TRISH-RFA-2001-PD: TRISH Request for Applications from Postdoctoral Fellows

October 24, 2019
TRISH-RFA-2001-PD

Translational Research Institute for Space Health (TRISH)
2450 Holcombe Blvd
TMCx
Houston, TX 77021

TRISH Announcement
Soliciting Postdoctoral Fellowship Applications

A Request for Applications to the
Translational Research Institute for Space Health

Applications Due: January 22, 2020 at 5:00 PM Eastern Time
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You must read and understand this solicitation in its entirety to prepare a competitive proposal. Key points are designated with the following icons:

- **Requirement**
- **Recommended**
- **Take Note**

- Proposals that do not conform to the requirements in this document may be declared non-compliant and declined without review.
- The postdoctoral fellow must contact and arrange for a mentor.
- The mentor and mentor’s organization must be registered with the NASA Solicitation and Proposal Integrated Review and Evaluation System (NSPIRES).
- The application must be submitted by an authorized representative of the mentor’s organization.
- The proposed work should be impactful in helping to reduce a risk to the health and performance of humans living and working in space. See the NASA Human Research Program’s risks on the Human Research Roadmap (HRR; https://humanresearchroadmap.nasa.gov/).
- The specific aims must be clearly outlined in the Research Plan.
- The length of the Research Plan cannot exceed 10 pages using 12-point font.
- The mentor must provide a Mentor Statement not to exceed 4 pages using 12-point font.
- The postdoctoral fellow must arrange for three letters of recommendation, not to exceed 2 pages each, none of which can be written by the proposed mentor.
- If using vertebrate animals, the application must meet requirements of the Vertebrate Animal Scientific Review section of this document (https://www.nasa.gov/sites/default/files/atoms/files/hrp_vertebrate_animal_scientific_review.pdf).
- If applicable to the proposed work, the Analog Study Resource Worksheet, or Retrospective Data Request Form should be included.
- TRISH follows National Institutes of Health (NIH) guidelines concerning the inclusion of women and minorities as research subjects. Women and members of minority groups must be included in TRISH-supported biomedical and behavioral research projects involving human subjects, unless a clear and compelling rationale and justification is provided stating that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. Non-compliance could result in termination of the fellowship.
# Soliciting Postdoctoral Fellowship Applications

## Class of 2020

### About the Solicitation

TRISH is soliciting applications for its Postdoctoral Fellowship Program.

The award is for two years of funding with an optional, competitively awarded third year of funding that may be available. Stipends will be $60,000 and an additional allocation for health insurance and some travel will be provided.

Start date will be August 2020.

See Section B

### About TRISH

TRISH is at the forefront of space health technology. Partnered with NASA via a cooperative agreement, TRISH provides funding for very early stage as well as late stage research that can quickly be adapted for use in space. TRISH has a high risk threshold and is solving space health issues as defined by NASA’s Human Research Program. It is not required that you fully understand NASA’s risks. If you are performing terrestrial human health and performance research, your work may be adapted for use in space. Find out more on our website [www.bcm.edu/spacehealth](http://www.bcm.edu/spacehealth).

See Section A

### Application Process Overview

1. Select mentor or look at our listing of mentors “List of Prospective Mentors open to collaboration” posted alongside the solicitation document and TRISH’s online community at [trish.force.com](http://trish.force.com).
2. Mentor and mentor’s organization register in NSPIRES. Mentor registers as Principal Investigator (PI) and the trainee registers as the postdoctoral fellow.
3. Create proposal.
4. Authorized organizational representative from the mentor’s institution submits the proposal. Deadline to submit proposals is January 22, 2020.
5. Review panel convenes in April 2020.
6. Award notification are made in July 2020.

Throughout Document

### Schedule

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### Eligibility

Applicants must be U.S. citizens, permanent residents, or persons with pre-existing visas obtained through their sponsoring academic institutions that permit postdoctoral training for the project’s duration.

See Section B

### Help

- To learn more about TRISH [www.bcm.edu/spacehealth](http://www.bcm.edu/spacehealth)
- To join TRISH’s online community and find a mentor [trish.force.com](http://trish.force.com)
- To follow TRISH [@bcm-spacehealth](https://twitter.com/bcm-spacehealth)
- To register and apply [nspires.nasaprs.com](http://nspires.nasaprs.com)
- Requests for assistance in accessing and/or using NSPIRES may be directed by email to [nspires-help@nasaprs.com](mailto:nspires-help@nasaprs.com) or by telephone to (202) 479-9376, Monday through Friday, 8 a.m. to 6 p.m., Eastern Time.

See Section C
A. Introduction and Overview

I. Introduction to TRISH

TRISH’s mission is to provide funding for early as well as late stage cutting-edge research that can be translated into validated human health and performance solutions for deep space exploration missions. The institute recognizes the importance of inspiring, educating, and advancing space health research of skilled researchers and especially the next generation of space life scientists.

Founded on October 1, 2016, TRISH works in partnership with NASA’s Human Research Program (HRP) through Cooperative Agreement NNX16AO69A. TRISH, led by Baylor College of Medicine’s Center for Space Medicine, is a consortium that includes the California Institute of Technology and the Massachusetts Institute of Technology. Membership in the consortium is NOT a prerequisite to apply for TRISH awards and investigators new to space life science research are particularly encouraged to apply to TRISH opportunities.

Operating as a virtual institute, TRISH employs multiple platforms to stay connected, inform and most importantly, source innovations. The institute maintains a small footprint via a modest office in Houston, TX and has representatives in innovation hubs on the east and west coasts.

For more details on TRISH, its mission and funding opportunities can be found at https://www.bcm.edu/spacehealth. For more information on NASA HRP see https://www.nasa.gov/hrp. Check out our website to see the work being done by existing TRISH postdoctoral fellows at https://www.bcm.edu/spacehealth/career-development/academy-of-bioastronautics. Join Orbit to stay connected with TRISH’s community, reach out to our current postdoctoral fellows, and learn more about us.

II. NASA’s Integrated Research Plan

The Integrated Research Plan (IRP) describes NASA’s research activities that address the needs of human space exploration and serve HRP stakeholders, such as flight surgeons and astronauts. The Human Research Roadmap (HRR) is the web-based tool for communicating IRP content that identifies the approach and research activities planned to address risk reduction strategies for human space exploration (https://humanresearchroadmap.nasa.gov/).

Potential applicants should review NASA’s HRR and explain how their proposed projects could impact specific risks and help close discrete knowledge or technology gaps, as defined in the HRR.

The proposed work must address at least one risk to the health and performance of humans living and working in space. Work which proposes to mitigate any of the risks detailed on NASA’s HRR may be funded under this program. Applicants must describe how their proposed line of investigation will shed light on better defining or mitigating the risk(s) and closing or partially closing specific gaps in knowledge as outlined in the HRR. Applications that do not comply with this requirement may be declined without review.
III. Digital Resources and Bibliography

1. Translational Research Institute for Space Health’s Website (https://www.bcm.edu/spacehealth) contains information on TRISH’s mission, funding opportunities and programs.

2. Translational Research Institute for Space Health's Orbit (trish.force.com), a place for TRISH’s space biomedical research community to network and learn more about TRISH.

3. NASA Human Research Program Integrated Research Plan (HRP-IRP). The IRP describes the portfolio of HRP research and technology tasks. The IRP is the HRP strategic and tactical plan for research necessary to meet HRP requirements. See the HRR website: https://humanresearchroadmap.nasa.gov/Documents/IRP_Rev-Current.pdf


6. Life Sciences Data Archive (LSDA). An online database containing descriptions and results of completed NASA-sponsored flight experiments. Descriptions include experiments, missions, procedures, hardware, bio-specimens collected, personnel, and documents. Bio-specimens that are available for research purposes are described in detail. A limited number of experiments contain final reports and spreadsheet data suitable for downloading. Data from human subjects are unavailable online for reasons of privacy. Please visit: https://lsda.jsc.nasa.gov/


B. Background Information

I. Research Opportunity

This Request for Applications (RFA) is soliciting applications for the TRISH Postdoctoral Fellowship Program. Postdoctoral fellowships will be competitively awarded in any laboratory in the United States (U.S.) conducting biomedical/biotechnological research aligned with TRISH’s mission and goals. Applications will be screened for compliance and undergo a scientific and technical peer review by an external peer review committee consisting of a number of experienced scientists. Relevance to TRISH’s and NASA’s programmatic needs and goals will also be evaluated by TRISH management. Selections will be performed by the TRISH Selection Official.

The award is for two years of funding with an optional, competitively awarded third year of funding that may be available. Requests for a third year of funding will take into account the awardee’s performance during the first two years of funding and be evaluated by TRISH’s science management. All researchers, regardless of support by NASA or TRISH, can serve as mentors for this opportunity. Investigators new to space life sciences are particularly encouraged to apply to TRISH opportunities.

Postdoctoral fellows are responsible for contacting and arranging for a mentor. TRISH facilitates introductions to mentors by using a “List of Prospective Mentors Open to Collaboration” posted alongside the solicitation document, also published in the Orbit platform’s Trainees topic. This list includes existing projects of potential interest to postdoctoral fellows. Please contact Aurelia Vergeade, averageade@nasaprs.com, if you are a mentor interested in being included on the list. Additional listings will not be accepted any later than December 6, 2019. Applicants may refer to the document “List of Prospective Mentors Open to Collaboration” for information regarding available mentors but are NOT limited to this list of mentors. No preference will be given to mentors listed in the “List of Prospective Mentors Open to Collaboration.” TRISH provides this list as a service to the community.

TRISH invites retrospective data, ground-based and analog definition applications for Postdoctoral Fellowships. Use of NASA Space Radiation Laboratory (NSRL) or analogs in proposals must be included in the mentor’s existing research support and fit within the timeline of the grant. For analog proposals, applicants must note on the appropriate worksheet the mentor’s grant number for the project that will provide a given measurement or sample. Newly proposed measurements or samples must be noted as “(this proposal)” and are subject to feasibility/technical review.

Applicants should familiarize themselves with NASA HRP’s Integrated Research Plan, which is the cornerstone for developing and implementing the Human Research Program’s strategic research plan (http://humanresearchroadmap.nasa.gov/).

TRISH recognizes and supports the benefits of having diverse and inclusive scientific, engineering, and technology communities and fully expects that such values will be reflected in the composition of all peer review panels and proposal teams.

All prospective applicants to this TRISH-RFA are advised that the highest priority in all of NASA’s programs is given to safety and mission assurance, occupational health, environmental protection, information technology, export control, and security. NASA’s safety priorities are to protect (i) the public, (ii) astronauts and pilots, (iii) the NASA workforce (including employees working under NASA instruments); and (iv) high-value equipment and property. All applications submitted in response to this solicitation are expected to comply with this policy.

II. Academy of Bioastronautics

Selected postdoctoral fellows are expected to participate in the TRISH Academy of Bioastronautics. Dr. Laurence Young, Apollo program professor emeritus of astronautics from the Massachusetts Institute of Technology, oversees the Academy and provides mentorship. The aim of the Academy is to offer a virtual
forum for the postdoctoral fellows to connect and collaborate with other researchers. Fellows will engage in networking opportunities, foster relationships with their colleagues, and gain the skills needed to succeed as an independent investigator.

III. Award Information

Applications submitted in response to this TRISH-RFA will undergo a compliance screen followed by a scientific and technical merit review by an objective, external peer-review committee. Relevance to TRISH’s and NASA’s programmatic needs and goals will be evaluated by TRISH management. Selections will be performed by the TRISH Selection Official.

Selected applications are expected to be funded for two years. A competitive opportunity for a third year of funding may be available depending on existing TRISH resources and evaluation by TRISH’s science management.

Selected postdoctoral fellows are required to commit 100% of their time to the fellowship, of which at least 90% must be research efforts towards the proposed project, if they accept TRISH postdoctoral fellowship funding. A postdoctoral fellow may choose to apply the remaining effort (10%) to advance the fellow’s career development, which includes but is not limited to: other grant collaborations related to their research, training opportunities, teaching assignments, career-development seminars, etc.

The assumed start date will be August 2020. The postdoctoral fellowship will be funded as a stipend of $60,000, plus a set allocation for health insurance and conference travel. If an institution requires a postdoctoral stipend in excess of the amount described above, the difference will need to be made up by the mentor or waived by the institution. The allocation should be used for health insurance and travel to the mandatory annual NASA HRP Investigators’ Workshop. The fellow is also encouraged, but not required, to attend an additional scientific meeting of their choice, as long as it is related to the fellow’s career development.

After postdoctoral fellowships have been awarded, TRISH will work with the awarded institutions to execute the awards, which will include development of a budget for funding and any additional requirements regarding the project or mentoring plan.

The mechanism of support will be a cooperative sub-agreement with funds provided by NASA to Baylor College of Medicine through NASA Cooperative Agreement NNX16AO69A.

IV. Eligibility

1. Eligibility Information

Participation in this TRISH-RFA is open to all categories of U.S. organizations, NASA laboratories, industry, educational institutions, other non-profit organizations, and other agencies of the U.S. Government. Investigators new to space life sciences are particularly encouraged to apply to TRISH opportunities.

Applicants must be U.S. citizens, permanent residents, or persons with pre-existing visas obtained through their sponsoring institutions that permit postdoctoral training for the project’s duration.

Note that restrictions at NASA installations may impede full participation in some learning experiences by persons who have certain visa classifications.

To be eligible for this program, postdoctoral fellows may not have more than five years (cumulative) of previous postdoctoral training as of the deadline for this proposal submission. The month and year of any previous postdoctoral experience(s) must be included in the CV and any gaps detailed, including the month and year. Those earning a terminal degree more than seven
years before the deadline for this solicitation (i.e., terminal degree conferred on or before January 22, 2013) are ineligible for this opportunity. Scientists or physician-scientists who hold any of the following degrees are eligible: Ph.D., M.D., M.D./Ph.D., D.Sc., Sc.D., D.V.M., D.O., or equivalent. Applicants must have completed the clinical portion of the training program, if applicable to their field, by the time of award activation. Applicants that anticipate earning a terminal degree (Ph.D., M.D./Ph.D., D.Sc., Sc.D., D.V.M., D.O., or equivalent) by January 22, 2020 are also eligible to participate. Applications (also called proposals) must be submitted from the institution where the work will take place.

Applications (see submission instructions below) will be accepted from all categories of U.S. organizations, public and private, as well as from for-profit and non-profit entities, such as universities, colleges, hospitals, laboratories, units of state and local governments, and eligible agencies of the federal government. Applicants may collaborate with universities, federal government laboratories, 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.

It is encouraged that the applying entity have in place a documented base of ongoing, high-quality research in science and technology or in those areas of science and engineering clearly relevant to the specific programmatic objectives and research emphases indicated in this RFA. Present or prior support by NASA is neither a pre-requisite to submission of an application nor a factor in the selection process. Researchers not previously supported by NASA are particularly encouraged to serve as mentors. All U.S.-based mentors are eligible to apply as principal investigators for this solicitation.

Historically Black Colleges and Universities (HBCUs), Hispanic Serving Institutions (HSI), and Tribal Colleges and Universities (TCU) as well as other minority educational institutions, and small businesses and organizations owned and controlled by socially and economically disadvantaged individuals or women, are particularly encouraged to apply. In accordance with Federal statutes and NASA policy, no eligible applicant shall be excluded from participation in, denied the benefits of, or be subjected to discrimination under any program or activity receiving financial assistance from NASA on the grounds of race, color, creed, age, sex, national origin, or disability.

The Institute recognizes that critical steps must be taken to broaden the participation of underrepresented groups and Minority Institutions in NASA space science missions, research, and education programs (NASA Science Plan, 2010). The institute is committed to increasing the participation of underrepresented groups in its activities, and it strongly encourages Minority Institutions to participate in proposals as Lead or Co-Institutions. NASA’s Office of Equal Opportunity Programs recognizes the definition of a Minority Institution as identified by the Office of Civil Rights, U.S. Department of Education. Additional information regarding the criteria for designation as a Minority Institution and the current list of qualifying institutions can be found at the following websites:

- For Tribal Colleges and Universities see: [http://www.aihec.org/who-we-serve/TCUroster-profiles.htm](http://www.aihec.org/who-we-serve/TCUroster-profiles.htm)
- For Historically Black Colleges and Universities see: [https://www2.ed.gov/about/offices/list/ocr/edlite-minorityinst-list-tab.html](https://www2.ed.gov/about/offices/list/ocr/edlite-minorityinst-list-tab.html)
- For Hispanic Serving Institutions see: [https://www2.ed.gov/about/offices/list/ocr/edlite-minorityinst-list-tab.html](https://www2.ed.gov/about/offices/list/ocr/edlite-minorityinst-list-tab.html)

2. Additional Guidelines Applicable to Foreign Applicants

The fellowship program is open to U.S. citizens, permanent residents, or persons with pre-existing visas obtained through their sponsoring institutions that permit postdoctoral training for the project’s duration.
Please note that restrictions at NASA installations may impede full participation in some learning experiences by persons who have certain visa classifications. All applications must be in English and comply with all other submission requirements stated in the TRISH-RFA.

3. Assurance of Compliance – China Funding Restriction

All submitted proposals must comply with the following: Assurance of Compliance with The Department of Defense and Full-Year Appropriation Act, Public Law 112-10 Section 1340(a); The Consolidated and Further Continuing Appropriation Act of 2012, Public Law 112-55, Section 539; and future-year appropriations herein after referred to as “the Acts,” whereas:

a) TRISH and NASA are restricted from using funds appropriated in the Acts to enter into or fund any grant or cooperative agreement of any kind to participate, collaborate, or coordinate bilaterally with China or any Chinese-owned company, at the prime recipient level and at all sub-recipient levels, whether the bilateral involvement is funded or performed under a no-exchange of funds arrangement.

b) Definition: “China or Chinese-owned Company” means the People’s Republic of China, any company owned by the People’s Republic of China, or any company incorporated under the laws of the People’s Republic of China.

c) The restrictions in the Acts do not apply to commercial items of supply needed to perform a grant or cooperative agreement.

d) By submission of its proposal, the proposer represents that the proposer is not China or a Chinese-owned company, and that the proposer will not participate, collaborate, or coordinate bilaterally with China or any Chinese-owned company, at the prime recipient level or at any sub-recipient level, whether the bilateral involvement is funded or performed under a no-exchange of funds arrangement.

For a practical interpretation and application of these “China Funding Restrictions”, proposers should carefully review the FAQ posted alongside the solicitation on NSPIRES.
C. Application Procedures for the TRISH Postdoctoral Fellowship Program

All information needed to submit an electronic proposal in response to this solicitation is contained in this RFA and in a companion document entitled “2018 NRA and CAN Proposers' Guidebook” that is located at: https://www.hq.nasa.gov/office/procurement/nraguidebook/proposer2018.pdf hereafter referred to as the “Guidebook for Proposers.” In cases where the Guidebook for Proposers and this RFA conflict, the RFA language shall take precedence.

Note that for this solicitation the terms application and proposal are synonymous.

Proposal submission questions will be answered and published in a FAQ document. This FAQ document will be posted on the NSPIRES solicitation download site alongside this RFA and will be updated periodically between submission release and the proposal due date. The “List of Prospective Mentors Open to Collaboration” will be updated periodically, until December 6, 2019, Proposers are encouraged to check the FAQ and the “List of Prospective Mentors Open to Collaboration” often as it may be updated.

I. Registering on NASA Solicitation and Proposal Integrated Review and Evaluation System (NSPIRES)

1. NSPIRES Registration

This RFA requires that the proposer register key data concerning their intended submission with NSPIRES located at https://nspires.nasapsr.com. Potential applicants and proposers are urged to access this site well in advance of the proposal due date(s) to familiarize themselves with its structure and enter the requested identifier information.

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 must be identified on the proposal cover page. Other named persons receiving payment for their contributions must also be identified on the proposal cover page. It is especially important to note that every individual named on the proposal’s Cover Page (see below) must be registered in NSPIRES and that such individuals must perform this registration themselves; that is, no one may register a second party, even the mentor of a proposal in which that person is committed to participate. This data site is secure, and all information entered is strictly for TRISH use only. Please note that in NSPIRES, the proposal submission system requires that the mentor is identified as the principal investigator (PI) and the trainee is identified as the postdoctoral fellow.

Every organization that intends to submit a proposal in response to this RFA, including educational institutions, industry, non-profit institutions, NASA Centers, and other U.S. Government agencies, must be registered in NSPIRES prior to submitting a proposal. Such registration must be performed by an organization’s electronic business point-of-contact (EBPOC) identified in the Federal Government’s System for Award Management (SAM; https://www.sam.gov). Note that registration in SAM may take several weeks for new organizations and is required for registering an organization in NSPIRES.

2. Electronic Submission

All proposers are required to use NSPIRES. Any proposal not submitted through the NSPIRES portal and sent directly to TRISH by email, fax, or other means will be declined. TRISH Postdoctoral Fellowship Program proposals must be submitted electronically by one of the officials at the mentor’s (i.e., principal investigator) organization who is authorized to make such a submission.
It is strongly recommended that the postdoctoral fellow work closely with his/her mentor to ensure the proposal is submitted by the due date and time listed in this solicitation. Proposals submitted after the listed due date and time may be declined without review.

NSPIRES accepts fully electronic proposals through a combination of data-based information (e.g., the electronic Cover Page and its associated forms) and an uploaded PDF file that contains the body of the proposal. The NSPIRES system will provide a list of all elements that make up an electronic proposal, and the system will conduct an element check to identify any item(s) that is (are) apparently missing or incomplete. Proposers are particularly encouraged to begin their submission process early.

Requests for assistance in accessing and/or using NSPIRES may be directed by email to nspires-help@nasaprs.com or by telephone to (202) 479-9376, Monday through Friday, 8 a.m. to 6 p.m., Eastern Time.

FAQs may be accessed through the Proposal Online Help site at https://nspires.nasaprs.com/external/help.do.

Tutorials of NSPIRES are available at: https://nspires.nasaprs.com/tutorials/index.html.

Before beginning an online application, the postdoctoral fellow must ensure that:

1) The organization under which the mentor/postdoctoral fellow is applying is registered with NSPIRES.
2) The mentor (Principal Investigator) is registered with NSPIRES and is affiliated with the organization under which the mentor/postdoctoral fellow is applying.
3) The mentor (Principal Investigator) knows the name of the Authorized Organizational Representative (AOR) of the organization, and the AOR is registered with NSPIRES.
4) The postdoctoral fellow is registered with NSPIRES.

II. Instructions for Preparation of Proposals

The NSPIRES system will guide proposers through submission of all required proposal information. Please refer to the online NSPIRES tutorials at https://nspires.nasaprs.com/tutorials/index.html for help. If you require additional assistance, please contact the NSPIRES Help Desk at nspires-help@nasaprs.com.

Proposals must be prepared by the postdoctoral fellow in conjunction with their mentor. Proposals will be submitted by the mentor (Principal Investigator) and the Authorized Organizational Representative (AOR) from the mentor’s organization after the mentor (Principal Investigator) has released the prepared proposal to the AOR.

It is strongly recommended that the postdoctoral fellow work closely with the mentor to ensure the proposal is submitted by the due date and time listed in this solicitation. Proposals should be written in their entirety by the fellow, with the exception of the Mentor Statement. However, mentors are encouraged to provide feedback and guidance particularly in regards to crafting and refining the specific aims and hypotheses of the proposed scientific research. Proposals will not be accepted after the listed deadline.

Only the mentor can initiate the creation of a new proposal and assign the postdoctoral fellow as a team member with editing privileges. The postdoctoral fellow will then be able to access and create the proposal application.

A budget is not necessary for completion of an application to this solicitation. Funding is not provided for administrative costs, research supplies, reagents, equipment and instrumentation, or animals. The mentor is responsible for supervision of the TRISH postdoctoral fellow and for providing all resources required for the completion of the research proposed by the fellow. After postdoctoral fellowships have been awarded, TRISH will work with the awarded institutions to execute the
awards, which will include development of a budget for funding and any additional instruction regarding the project or mentoring plan.

**Indirect costs will not be awarded to the funded institution.** Additionally, TRISH welcomes, but does not require, cost sharing of 10% of the funded award from institutions who receive awards for the training of TRISH postdoctoral fellows.

Proposal sections each have their own page limits, described below. If a page limit is not given for a section, it is "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. To ensure proper proposal transmission, please provide only one PDF attachment upload ordered as follows (with the exception of the Data Management Plan [DMP] which is a component of the cover pages):

1. Table of Contents
2. Mentor Statement (See Section C. II.1.)
3. Three Letters of Recommendation (See Section C. II.2.)
4. Biographical Sketches for the Mentor, Postdoctoral Fellow, and any other involved personnel, if applicable (See Section C. II.3.)
5. Facilities and Equipment (See Section C. II.4.)
6. Research Plan (See Section C. II.5.; 12 page limit)
7. Data Management Plan (See Section C. II.6.)
8. Current Support (See Section C. II.7.)
9. Analog Study Resource Worksheet or Retrospective Data Request Form, if applicable (posted on NSPIRES alongside this document) (See Section C. II.8.)
10. Special Matters - Animal Care or Human Subjects Certifications, if applicable (see Section C. II.9.)
11. Vertebrate Animal Scientific Review (VASR), if applicable (see Section C. II.10.)
12. References and Citations (See Section C. II.11.)

Please note that the Proposal Summary, Business Data, Program Specific Data, and Proposal Team are required NSPIRES Cover Page Elements for a proposal that are collected by the NSPIRES system. The proposal summary should be between 100-300 words and written for the lay reader.

The NSPIRES proposal submission process ensures that a minimum set of required proposal cover page fields are completed. Provision of the proposal summary and business data elements of the cover page will be necessary in order for the AOR to submit the proposal. If either of these two proposal elements is incomplete, the “View Proposal/Check Elements” function of NSPIRES will display red “error” flags and messages to alert the user to the information that is required yet missing, and the “Submit Proposal” button will not be available. Although the Principal Investigator will be able to release the proposal to the AOR, the proposal cannot be submitted by the AOR until these required fields are completed.

Any additional information that is missing will be identified by yellow “warning” flags. Proposers are reminded to check the solicitation instructions to ensure compliance with all instructions, as adherence to these two-element validation checks alone is insufficient to guarantee a compliant proposal. Additionally, in those cases where instruction in the RFA contradicts an NSPIRES warning, the NSPIRES yellow “warning” may be ignored. Proposers should follow the RFA instructions closely to help ensure submission of a compliant proposal.

It is essential that the PDF file generated and submitted meets TRISH requirements.

It is the responsibility of the proposer to ensure that the PDF file is unlocked and that edit permission is enabled – this is necessary to allow NSPIRES to concatenate submitted files into a single PDF document; and ensure that all fonts are embedded in the PDF file and that only Type 1 or TrueType fonts are used. In addition, any proposer who creates files using TeX or LaTeX is required to first create a DVI file and then convert the DVI file to Postscript and then to PDF.
The NSPIRES system is limited in the character sets that can be used for filling out online forms. Please refer to the online tutorials when using special characters, including “smart” quotes. Alternatively, spell-out special characters where possible (such as micro rather than the Greek symbol μ). Applicants and proposers are encouraged to preview their proposal prior to releasing the proposal to their designated organization by clicking the “Generate” button at the bottom of the “View Proposal” screen in NSPIRES. The “Generate” feature allows applicants or proposers to preview their entire proposal in a single PDF file prior to submittal, but it is not a required step in the submission process.

Applicants are encouraged to use a stand-alone PDF converter, such as Adobe Writer, to convert your proposal document to PDF for transmission. See http://nspires.nasaprs.com/tutorials/PDF_Guidelines.pdf for more information on creating PDF documents that are compliant with NSPIRES.

There is 20 MB size limit for proposals (Section 3.23 of the NASA Guidebook for Proposers). Large file sizes can impact the performance of the NSPIRES system. Most electronically submitted proposals will be less than 2 MB in size.

1. Mentor Statement

The mentor for the postdoctoral applicant must provide a Mentor Statement indicating that the research of the postdoctoral fellow candidate will be fully supported, scientifically as well as financially, by his/her laboratory if the fellowship is granted.

A single mentor should be identified as the Principal Investigator for the proposal and s/he should generate and provide the Mentor Statement. Colleagues of the mentor can be involved in the training and career development of the postdoctoral fellow; however, they should not provide separate Mentor Statements but may provide a recommendation letter.

The mentor is responsible for supervision of the postdoctoral fellow’s work. Mentors and/or other involved personnel should have previous experience in training postdoctoral fellows (and/or graduate students), and in their mentor statement should indicate their ability and commitment to financially and intellectually support the research activities of the trainee.

The Mentor Statement should consider TRISH's scientific and educational goals and indicate that a structured mentoring program is or will be put in place.

The Mentor Statement in particular must address the following topics:

1. A brief (1-3 paragraphs) description of the proposed research topic – including background, specific aims, hypotheses, experimental schema, and key references;
2. The mentor’s current research support including the funding organization and funding duration with particular emphasis on the proposed project that the mentee will work on;
3. The mentor’s ability to cover the costs of all research to be performed by the postdoctoral fellow including animals, reagents and any unique support and/or required expertise beyond that of the mentor’s laboratory (i.e., facilities, other scientific or technical expertise);
4. The postdoctoral fellow applicant’s strengths and weaknesses, accomplishments, and potential to significantly contribute to the scientific field and the space program;
5. A plan for development of the fellow’s career to include training in research ethics, grant preparation, effective scientific writing, communication skills, career interview skills, effective CV preparation, and teaching methods and plans (and human subjects and animal use, as applicable) for continuing education. Partnering with established outreach programs is particularly encouraged; and
6. Previous successful experiences in guiding the research efforts and career development of students and postdoctoral fellows including but not limited to the number of previous trainees, number of publications by previous trainees, and success of previous trainees, in obtaining subsequent independent funding. If a more senior co-mentor is involved, the mentor may also...
describe the co-mentor’s experiences with previous trainees. Co-mentors may not prepare a separate Mentor Statement.

The entire Mentor Statement shall not exceed four pages of single-spaced text using 12-point font with 1-inch margins.

2. Letters of Recommendation

The applicant must obtain three letters of recommendation. The letters must not exceed two pages each and should be from faculty members or professionals with detailed knowledge of the trainee’s abilities. Letters should be on institutional letterhead and must be signed. Letters should be sent to the applicant or the applicant’s mentor to append to the application and will be visible to the applicant through NSPIRES. Recommendation letters with more than two pages will be redacted and the proposer notified.

The applicant’s proposed mentor and co-mentor(s) (if applicable) may not provide one of the three letters of reference since an opportunity was presented to address the applicant’s strengths in the Mentor Statement. Team members, not involved in the writing of the mentor statement may provide a letter of reference.

Applications without the three required letters will be considered incomplete and may be declined. Applications submitted with excess letters of recommendation will be redacted and the proposer notified.

3. Biographical Sketches and Information

The postdoctoral fellowship applicant should provide a comprehensive biographical sketch in a format of his/her choice; this document should include the month and year (or anticipated month and year) of the award of the professional degree. The inclusive months and years of any previous postdoctoral experience(s) must be included in the biographical sketch and any gaps in professional training must also be detailed. If not included elsewhere, list the previous and current teaching responsibilities and educational outreach activities of the candidate.

A biographical sketch must be provided for the mentor and any other involved personnel, if applicable. The postdoctoral fellowship applicant and mentor’s biographical sketch should each include a list of principal publications and any exceptional qualifications. Omit social security numbers and other personal items which do not merit consideration in evaluation of the proposal.

No biographical sketch should exceed four pages. NIH-style biographical sketch format is acceptable but not required.

4. Facilities and Equipment

Describe available facilities and major items of equipment relevant to the proposed project, and any additional major equipment that will be required. Identify any Government-owned facilities, industrial plant equipment, or special tools that are proposed for use. Include evidence of the availability of facilities and equipment, and the cognizant Government points of contact.

5. Research Plan

The main body of the proposal shall be a detailed statement of the work (or Research Plan) to be undertaken and should include objectives and expected significance; relation to the present state of knowledge; and relation to previous work performed on the project and to related work in progress elsewhere. Use of NSRL or analogs in proposals must be included in the mentor’s existing research support and fit within the timeline of the grant. The statement should outline the plan of work, including the broad design of experiments to be undertaken, and a description of experimental methods and
procedures. Mentors should not contribute to the narrative of the research plan, other than to review this section and provide editorial comments. The research plan should also address the evaluation factors in these instructions and any specific factors in this TRISH-RFA. Any substantial collaboration with individuals other than the mentor should be described. Subcontracting significant portions of a fellowship research project is discouraged.

The proposal should contain sufficient detail to enable reviewers to make informed judgments about the overall scientific merit of the proposed research and about the probability that the postdoctoral fellow will be able to accomplish the stated objectives with the resources available and within the timeframe of the fellowship. The proposed research should directly benefit the career path of the potential postdoctoral fellow and allow the fellow to develop an independent research path. The hypotheses and specific aims of the proposed research must be clearly stated.

To be considered for award, a submission must present a specific project which proposes to impact one or more of the risks on NASA’s Human Research Roadmap (https://humanresearchroadmap.nasa.gov/).

The Research Plan cannot exceed 12, 8½-by-11-inch pages using a standard 12-point font and 1-inch margins. The Research Plan must be single-spaced, typewritten, English-language text, using an easily read font. In addition, there shall be no more than 5.5 lines per inch of text. Proposers should not use a smaller font or squeeze lines of text to gain more text per page as it makes the evaluation process difficult. Images and figures must be embedded. Please note that the Proposal Summary on the Cover Page is not considered part of the 12-page Research Plan and need not be repeated in the research plan.

Referenced figures must be included in the 12 pages of the research plan; however, figure captions can use a 10-point font. The figures and legends should be of a size that is easily discernible to the reviewer.

Research Plans that exceed the 12-page limit will be redacted to 12 pages and the proposer notified. Literature cited and other proposal sections are not considered part of the 12-page limit. Note that reviewers are not required to view and/or consider web links in their evaluation of the proposal.

6. Data Management Plan

Each proposal must include a Data Management Plan (DMP) 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 de-identified 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 4,000 characters and is a required program specific data question.

7. Current Support

For other current projects being conducted by the postdoctoral fellow and mentor, provide title of project, sponsoring agency, percent effort, and project starting and end dates. Include a brief description of any potential overlap or leveraging with the work described in this TRISH Postdoctoral Fellowship Program application. Please keep in mind that elected postdoctoral fellows are required to commit 100% of their time to the fellowship, of which at least 90% must be research efforts towards the proposed project. The remaining effort (10%) may be used to advance the fellow’s career development.
8. Analog Study Resource Worksheet or Retrospective Data Request Form, if applicable

**Analog Definition Proposals**
Some analog definition proposals may undergo additional reviews for analog feasibility. A panel of technical experts drawn from TRISH and NASA will evaluate the feasibility of carrying out the analog experiment and the potential for establishing teams of investigators to optimize utilization of human subjects, samples, data, and analog resources. This review will be conducted by technical experts familiar with the development and conduct of analog studies.

**Retrospective Data Proposals**
Access to NASA’s life sciences data can assist the research community in providing a better understanding of the appropriate strategies required to mitigate spaceflight-related health risks.

These archives include data collected on astronauts as part of medical evaluations and research studies and research data collected on ground test subjects, animal subjects, and plants. Researchers who are awarded a fellowship may submit requests for retrospective data, which are evaluated on a case-by-case basis. Astronaut data are preferentially provided in grouped or de-identified format; however, not all types of data can be de-identified. Identifiable (attributable) human medical and research data are only available with the informed consent of the astronaut.

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

For proposals employing human subjects and/or animals, assurance of compliance with human subjects and/or animal care and use provisions is required. In addition, the application must include a statement from the proposing institution certifying that the proposed work will meet all federal and local human subject requirements and animal care and use requirements.

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. Please select “pending” or “approved” for the Institutional Review Board (IRB)/Animal Care and Use Committee (IACUC) question on the Proposal Cover Page. If the IRB/IACUC certification is already approved at proposal submission, attach a copy of the certification as part of the proposal upload and select “approved.” Otherwise, select “pending.”

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.


Animal use and care requirements are described in the NASA Code of Federal Regulations (CFR) 1232 (Care and Use of Animals in the Conduct of NASA Activities).

**Inclusion of women and minorities as research subjects**
TRISH follows NIH guidelines concerning inclusion of women and minorities as research subjects ([https://grants.nih.gov/grants/funding/women_min/women_min.htm](https://grants.nih.gov/grants/funding/women_min/women_min.htm)). Women and members of minority groups and their sub-populations must be included in TRISH-supported biomedical and behavioral research projects involving human subjects, unless a clear and compelling rationale is provided stating
that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. Non-compliance could result in termination of the grant. All applications will also be reviewed with respect to:

- Adequacy of plans to include males and females, members of minority groups and their subgroups, as appropriate for the scientific goals of the research;
- Plans for the recruitment and retention of subjects;
- Reasonableness of the proposed budget and duration in relation to the proposed research;
- Adequacy of the proposed protection for humans, animals, or the environment to the extent they may be adversely affected by the project proposed in the application.
- For proposals requiring vertebrate animals, coding of the Vertebrate Animal Scientific Review (VASR) rated as Acceptable is required prior to award. TRISH science management will work with the applicant to resolve concerns prior to award.

10. Vertebrate Animal Scientific Review (VASR), if applicable

Responses to this solicitation proposing experiments that require vertebrate animals must address the five points outlined in Section G. 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 12-page Research Plan. A sample VASR is provided in Section G.

11. References, Citations, and Web Links

References cited are not considered part of the 12-page Research Plan. Reviewers are not, however, required to consider web links in their evaluation of the proposal.
D. Review and Selection Process

Proposals received in response to a TRISH RFA will be used only for evaluation purposes. TRISH does not allow a proposal or any unique ideas submitted in response to a TRISH-RFA to be used as the basis of a solicitation nor in negotiation with other organizations. TRISH and NASA reserve the right to act in the best interests of the Federal Government in the matter of acceptance and evaluation of all proposals. TRISH may share information from proposals received in this RFA with NASA Human Research Program, Space Biology, and NASA Innovative Advanced Concepts.

Applications may be withdrawn at any time before award. Applicants are requested to notify TRISH if the proposal is to be funded by an organization other than the one initially used in NSPIRES or of any other changed circumstances which dictate termination of evaluation.

Upon receipt, applications will be reviewed for compliance with the requirements of this RFA. This includes the following:

1. Submission of a complete application as specified in this RFA (containing a Mentor Statement, three Letters of Recommendation, Biographical Sketches for the mentor and applicant, and a Research Plan, etc.).
2. Adherence to the page limits outlined in this solicitation.
3. Eligibility of the applicant according to the information provided in NSPIRES.

Note: Non-compliant applications may be withdrawn from the review process and declined without further review.

Compliant applications submitted in response to this TRISH-RFA will undergo a scientific and technical merit review by an objective, external peer-review committee, namely the Postdoctoral Fellowship Committee, which will be established by TRISH. All committee members will be eminent scientists, some familiar with space biomedical/biotechnological research.

Criteria for Evaluation of Applications

Applications will be evaluated by the TRISH Postdoctoral Fellowship Committee based on the following three criteria:

(i) Scientific merit and programmatic/operational relevance of the proposal and the probability that the stated research objectives will be accomplished with the resources available (Approximately 50%). Specifically, the TRISH Postdoctoral Fellowship Committee will consider whether the proposed project addresses research emphases that have the potential to impact one or more risks detailed on NASA’s HRR. This committee will also consider what will be the effect of these studies on the concepts, methods, or products that drive this field and, if the aims of the application are achieved, how scientific knowledge or technology will be advanced. Peer reviewers will also evaluate whether it is likely that the stated research objectives will be accomplished with the resources available and if the approach is sufficient and appropriate to give confidence that the objectives will be achieved. TRISH has a high risk threshold and projects that are particularly innovative should be encouraged.

(ii) Training environment and mentoring plan (Approximately 30%). Specifically, the TRISH Postdoctoral Fellowship Committee will consider whether the mentor provided a clear training plan and included professional development in appropriate areas such as research ethics, human subject research, use of animals in research, proposal preparation, career interview skills, scientific writing and communication skills, and mentoring skills. This committee will also consider if the training environment is adequate.

(iii) Research, teaching, and educational outreach background and qualifications of the postdoctoral fellow candidate (Approximately 20%). Specifically, the TRISH Postdoctoral Fellowship Committee will consider if the candidate possesses the educational background and, with guidance from the mentor, the research experience to achieve the research objectives as outlined in the proposal. Moreover, this committee will evaluate whether the candidate has demonstrated the ability to learn and/or develop new strategies or procedures.
The committee will also consider whether the candidate has demonstrated teaching and educational outreach activities that qualify him/her to be an effective communicator to peers and diverse public audiences.

The TRISH selection official will make selection decisions based on both external peer review (the Postdoctoral Fellowship Committee) and programmatic relevance to TRISH. TRISH’s obligation to make award(s) is contingent upon the availability of appropriated funds from which payment can be made and the receipt of applications that TRISH determines are acceptable for award under this TRISH-RFA.

Final selections for funding of proposals will be made by the TRISH Selection Official. Applicants may review detailed project summaries for currently funded and completed NASA HRP and TRISH research projects at https://taskbook.nasaprs.com/Publication/welcome.cfm. The technical summaries appear in the “Science and Technology Research Areas” section.

**Development of a Selection Recommendation**

A selection recommendation will be developed based on the criteria as described above.

- **Deficiencies in any of these three criteria may prevent selection of an application.**

The development of selection recommendations is the responsibility of the TRISH Postdoctoral Fellowship Committee. Final selections for funding of proposals will be made by the TRISH Selection Official. Only fellowship grants will be awarded through this TRISH-RFA.
E. Award Information

TRISH reserves the right to make no awards under this TRISH-RFA and to cancel this TRISH-RFA. TRISH assumes no liability for canceling the TRISH-RFA or for anyone’s failure to receive notice of cancellation.

I. Award Notice

When an application is not selected for award, the proposer will be notified.

When an application is selected for award, negotiation and award will be handled by TRISH in the funding installation. The application is used as the basis for negotiation. The contracting officer may request certain business data and may forward a model award instrument and other information pertinent to negotiation.

A sub-award agreement will be used to accomplish an effort funded in response to this solicitation. TRISH will coordinate the implementation of the award instrument. Contracts resulting from this solicitation are subject to the Federal Acquisition Regulation (FAR) and the NASA FAR Supplement. Any resultant grants or cooperative agreements will be awarded and administered in accordance with the NASA Grant and Cooperative Agreement Handbook (NPG 5800.1).

II. Award Requirements

Travel Requirements

Annually, postdoctoral fellows selected in response to the TRISH-RFA will be required to attend a meeting of postdoctoral fellows at the annual NASA Human Research Program Investigators’ Workshop in the Houston/Galveston area. Fellows are also encouraged to attend one scientific meeting of the postdoctoral fellow’s choice.

Peer-Reviewed Publications, Poster Presentations and Abstracts

It is expected that results from funded research will be published in peer-reviewed journals as the work is completed.

\[\text{Published papers, as well as posters, abstracts, invention disclosures, copyrights, and patents must acknowledge TRISH support} \]

by inclusion of the following phrase: “This work is supported by the Translational Research Institute through NASA Cooperative Agreement NNX16AO69A.”

Note that prior to submission for publication, any research publications or presentations utilizing research data from Life Sciences Data Archive (LSDA) or crew medical data from the Lifetime Surveillance of Astronaut Health (LSAH; https://lsda.jsc.nasa.gov/lsah/LSAH_Home) must be submitted to the organization that supplied the data for review to ensure that no personally identifiable information data is included. In addition, recognition of either or both of these data sources must be included in the publication’s or presentation’s acknowledgments section if not otherwise included in the document.

TRISH-funded authors and co-authors will be required to deposit copies of their peer-reviewed scientific publications and associated data into NASA’s publication repository called NASA PubSpace (https://www.ncbi.nlm.nih.gov/pmc/funder/nasa/), managed by the NIH’s PubMed Central. This excludes patents, publications that contain material governed by personal privacy, export control, proprietary restrictions, or national security law or regulations.

For all funded projects, TRISH requests that scientific manuscripts prepared with TRISH support be sent to the offices of both the TRISH Director (spacehealth-info@bcm.edu) and HRP Chief Scientist (jennifer.fogarty-1@nasa.gov) before submission for publication. Scientific papers that report operationally relevant data or particularly controversial findings should however always be reported to the
TRISH-RFA-2001-PD: TRISH Request for Applications from Postdoctoral Fellows

TRISH and HRP Chief Scientists at least one week prior to publication. This is to determine if there may be inadvertent release of identifiable crew information and prepare for any subsequent inquiries. It will not be used to control the content of such manuscripts.

**Annual Report**
TRISH uses annual reports to assess progress relative to stated research objectives and hypotheses as declared in the original grant proposal by the postdoctoral fellow. An annual report is due to TRISH no later than 30 days before the end of the first year of funding to communicate the status of the completed research and to identify peer-reviewed publications to date. A format outlining the report requirements will be provided. The report will be evaluated for satisfactory progress as a requirement for continued funding.

**Annual Virtual Review**
The postdoctoral fellow will also deliver a brief annual oral virtual review to TRISH management every 12 months. The virtual review will be staggered approximately six months prior to submission of each annual written report, thus providing project updates every six months. The annual virtual review will consist of:
- Review of specific aims.
- Project progress.
- Data and results.

TRISH expects these virtual reviews to include in-depth examinations of results. Any deviations from the planned schedule or aims will be discussed. Additional reporting requirements may be added to ensure timely integration of the research or technology development into TRISH’s portfolio.

**Final Report**
A final report is required which will address the entire scope of the project and link the research to HRR risks. The report will also include peer-reviewed publications and intellectual property disclosures resulting from TRISH-supported work. This report must be submitted to TRISH headquarters within 60 days after the end of the fellowship.

Postdoctoral fellows will be required to deliver a virtual, oral presentation summarizing their project and findings to TRISH scientific leadership, as well as to NASA stakeholders within 60 days following submission of their final Annual Progress Report.

**Outreach**
TRISH feels strongly that postdoctoral fellows should learn to present their scientific findings to the space biomedical community as well as to the general public. Therefore, each postdoctoral fellow should plan for involvement in public outreach activities. Examples include:
- Creating a lesson plan for K-12 teachers for posting on TRISH’s website.
- Recording a video of an experiment for posting on TRISH’s website.
- Collaborating with a museum to create a display.
- Delivering a talk in a local school system or museum about the postdoctoral fellow’s TRISH-funded research.

TRISH offers opportunities to help early career scientists learn more about operating in the research world – everything from presentation skills to connecting researchers with subject matter experts to access to spaceflight analogs. Check out the Career Development page of the TRISH website (bcm.edu/spacehealth) for more information.

**Career Tracking**
To assess the impact of postdoctoral fellowships on the career advancement of young scientists and to provide an active network of investigators in space biomedical research, TRISH will request brief, periodic updates on the career status and accomplishments of TRISH postdoctoral fellows throughout their careers. Requests for updates will be facilitated mainly by TRISH management and may include interviews or requested current CVs from participants.
Formative Assessment
TRISH will be actively engaged in the on-going assessment of the Postdoctoral Fellowship Program to assure that the program has been implemented as planned and to make program enhancements. Formative assessments during the funding period will include virtual meetings and possibly institutional site visits to assess research facilities and accomplishments, and to interview the postdoctoral fellows and mentors. This formative assessment will be facilitated mainly by TRISH management. It is expected that both the postdoctoral fellow and the mentor cooperate with these assessments.
F. Submission Dates/Additional Information

The following items apply only to this TRISH-RFA:

**Solicitation TRISH-RFA Identifier:** TRISH-RFA-2001-PD

**Required:** Electronic application using NASA’s NSPIRES System (See Section C, Part I for details)

**Proposals Due:** January 22, 2020, 5:00 p.m. Eastern Time

**Selection Announcement:** July 2020

**Funding Begins:** Approximately 30-60 days following notification of selection

**Selection Official:** Dr. Dorit Donoviel, Director, Translational Research Institute for Space Health

Additional Information about TRISH’s research programs and the TRISH’s Postdoctoral Fellowship Program is available from:

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G. Vertebrate Animal Scientific Review (VASR)

I. Vertebrate Animal Scientific Review (VASR) Worksheet Instructions

If vertebrate animals are to be used, the following five points must be addressed completely by applicants in the VASR worksheet of their proposal:

1. Detailed description of the proposed use of animals, including species, strains, ages, sex, and number to be used.
2. Justification of the use of animals, choice of species and numbers to be used (it is strongly suggested that power calculations be included to justify numbers of animals), and proposer's assessment of potential benefits and knowledge to be gained.
3. Information on the veterinary care of the animals.
4. Description of procedures for ensuring discomfort, distress, pain, and injury are minimized.
5. Method of euthanasia and the reasons for its selection.

Each of the five points must be addressed, for all performance sites, in the VASR worksheet. The VASR worksheet will be reviewed by the First Award Fellowship Committee and the proposal coded as either "No Vertebrate Animals," "No Concerns/Acceptable," or "Concerns/Unacceptable." If coded as "Concerns/Unacceptable," TRISH staff will work with the applicant to resolve concerns prior to award. Coding of the proposal as "No Concerns/Acceptable" or "No Vertebrate Animals" is required prior to award.

In order to be coded as "No Vertebrate Animals," the vertebrate tissue used in the study must be obtained from other sources (e.g., tissue repository, animals euthanized for an unrelated purpose). The source of the tissue should be included in the VASR to validate the coding as "No Vertebrate Animals" used. If vertebrate tissues are obtained through euthanasia for tissue harvest, the proposed research is coded as "Use of Live Vertebrate Animals." The generation of custom antibodies is coded as "Use of Live Vertebrate Animals."

A "performance site(s)" is defined as the institutions where procedures with animals will be performed. If the proposing institution is not the site where animal work will be performed, the performance site must be identified. If there is more than one performance site, the description of animal care and use at each site must be included and must address the five points.

Applicants and proposers should be aware that TRISH may release information contained in specific funded proposals pursuant to Freedom of Information Act requests.

II. Detailed Instructions for Preparation of the VASR

These instructions are to assist applicants in preparing their VASR information.

Preparation of the VASR Worksheet:
Typically, all of the required elements for the VASR can be addressed within 1-2 pages.

Point 1 - Description of animals and how they will be used
A concise, complete description of the proposed procedures must be included in the VASR. While additional details may be included in the Research Strategy, a coherent, albeit brief, description of the proposed use of the animals must be provided within the VASR. The description must include sufficient detail to allow evaluation of the procedures. Examples of the types of procedures that should be described include blood collection, surgical procedures, administration of substances, tumor induction, and post-irradiation procedures. In describing the animals, investigators must provide the following information for each species and/or strain to be used:

• Species
• Strain
• Ages
• Sex
• Number of animals to be used (power calculations are suggested)

Point 1 - Describe the animals and their proposed use; address the following for all species to be used:
  __ Species
  __ Strains
  __ Ages
  __ Sex
  __ Number of animals to be used
  _ A concise, but complete, description of proposed procedures (i.e., sufficient information for evaluation)

Point 2 - Justifications for use of animals
Investigators must justify the use of animals in the proposed research. The justification must indicate why alternatives to animals (e.g., computer models, cell culture) cannot be used and should indicate the potential benefits and knowledge to be gained. In addressing this point, researchers are encouraged to consider means to replace, reduce, and refine the use of animals. Rationale for the choice of species must be provided. The rationale should indicate the advantages of the species chosen and why alternative species are not appropriate. If less highly evolved or simpler animal models are available, justification must be provided for using more advanced species. For example, the use of non-human primates (NHP), dogs or cats, should be thoroughly justified. If NHP species are to be used, a comparison to other NHP species may be appropriate. If animals are in short supply, costly, or to be used in large numbers, provide an additional rationale for their selection and power calculations for the number of animals used.

Estimates for the number of animals to be used should be as accurate as possible. Justification for the number of animals to be used should include considerations of animal availability, experimental success rate, inclusion of control groups, and requirements for statistical significance; cite power calculations where appropriate.

Point 2 - Provide justifications for:
  __ The use of animals
  __ Choice of species
  __ Number of animals to be used (cite power calculations, if appropriate)

Point 3 - Veterinary care
Descriptions of veterinary care should indicate the availability of veterinarians or veterinary technicians. For example, the VASR might indicate the number of veterinarians and veterinary technicians associated with the proposing institution, and their proximity to the performance site(s). The frequency with which veterinary staff observe or monitor animals should be stated. If survival surgeries are proposed, veterinary involvement or post-surgical monitoring should be described. For example, if animal use involves invasive approaches that might result in discomfort, distress, or pain, the investigator should indicate if or when veterinary care is necessary. The indicators for veterinary intervention to alleviate discomfort, distress, or pain should be described. The ways in which veterinary staff may intervene should be described.

Point 3 - Provide a general description of veterinary care, including veterinary support that is specifically relevant to the proposed procedures. Indicate the following:
  __ A brief account of veterinary staff and their availability
  __ The regular schedule of monitoring of animals by veterinary staff
  __ Any additional monitoring and veterinary support that may be required to ensure humane care, if relevant to the procedures proposed (e.g., post-surgical)
  __ Indicators for veterinary intervention to alleviate discomfort, distress, or pain, if relevant

Point 4 - Provisions to minimize discomfort, distress, pain, and injury
Procedures or circumstances that may result in more than momentary discomfort, distress, pain, or injury
should be identified. Methods to alleviate discomfort, distress or pain should be described. If pharmacological agents are used, the agent(s) should be specified by name or class. Any additional (e.g., non-pharmaceutical) means to avoid discomfort, distress, pain, or injury should be described briefly. The manner, circumstances and duration of all post-surgical provisions and care should be described. If special housing is necessary following surgery or manipulations, the VASR should describe these provisions and the duration and type of monitoring provided. If procedures (e.g., pharmacological or surgical) might lead to severe discomfort, distress, pain, or injury, indicators for humane endpoints and euthanasia (e.g., severe infection, respiratory distress, failure to eat, tumor size) should be described. All of these issues are particularly important for survival surgeries. If multiple surgeries are proposed, these must be well justified and provisions to avoid any potential complications must be described. Describe how restraining devices will be used, if applicable.

**Point 4 - Describe procedures to minimize discomfort, distress, pain, and injury. Indicate the following:**

- Circumstances relevant to the proposed work, when animals may experience discomfort, distress, pain, or injury
- Procedures to alleviate discomfort, distress, pain, or injury
- Identify (by name or class) any tranquilizers, analgesics, anesthetics, and other treatments (e.g., antibiotics) and describe their use
- Provisions for special care or housing that may be necessary after experimental procedures
- Plans for post-surgical care, if survival surgeries are proposed
- Indicators for humane experimental endpoints, if relevant
- Describe the use of restraint devices, if relevant

**Point 5 - Euthanasia**
The method(s) of euthanasia must be described and must comply with the *American Veterinary Medical Association (AVMA) Guidelines on Euthanasia*. If the method(s) do not comply with AVMA recommendations, the rationale and scientific justification for use of the method(s) must be provided. The indicators for euthanasia (i.e., termination of experiment or humane endpoints) should be stated. It is not sufficient to state simply that humane methods consistent with the recommendations of the *AVMA Guidelines on Euthanasia* or the IACUC will be used.

**Point 5 - Describe methods of euthanasia:**

- Describe the method(s) of euthanasia and rationale for selection of method(s)
- Indicate if the method is consistent with AVMA Guidelines on Euthanasia
- Provide a scientific justification for the choice of method if not AVMA recommended

**Performance site(s):**
The five points must be addressed for all performance sites.

- If the proposing institution is not where animal work will be performed, are all collaborative performance site(s) identified?

- If more than one performance site is planned, are descriptions of animal care and use for each site provided?

**References**
Guidance in this document is based on NASA and Public Health Service (PHS) Policy, and federal requirements. The NASA and PHS Policy incorporate the standards in the *Guide for the Care and Use of Laboratory Animals* and require that euthanasia be conducted according to the *AVMA Guidelines on Euthanasia*. Additional background information and references are available on the Office of Laboratory Animal Welfare website ([http://grants.nih.gov/grants/olaw/olaw.htm](http://grants.nih.gov/grants/olaw/olaw.htm)).

**NASA Policy and Requirements**
[http://nodis3.gsfc.nasa.gov/displayDir.cfm?t=NPR&c=8910&s=1B](http://nodis3.gsfc.nasa.gov/displayDir.cfm?t=NPR&c=8910&s=1B)
II. Getting Started

Aims

Concisely

Guide

PHS

Example

3)

1)

1

2)

2

3

3

1. Aims

Female Balb/c mice will be used to determine if virions treated with enzyme can cause viral keratitis, and to test the in vivo efficacy of the test articles. The studies will require 700 mice, 4 to 6 weeks old. Based on prior experience, 70 groups, each including 10 mice will be required over five years to achieve adequate statistical power. Ocular infection is accomplished by scratching the cornea of anesthetized mice with a sterile needle and exposing the scarred portion of the cornea to inoculum. Test articles are applied directly to the scarified cornea as liquid or cream. Following inoculation and recovery, mice are monitored for 30 days. With the mice under anesthesia, the eyes will be examined at intervals, microscopically, and are flushed with medium with 2% serum to determine viral titers. Thirty days post-infection, with the mice under deep anesthesia, the trigeminal ganglia are removed aseptically for viral assay, followed immediately by euthanasia.

2. The proposal is to study mechanisms for the prevention of ocular disease caused by viral infections, a leading cause of blindness in the U.S. Mice are needed for these experiments because no alternative in vitro model incorporates all elements of the mammalian ocular immune system; too little is known about this system for the development of computer simulations. Mice are a well-accepted model for studying viral keratitis, assessing the virulence of viral strains and testing the efficacy of antiviral. Mice provide several advantages: a) The murine ocular immune system is similar enough to that of humans to allow extrapolation of the results; b) Their small size allows the use of smaller amounts of drugs for testing; and c) The entire mouse genome is known and easily manipulated genetically, allowing extension of the work in future genetic studies. Female mice will be used due to compatibility issues. Balb/c mice will be used because they have intermediate resistance to infection. ABC-4 knockout and ABC-4 test-strains will be used. For the enzyme study, we will use 4 treatment groups: enzyme-1, enzyme-2, enzyme-3, and mock treated virus. We will also use different amounts of inoculum for each condition allowing a more accurate calculation as to the effect of the digestions on infectivity. For the test-article peptide study, we will use two formulations (one aqueous and one hydrophobic), test four different concentrations and also vary the treatment protocol. Two groups will receive a single dose of drug in each of the two formulations prior to the addition of virus to assess prophylactic activity. These groups will not receive any additional enzyme treatments. Two groups will be infected with virus and beginning 4 h post-infection, we will treat with each formulation and concentration four times daily for seven days.

3. All mice are housed in the Animal Resources Center of the University. Animal housing rooms are under temperature and humidity control. The mice will not be subjected to water or food restrictions, and bedding material is placed in each cage. The facility is staffed by four full time veterinarians and six veterinary technicians; the veterinary staff is on-site and a clinical veterinarian is available at all times. Animal care staff conducts routine husbandry procedures (e.g., cage cleaning, feeding, and watering) and checks animals daily to assess their condition.

III. Example of a complete VASR

(This example VASR worksheet has been modified from the original. It addresses all five points concisely).

Vertebrate Animals

Aims 1-3 will be addressed in vitro; Aim 4 will be addressed using a mouse model of ocular infection.

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PHS Policy
http://grants.nih.gov/grants/olaw/references/phspol.htm

Guide for the Care and Use of Laboratory Animals
http://www.nap.edu/openbook.php?record_id=5140

AVMA Guidelines on Euthanasia
Laboratory staff monitors mice when treatments are given, disease is scored, or samples are collected for titering. The veterinary staff monitors mice in their home cages weekly. If animals exhibit any indication of infection or distress, the veterinary staff confers with laboratory personnel to recommend appropriate antibiotics, analgesics, or other pharmaceuticals. The veterinary staff may intervene or recommend euthanasia based on animal welfare concerns.

4) Mice will be anesthetized with isoflurane (3-5%) during the infection process, when treatments are administered and titer samples are collected. This eliminates the need for restraint devices and topical anesthetics that would interfere with the infection and disease process. For post-procedural pain relief, we will administer buprenorphine twice daily for the duration of the experiments (i.e., approximately two weeks post-inoculation). Death is not an endpoint for the studies; the Balb/c strain was chosen because of its resiliency and resistance to this particular virus. Our goal is to avoid severe infections leading to death. Though unlikely, if an animal reacts severely, it will be euthanized, based on humane indicators (e.g., failure to groom or feed). These experiments involve no post-surgical survival animals.

5) All mice will be euthanized by cervical dislocation under isoflurane anesthesia. Isoflurane ensures that the mice are unconscious, while dislocation ensures quick death. This minimizes animal distress, is effective and efficient; it is consistent with the recommendations of the AVMA Guidelines on Euthanasia.