocations to participating investigators will be based on the submitted budget, available funds, programmatic alignment, and project review.

D. Submitting information

Proposals for funding are accepted at any time. Proposers considering applying should register in system for award management (SAM) database (<u>www.sam.gov</u>) to ensure ability to receive funds if selected. Proposals should be submitted through the TRISH Grant Research Integrated Dashboard (GRID - <u>https://spacehealth.bcm.edu/</u>). Format and template will be available on GRID and are detailed below. Proposals that do not conform to these requirements may be declared noncompliant and declined without review.

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 (see <u>Section D.g.</u>)
- 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

b. Project Description

The maximum page limit for the Project Description for Tier 1 is 8 pages and Tier 2 is a maximum of 15 pages, using 8 ½ by 11-inch pages using a standard 12-point font and one-inch margins. The page limit for 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. Figures and tables must, in the judgment of reviewers, be legible without magnification. The submission of appendices along with the proposals 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 Space Flight, 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 available);
- 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;
- Description of deliverables along with timeline in table format;

For Tier 1, proposers should submit a proposal of 8 pages maximum that should include a validation/testing plan, medical or operational need to be fulfilled and future development of concept related to deep space. The timeline is for 1 year of funding.

For Tier 2, proposers should submit a proposal of 15 pages maximum for a timeline for 2 years of funding that include, **in addition to the requirements of Tier 1**:

- The feasibility of completing the proposed building capabilities with the proposed timeframe;
- How this new build will be tested, validated, and characterized. A transition plan on how this would be delivered to NASA, or other stakeholders (such as venture capital, other federal funding, etc.). Please note that this is not a POC proposal and should include some background and preliminary data;

References <u>must be included</u> and support the scientific/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 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 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 appropriate) 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., \$50 k/year); and

• Time commitment by the investigator for each year of the period of performance.

The proposing PI must notify the TRISH Director Dr. Dorit Donoviel (spacehealth-info@bcm.edu) 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. Budget form and budget justification.

- TRISH caps indirect rates at negotiated federal rates.
- Proposals must include at least 10% cost sharing in the budget. Please refer to <u>FAQ</u> for more details.
- 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)

g. Letters of Collaboration and Resource Support

Every person who is expected to have 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. On 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 members(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 or agency authorized to make such a commitment.

h. IRB, IACUC approval, and VASR

For proposals using human subjects and/or animals, assurance of compliance with human subjects and/or animal care and use provisions is required. Policies for the protection of human subjects in NASA-sponsored research projects are described in the NASA Policy Directive (NPD) 7100.8E "Protection of Human Research Subjects" (http://nodis3.gsfc.nasa.gov/displayDir.cfm?t=NPD&c=7100&s=8E). Animal use and care requirements are described in the NASA Code of Federal Regulations (CFR) (http://www.gpo.gov/fdsys/granule/CFR-2012-title14-vol5/CFR-2012-title14-vol5/

<u>part1232/content-detail.html</u>). TRISH utilizes a just-in-time practice for approval of the use of human subjects or animals. If the IRB/IACUC certification is already approved at the time of proposal submission, attach a copy of the certification as part of the proposal.

Each Catalyst grant proposal that requires vertebrate animals **must address** the five points outlined in the <u>Vertebrate Animal Scientific Review (VASR)</u> instructional document posted alongside this document. A sample VASR is provided in the VASR instructional document posted alongside this document. **TRISH will require current IRB and IACUC certification prior to each year's start date of award.**

E. 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.

F. Review and selection

1. All proposed research will be initially screened by the TRISH Science Office for availability of funds, programmatic relevance (Phase 1) and compliance with this solicitation for the following attributes:

- a. utilizes innovative and cutting-edge methodologies or technologies in alignment with TRISH's mission;
- b. is not already being addressed by NASA or TRISH;
- c. has appropriate budget, timeline and feasibility;
- d. is eligibility for federal funding support (see Eligibility Criteria for details).

2. For proposals declined during initial review the proposer will receive a letter by email indicating the proposal is not going to be reviewed. The proposer can request, within 30 calendar days after issuance of the notification letter, a verbal debrief from TRISH if desired.

3. Proposals that are within scope of the TRISH mission and have programmatic relevance above the Simplified Acquisition Threshold (\$150K) will then be considered for technical and scientific merit review (external peer 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.

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? Is it a disruptive/paradigm shifting idea? Is the approach new to NASA? Will the study meet the expectations of TRISH that studies go beyond merely taking an incremental step following prior studies?

Significance:

If the aims of the application are achieved, how will it affect TRISH's mission of augmenting spaceflight research? 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?

Non-merit:

Is the budget appropriate? Is the project feasible in the proposed timeline? Is the vertebrate animal scientific review appropriate(if corrections would not significantly affect the experimental design)? Is data management plan present and acceptable?

4. 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 Director (Phase 2). TRISH may allow for one resubmission of the proposal, if programmatically relevant and funds are available. The resubmission will also undergo peer-review. A score of NRFC (Not Recommended for Further Consideration) will not be allowed resubmission.

5. TRISH will notify the proposer of the final decision, usually within 8 weeks after submission. Redacted reviews will be provided to the proposer regardless of outcome. 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.

6. Institutions must be registered in the system for award management (SAM) database (www.sam.gov) prior to receipt of funds. SAM registration usually takes around 20 business days to complete, though new policies may temporarily lengthen the registration time.

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. Please allow up to 8 weeks for response after submitting the proposal.

G. Reporting

As previously stated, the Catalyst Grants support investigators working on high-risk projects for deep spaceflight. 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 Officer 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 quarterly virtual meetings. 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:

- Required, virtual quarterly meetings to ensure progress is being made on aims, timelines, 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 a 2-year project, the report is due 60 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. This reporting tool will be provided by TRISH.
- 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 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, <u>Section § 1260.161</u>.

Resolution of concerns during the pre-award and post-award phases is under the purview of TRISH Science Office at <u>SpaceHealth-Info@bcm.edu</u>