

**May 26, 2017  
TRI-RFA-17-01**

**Translational Research Institute (TRI)  
c/o TMCx<sup>+</sup>  
Texas Medical Center Innovation Institute  
2450 Holcombe Blvd, Suite X  
Houston, TX 77021**

**TRI Announcement  
Soliciting Postdoctoral Fellowship  
Applications**

**A Request for Applications to the  
Translational Research Institute**

**Applications Due: July 31, 2017 at 5:00 PM Eastern Time**

**TRI-RFA-17-01: TRI Request for Applications Soliciting Postdoctoral Fellows**

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## **TRI-RFA-17-01: TRI Request for Applications Soliciting Postdoctoral Fellows**

### **Executive Summary of Opportunity**

**NOTE: It is critical for Postdoctoral Fellowship Program applicants to carefully read all of the instructions in this Translational Research Institute (TRI)-Request For Applications (RFA).** Each Section includes guidelines, requirements, and instructions for preparing and submitting applications (also referred to as proposals) and defines the administrative policies governing the particular components described in this TRI-RFA.

This TRI RFA is soliciting applications for its Postdoctoral Fellowship Program. Postdoctoral Fellowships will be competitively awarded in any laboratory in the U.S. conducting biomedical/biotechnological research aligned with TRI's mission and goals (Section A). Applications will be screened for compliance and undergo a scientific/technical peer-review by an external peer-review committee consisting of a number of eminent scientists that are familiar with space biomedical/biotechnological research. Relevance to TRI's and NASA's programmatic needs and goals will also be evaluated by TRI management. Selections will be performed by the TRI Selection Official. The award is for two years of funding with an optional, competitively awarded third year of funding that may be available depending on existing TRI resources. 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 via external peer-review and also by TRI's Executive Council (TRIEC). All researchers, regardless of support by NASA or TRI, can serve as Mentors for this competitive funding.

**The Fellowship is open to any researcher who is legally resident and/or working in the United States i.e., 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. To be eligible for this program, applicants may not have more than five years (cumulative) 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 curriculum vitae (CV) and any gaps in training detailed. Additionally, those earning a terminal degree more than seven years before the deadline for proposal submission (i.e., terminal degree conferred on or before July 31, 2010) are ineligible for this opportunity. Applicants that anticipate earning a terminal degree (Ph.D., M.D., M.D./Ph.D., D.Sc., Sc.D., D.V.M., D.O., or equivalent) by November 1, 2017 are eligible to apply to this opportunity. See the eligibility section for more information.**

All U.S.-based Mentors are eligible to apply as principal investigators for this solicitation. The Postdoctoral Fellowship will be funded as a stipend for salary at \$47,484 for the first year, plus an additional \$7,500 per annum allowance for health insurance and travel will be provided. The second year stipend will be \$47,844 plus \$7,500. Adjustments to stipend levels may be made to make them commensurate with experience but in all cases will be in accordance with salaries posted for postdoctoral fellows by the National Institutes of Health (NIH). Fellows will be required to travel to the annual NASA Human Research Program Investigators' Workshop, as well as to at least one relevant, discipline specific scientific meeting, to be determined by the Fellow.

Postdoctoral Fellows will also be expected to participate in TRI's Virtual Community. The TRI Virtual Community provides a digital forum that will allow Fellows to connect and collaborate with other TRI-funded researchers. By participating, graduates of TRI-funded career development and training programs will solidify and sustain requisite relationships with their colleagues and may be better equipped to apply for future funding.

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Postdoctoral Fellows are encouraged to consider, in addition to NASA laboratories, other U.S. laboratories and commercial entities focused on the advancement of human spaceflight endeavors. These entities can include government contractors and corporations aligned with the missions of either TRI or NASA. Postdoctoral Fellows are ultimately responsible for identifying an appropriate Mentor whose research aligns with the objectives outlined by TRI and NASA. TRI can facilitate introductions to Mentors; existing projects of potential interest to Postdoctoral Fellows are listed in an associated Frequently Asked Questions (FAQ) document. Please contact [TRI@nasaprs.com](mailto:TRI@nasaprs.com), if you are a Mentor interested in being included. Additional listings will not be accepted any later than June 29, 2017.

**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 TRI Postdoctoral Fellow and for providing all resources required for the completion of the research proposed by the Fellow. After Postdoctoral Fellowships have been awarded, TRI 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, TRI welcomes, but does not require, cost sharing of 10% of the funded award from institutions who receive awards for the training of TRI Postdoctoral Fellows.

TRI Postdoctoral Fellowship Program applicants must prepare applications with the support of a Mentor and institution (i.e., NASA, university, national laboratory, commercial entity, etc.). Applications should be written in their entirety by the applicant, with the exception of the Mentor Statement. However, Mentors are encouraged to provide feedback and guidance, particularly in regards to developing and refining the specific aims and hypotheses of the proposed research. **In order to facilitate electronic submission from the institution at which the Postdoctoral Fellow will conduct the research, please note that the NASA Solicitation and Proposal Integrated Review and Evaluation System (NSPIRES; <https://nspires.nasaprs.com>) proposal submission system requires that the Mentor be identified as the PI and the trainee be identified as the Postdoctoral Fellow.**

Mentors should have previous experience in training postdoctoral fellows (and/or graduate students), and in their letter of support should indicate their ability and commitment to financially and intellectually support the research activities of the trainee. **It is the responsibility of the Postdoctoral Fellowship Program applicant to contact and arrange for a Mentor.** Additionally, it is also the responsibility of the Postdoctoral Fellowship Program applicant to arrange for three letters of recommendation.

Applicants may refer to the FAQ for information regarding available Mentors but are not limited to that list.

**The proposed work must address a 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 Human Research Roadmap (HRR; <https://humanresearchroadmap.nasa.gov/>) may be funded under this Program, however projects should be well aligned with TRI's mission which is to "lead a national effort in translating cutting-edge, emerging terrestrial research into applied spaceflight human risk mitigation strategies for exploration missions." More details on TRI and its mission can be found at

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<https://www.bcm.edu/centers/space-medicine/translational-research-institute>.

Each Postdoctoral Fellowship Program applicant **must** identify the Countermeasure Readiness Level (CRL) and/or Technology Readiness Level (TRL) of the project at its conclusion. Given that TRI is focused on harnessing cutting edge terrestrial research and technology to the benefit of NASA, proposed work that describes basic research projects with concomitantly low CRL and/or TRL values, is unlikely to be funded. Applicants should refer to Figure 1 and Table 1 in Section A, of this RFA for detailed descriptions of CRLs and TRLs.

In this TRI-RFA,

**Section A** provides an introduction and overview of the goals, objectives, and research implementation strategies of TRI.

**Section B** contains descriptions of the opportunity and eligibility, and instructions for proposal submission.

**Section C** contains the standard instructions for responding to TRI-RFAs.

**Section D** contains information on additional requirements for proposed work utilizing vertebrate animals.

TRI's scientific and education goals are to fund research and development that will result in the delivery of high CRL/TRL countermeasures and technologies to ensure and improve the health and performance of astronauts in response to the space environment. TRI is committed to maintaining a strong, openly competitive, peer-reviewed research program. TRI also aims to inspire the next generation of space life scientists.

Relevance to TRI's and NASA's programmatic needs and goals will also be evaluated by TRI's management. TRI'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 TRI determines are acceptable for award under this TRI-RFA. Participation in this TRI-RFA is open to all categories of organizations, NASA laboratories, industry, educational institutions, other non-profit organizations, and other agencies of the U.S. Government.

**Inclusion of Women and Minorities in Research Involving Human Subjects** – NASA and TRI have adopted the policy of the NIH regarding this matter. Women and members of minority groups and their sub-populations must be included in TRI-supported biomedical and behavioral research projects involving human subjects, unless a clear and compelling rationale is provided that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research.

**Applications must be submitted electronically by July 31, 2017, 5:00 PM Eastern Time.** (See Section B, Part IV of this TRI-RFA for specific instructions regarding electronic submission of Applications). If you require assistance submitting a proposal, please contact the NSPIRES Help Desk ([NSPIRES-help@nasaprs.com](mailto:NSPIRES-help@nasaprs.com)).

All prospective applicants to this TRI-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

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response to this solicitation are expected to comply with this policy.

TRI's points of contact will be identified in selection letters to begin the funding process. Potential Postdoctoral Fellowship Program applicants should carefully review NASA's HRR as well as the sample programs involving Mentors with existing supported projects, (as detailed in the FAQ document associated with this research announcement), and focus their proposed projects on mitigating specific risks and closing discrete knowledge or technology gaps, as defined in the HRR. Your interest and cooperation in participating in this effort are appreciated.

**SECTION A**

**Introduction and Overview: Mission and Research Implementation  
Strategies of TRI**

**I. Introduction to TRI**

TRI was established following an award made by NASA to Baylor College of Medicine (BCM) in collaboration with its consortium partners the Massachusetts Institute of Technology and the California Institute of Technology. **Consortium membership is not a requirement for Postdoctoral Fellowship Program participation and non-NASA researchers are encouraged to serve as Mentors.**

TRI will apply findings from terrestrial science to enhance human health, performance, and well-being during spaceflight. In a medical research context, TRI aims to translate findings from terrestrial research into medical and operational practice and meaningful health outcomes for astronauts during exploration missions. Translational research implementing a bench-to-spaceflight model will move results and/or methods from laboratory experiments and/or clinical trials to point-of-care astronaut health and performance applications. The end point of these translational research efforts is the production of a promising new approach, treatment, countermeasure, or technology that has practical applications to spaceflight. The expectation is that the translational research will move solutions into practical application much faster than traditional research approaches. TRI has been tasked with identifying and translating promising, cutting-edge human health and performance methodologies into validated spaceflight human health and performance prediction, prevention, monitoring, detection, maintenance, and treatment capabilities for exploration missions.

TRI works in partnership with NASA, and in particular with NASA's Human Research Program (HRP; <https://www.nasa.gov/hrp>). Research, development, testing, and evaluation are conducted with the goal of ensuring safe and productive long-term human exploration of space. Applications that develop operationally relevant countermeasures and technologies in high priority areas are encouraged. Moreover, where appropriate, applications should take into consideration research resources, as listed in section G of the Human Exploration Research Opportunities (HERO) Overview document. The 2016 HERO Overview document is posted at <http://nspires.nasaprs.com> for reference.

NASA and TRI recognize and support the benefits of having diverse and inclusive scientific, engineering, and technology communities and fully expect that such values will be reflected in the composition of all peer review panels.

TRI invites ground-based, analog definition, and spaceflight definition research applications for Postdoctoral Fellowships. Applications should address one or more risks and concomitant gaps detailed on NASA's Human Research Roadmap (see Section A, Part III). Applicants should familiarize themselves with NASA HRP's Integrated Research Plan (see Section A, Part III), which is the cornerstone for developing and implementing the Human Research Program's strategic research plan.

Please refer to the Frequently Asked Questions (FAQ) for information regarding some available

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Mentors. Applicants should not feel limited to this list of Mentors. These sample programs will be updated in the FAQ document until June 29, 2017.

### **II. The Translational Research Institute’s Mission**

The Institute leads a national effort in applying cutting edge terrestrial research to spaceflight human risk mitigation strategies for long-duration exploration missions.

### **III. NASA’s Integrated Research Plan**

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

**Postdoctoral Fellowship Program applicants should carefully review these documents and must identify in their Applications the risk(s) and specific gaps, as listed in the HRP HRR, addressed by the proposed research. Applicants must also 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 returned without review.**

### **IV. Countermeasure Readiness Levels (CRLs) and Technology Readiness Levels (TRLs)**

#### **Countermeasure Readiness Level (CRL)**

The use of the CRL scale allows TRI to:

- 1) define, assess, and quantify the level of “countermeasure readiness;”
- 2) determine and describe how each funded research project fits into the countermeasure development “flow;” and
- 3) monitor progress in countermeasure development. This section describes this scale and how it is used. **The CRL of the proposed research at conclusion of the project must be identified in the application.**

Figure 1 illustrates the CRL scale. It describes an incremental research program ranging from fundamental studies that suggest potential countermeasures to applied studies that allow the systematic evaluation and validation of countermeasures ready for operational implementation. Countermeasure development usually progresses through systematic research. Research flows through various levels of countermeasure readiness.

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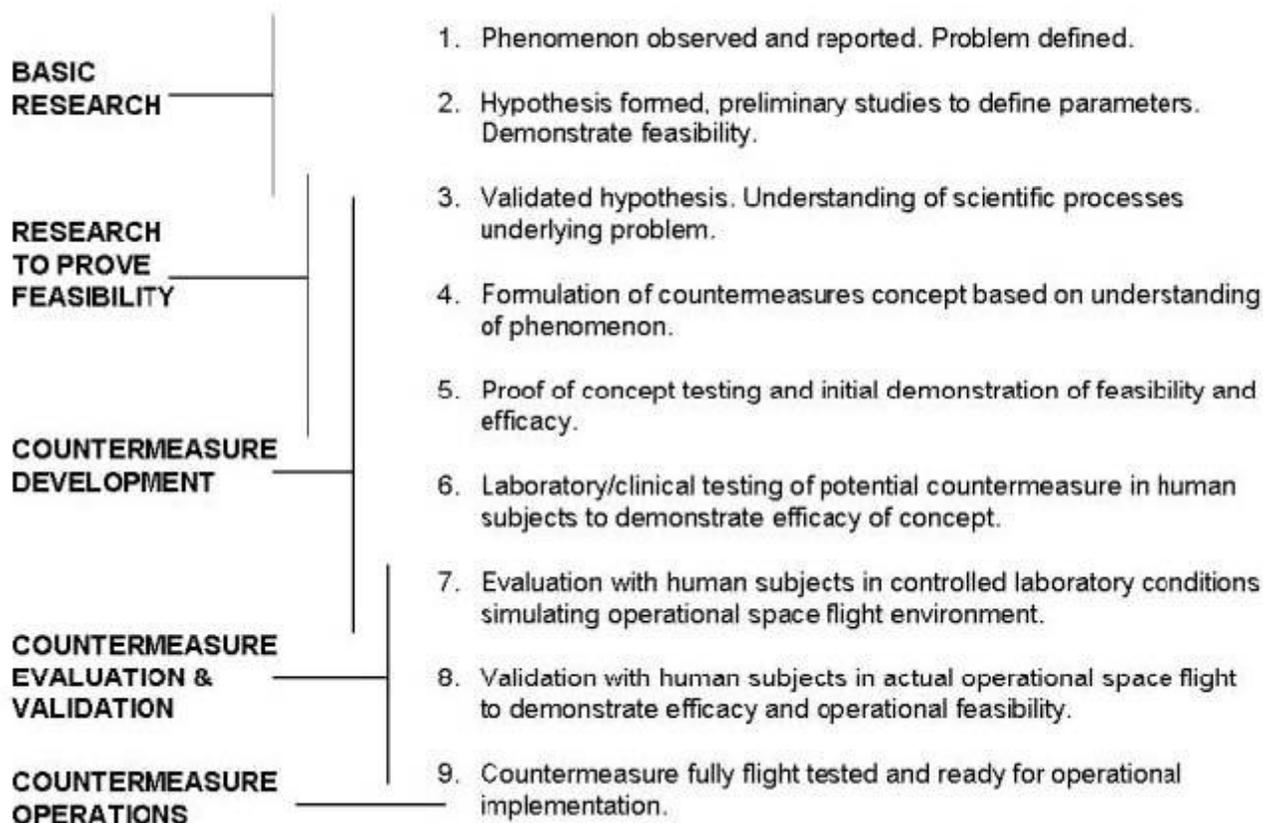


Figure 1. Countermeasure Readiness Level Scale

### Technology Readiness Level (TRL)

The Technology Readiness Level scale is a systematic measurement system that supports assessments of the maturity of a particular technology and the consistent comparison of maturity between different types of technologies. In short, a TRL is a technology milestone (see Table 1 below). **Technology projects must identify the TRL of the proposed research.**

| Level       | Definition  |
|-------------|---|
| <b>TRL1</b> | Basic principles observed   |
| <b>TRL2</b> | Technology concept or application formulated                                    |
| <b>TRL3</b> | Concept or application proven through analysis and experimentation              |
| <b>TRL4</b> | Basic prototype validated in laboratory environment                             |
| <b>TRL5</b> | Basic prototype validated in relevant environment                               |
| <b>TRL6</b> | System or subsystem model or prototype demonstrated in a relevant environment   |
| <b>TRL7</b> | System prototype demonstrated in a relevant environment                         |
| <b>TRL8</b> | Actual system completed and qualified for flight through test and demonstration |
| <b>TRL9</b> | Actual system proven through successful operation                               |

Table 1. Technology Readiness Level Scale

## **V. Digital Resources and Bibliography**

1. **Translational Research Institute's Website** (<https://www.bcm.edu/centers/space-medicine/translational-research-institute>) contains information on the Institute's mission, leadership, and science, technology, and education announcements.
2. **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: <http://humanresearchroadmap.nasa.gov/>
3. **NASA Human Research Program Evidence Books**  
<http://humanresearchroadmap.nasa.gov/Evidence/>
4. **Space Life Sciences Directorate Website**  
<http://www.nasa.gov/centers/johnson/slsd/>
5. **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: <http://lsda.jsc.nasa.gov/>
6. **Small Clinical Trials: Issues and Challenges**. Institute of Medicine, National Academy Press, Washington, DC. <http://www.nap.edu/books/0309073332/html/>
7. **Sex and Gender: Exploring the Biological Contributions to Human Health** *NIH Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research*, 59 Fed. Reg. 14508 (2001). [http://grants1.nih.gov/grants/funding/women\\_min/guidelines\\_amended\\_10\\_2001.htm](http://grants1.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm)
8. **Safe Passage, Astronaut Care for Exploration**. Institute of Medicine, National Academy Press, Washington, DC (2001). <http://www.nap.edu/openbook.php?isbn=0309075858>

**SECTION B**

**Specific Details Related to the Request for Applications**

**I. Research Opportunity – General Information**

TRI's mission is to lead a national effort in applying cutting-edge, terrestrial research to spaceflight human risk mitigation strategies for long-duration exploration missions. The Institute focuses its research program on the primary needs of long-duration missions [e.g., several months on the International Space Station (ISS) or exploration-class missions outside of low Earth orbit (LEO)]. These missions pose the greatest challenge to present and future space travelers, and responding to these challenges with game-changing countermeasures and technologies lies at the core of TRI's responsibility.

Potential physiological changes that may occur during prolonged spaceflight include, among others, significant loss of muscle and bone mass, decreased dietary intake of nutrients, metabolic and endocrine alterations, important changes in cardiovascular function and deleterious effects on sensorimotor performance. By addressing long-term missions, increased crew safety, health, and performance will be realized for shorter-duration spaceflights.

TRI's funded research will be conducted in partnership with NASA. TRI-funded research will focus on high-priority biomedical research problems and TRI will facilitate contact between TRI investigators and appropriate NASA HRP discipline leads and risk owners. Funded investigators will address complex risks that often require interdisciplinary expertise and resources.

TRI has a game-changing enabling role for NASA: providing novel research capabilities for the development of countermeasures, technologies and new knowledge. TRI will engage scientists, engineers, and clinicians to form a biomedical research community. Countermeasure and technology development research conducted by TRI's research community will be integrated with the engineering and operational expertise of NASA to effectively manage health risks for long-duration human spaceflight.

**The projected CRL and/or TRL that will result from the funding and conduct of the proposed research must be identified in the proposal.** For further information, refer to Section A, Part IV.

**II. Award Information**

Applications submitted in response to this TRI-RFA will undergo a compliance screen followed by an intrinsic scientific and technical merit review by an objective, external peer-review committee. Relevance to TRI's and NASA's programmatic needs and goals will also be evaluated by TRI management. Selections will be performed by the TRI Selection Official. Selected Applications are expected to be funded for two years. **Postdoctoral Fellows are required to allocate 100% of their efforts towards the proposed project if they accept TRI Postdoctoral Fellowship funding.** A competitive opportunity for a third year of funding may be available depending on existing TRI resources and if evaluation via external peer-review and TRI's Executive Council (TRIEC) determines that this is warranted based on the awardee's performance during the first two years of funding. The assumed start date will be November 1, 2017. This date is somewhat flexible, however, and will be negotiated with each selected Postdoctoral Fellow. The Postdoctoral Fellowship will be

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funded as a stipend of \$47,484 for the first year, plus an additional \$7,500 per annum allowance for health insurance and travel will be provided. The second year stipend will be \$47,844 plus \$7,500. Adjustments to stipend levels may be made to make them commensurate with experience but in all cases will be in accordance with salaries posted for postdoctoral fellows by the National Institutes of Health (NIH). The allowance should be used for health insurance and/or travel to the mandatory annual NASA HRP Investigators' Workshop and at least one scientific meeting of the Postdoctoral Fellow's choice.

After Postdoctoral Fellowships have been awarded, TRI 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. The mechanism of support will be a cooperative sub-agreement with funds provided by NASA to BCM through a cooperative agreement (Cooperative Agreement NNX16A069A).

### **III. Eligibility**

#### **A. Eligibility Information**

**Applicants may 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. Please 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. Additionally, those earning a terminal degree more than seven years before the deadline for this solicitation (i.e., terminal degree conferred on or before July 31, 2010) 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., M.D./Ph.D., D.Sc., Sc.D., D.V.M., D.O., or equivalent) by November 1, 2017 are also eligible to participate in this opportunity.**

Applications (also called proposals) must be submitted from the institution where the work will take place (see submission instructions below) and will be accepted from all categories of United States (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. Postdoctoral Fellowship Program 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.

The applying entity must 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**

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**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.**

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 under-represented 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>
- For Historically Black Colleges and Universities see:  
<http://www2.ed.gov/about/offices/list/ocr/edlite-minorityinst-list-tab.html>
- For Hispanic Serving Institutions see:  
<http://www2.ed.gov/about/offices/list/ocr/edlite-minorityinst-list-tab.html>

### **B. Additional Guidelines Applicable to Foreign Applicants**

The 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 TRI-RFA.

### **C. 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) TRI 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.

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- 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 PRC FAQ for ROSES: <http://science.nasa.gov/researchers/sara/faqs/prc-faq-roses/>

### **IV. Application Procedures for the TRI Postdoctoral Fellowship Program**

#### **A. Source of Application Materials**

All information needed to submit an electronic proposal in response to this solicitation is contained in this RFA and in a companion document entitled “2017 NRA and CAN Proposers' Guidebook” that is located at: <http://www.hq.nasa.gov/office/procurement/nraguidebook/> 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.

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. Proposers are encouraged to check the FAQ often as it may be updated.**

#### **B. Content and Form of Proposal Submission**

##### **1. NASA Solicitation and Proposal Integrated Review and Evaluation System (NSPIRES)**

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

##### **a) NSPIRES Registration**

This RFA requires that the proposer register key data concerning their intended submission with the NSPIRES located at <http://nspires.nasaprs.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.** 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 TRI use only. In NSPIRES, the Mentor is

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identified as the 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; [www.sam.gov](http://www.sam.gov)).

### **b) Electronic Submission**

**All proposers are required to use NSPIRES. Any proposal not submitted through the NSPIRES portal and sent directly to TRI by email, fax, or other means will be returned without review.** TRI Postdoctoral Fellowship Program proposals must be submitted electronically by one of the officials at the Mentor's (i.e., PI) 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 will not be accepted after the listed due date and time.

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. Note that a failed element check will not preclude submission, but rather it will serve as a warning that a proposal may be 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](mailto: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 <http://nspires.nasaprs.com/external/help.do>. Tutorials of NSPIRES are available at: <http://nspires.nasaprs.com/tutorials/index.html>.

Before beginning an online application, the Postdoctoral Fellow must ensure that:

- 1) The organization to which the Postdoctoral Fellow is applying is registered with NSPIRES.
- 2) The Mentor (PI) is registered with NSPIRES and is affiliated with the organization to which the Postdoctoral Fellow is applying.
- 3) The Mentor (PI) 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.

### **2. 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 <http://nspires.nasaprs.com/tutorials/index.html> for help. If you require additional assistance, please contact the NSPIRES Help Desk [NSPIRES-help@nasaprs.com](mailto:NSPIRES-help@nasaprs.com).

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**Proposals must be prepared by the Postdoctoral Fellow in conjunction with their Mentor. Proposals will be submitted by the Mentor (PI) and the Authorized Organizational Representative (AOR) from the Mentor's organization after the Mentor (PI) 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. Please note that the PI (Mentor) and Postdoctoral Associate are required roles for responding to this solicitation. Roles for additional team members, if any, are restricted to Collaborator, Graduate/Undergraduate Student, and Other Professional.

**Please note that the Proposal Summary, Business Data, Program Specific Data, and Proposal Team are required Cover Page Elements for a proposal. A budget is not required for this solicitation, and the budget forms do not need to be completed. The proposal summary should be between 100-300 words and written for the lay reader. A Data Management Plan (DMP; limited to 4000 characters, including spaces) is also required as one of the Program Specific Data questions, as described in the NASA Guidebook for Proposers and below.**

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 the NASA Life Sciences Data Archive (LSDA) (<http://lsda.jsc.nasa.gov/>). TRI will review DMPs during the programmatic review of the application.

To ensure proper proposal transmission, please provide only one PDF attachment upload ordered as follows:

1. *Mentor Statement* (See [Section B, IV.B.2.a](#))
2. *Three Letters of Recommendation* (See [Section B, IV.B.2.b](#))
3. *Biographical Sketches for the Mentor and Postdoctoral Fellow* (See [Section B, IV.B.2.c](#))
4. *Facilities and Equipment* (See [Section C, c.6](#))
5. *Research Plan* (See [Section B, IV.B.2.e](#); 12 page limit)
6. *Current Support* (See [Section C, c.8](#))
7. *Special Matters - Animal Care or Human Subjects Certifications, if applicable* (see [Section B, IV.B.2.g](#))
8. *Vertebrate Animal Scientific Review (VASR), if applicable* (see [Section B, IV.B.2.h](#))
9. *References and Citations* (See [Section B, IV.B.2.i](#))
10. *Appendices and Reprints* (See [Section B, IV.B.2.j](#))

The NSPIRES proposal submission process ensures that a minimum set of required proposal cover

## TRI-RFA-17-01: TRI Request for Applications Soliciting Postdoctoral Fellows

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 PI 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 NASA requirements. At a minimum, it is the responsibility of the proposer to:

1. 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. Alternatively, spell-out special characters where possible (such as micro rather than the Greek symbol  $\mu$ ). 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.

You 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](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.

### a) Mentor Statement

The Mentor for the postdoctoral applicant must provide a “Mentor Statement” indicating that 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 PI 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.**

## **TRI-RFA-17-01: TRI Request for Applications Soliciting Postdoctoral Fellows**

The Mentor Statement should consider the mission as well as the scientific and educational goals of TRI which as stated above is to “lead a national effort in translating cutting edge emerging terrestrial research into applied spaceflight human risk mitigation strategies for exploration missions.” In particular, potential Mentors should be mindful that the goal of TRI’s Postdoctoral Fellowship Program is to train outstanding independent, productive investigators in applied, operationally relevant space-related biomedical/biotechnological research.

The Mentor Statement should indicate that a structured mentoring program is or will be put in place and 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 funding 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 contribute to the space program;
- (5) A plan for development of the fellow’s career to include training in research ethics, human subjects, animal use, grant preparation, effective CV preparation, career interview skills, effective scientific writing, communication skills, and teaching methods and plans 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 students, number of publications by previous students, and success of previous students in obtaining subsequent independent funding.

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

### **b) Letters of Recommendation**

The applicant must obtain three letters of recommendation 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.

**The applicant’s proposed Mentor 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.**

**Applications without the three required letters will be considered incomplete, and may be returned without review.**

### **c) Biographical Sketches and Information**

The Postdoctoral Fellowship applicant should provide a comprehensive CV in a format of his/her choice; this document will not count toward the application page limitation, and should include the month and year of the award of the professional degree. The inclusive months and years of any

## **TRI-RFA-17-01: TRI Request for Applications Soliciting Postdoctoral Fellows**

previous postdoctoral experience(s) must be included in the CV and any gaps in professional training must also be detailed. If not included elsewhere, please list the previous and current teaching responsibilities and educational outreach activities of the candidate. The candidate's CV should include professional activities during all months after the award of the terminal degree. A biographical sketch must be provided for the Mentor. Neither biographical sketch should exceed four pages. NIH-style Biographical Sketch format is acceptable. See Section C, c.5 for more information.

### **d) Facilities and Equipment**

See [Section C, c.6](#) for more information.

### **e) Research Plan**

The length of the Research Plan cannot exceed 12 pages. Please note that the Proposal Summary on the Cover Page is not considered part of the 12-page Research Plan. The Research Plan must be single-spaced, typewritten, English-language text, using an easily read font having no more than ~10 characters per inch (typically a 12-point 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 in order to gain more text per page as it makes the evaluation process difficult. Pages should have at least 1-inch (2.5 cm) margins on all sides. Images and figures must be embedded.

Referenced figures must be included in the 12 pages of the project description; 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. 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.

**Research Plans that exceed the 12-page limit may be declined without review.** Literature cited and other proposal sections are not considered part of the 12-page limit. **Please note that reviewers are not required to consider information presented as appendices or to view and/or consider web links in their evaluation of the proposal. Please do not submit publication manuscripts.**

### **f) Current Support**

See [Section C, c.8](#) for more information.

### **g) 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.

TRI utilizes just-in-time practices for approval of the use of human subjects or animals. For

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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 TRI 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.

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

Policies for the protection of human subjects in NASA-sponsored research are described in the [NASA Policy Directive \(NPD\) 7100.8E “Protection of Human Research Subjects \(Revalidated with admin. Changes 12/18/2012\)”](http://nodis3.gsfc.nasa.gov/displayDir.cfm?t=NPD&c=7100&s=8E)  
<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 \(CFR\) 1232 \(Care and Use of Animals in the Conduct of NASA Activities\):](http://law.justia.com/cfr/title14/14-5.0.1.1.22.html)  
<http://law.justia.com/cfr/title14/14-5.0.1.1.22.html>

### **Additional Requirements for Research Employing Human Subjects and/or Animals**

#### **h) 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 D. 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 D.

#### **i) 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.

#### **j) Appendices and Reprints**

If included, reprints and appendices do not count toward the Research Plan page limit and are to be included following all other sections of the proposal. **However, reviewers are not required to consider information presented in reprints or as appendices. Un-refereed preprint material may not be included in this section.**

## **TRI-RFA-17-01: TRI Request for Applications Soliciting Postdoctoral Fellows**

### **C. Submission Dates/Additional Information**

The following items apply only to this TRI-RFA:

**Solicitation TRI-RFA Identifier:** TRI-RFA-17-01

**Required:** Electronic application using NASA's NSPIRES System (See Section B, Part IV for details)

**Proposals Due:** July 31, 2017, 5:00 p.m. Eastern Time

**Selection Announcement:** Fall 2017

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

**Selection Official:** Dr. Dorit Donoviel, Interim Director, Translational Research Institute

Additional Information about TRI's research programs and the TRI's Postdoctoral Fellowship Program is available from:

Dorit B. Donoviel, Ph.D.

Interim Director

Translational Research Institute

c/o TMCx<sup>+</sup>

Texas Medical Center Innovation Institute

2450 Holcombe Blvd, Suite X

Houston, TX 77021

Telephone: (713) 357-1038

Email: [donoviel@bcm.edu](mailto:donoviel@bcm.edu)

Website: <https://www.bcm.edu/centers/space-medicine/translational-research-institute>

### **V. Review and Selection Process**

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).
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 returned without further review.**

Compliant applications submitted in response to this TRI-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 TRI. All committee members will be eminent scientists, familiar with space biomedical/biotechnological research.

#### **Criteria for Evaluation of Applications**

Applications will be evaluated by the TRI Postdoctoral Fellowship Committee, on the basis of 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**

## **TRI-RFA-17-01: TRI Request for Applications Soliciting Postdoctoral Fellows**

- resources available (Approximately 50%).** Specifically, the TRI Postdoctoral Fellowship Committee will consider whether or not the proposed project addresses research emphases that have the potential to mitigate 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 or not 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.
- (ii) **Training environment and mentoring plan (Approximately 30%).** Specifically, the TRI Postdoctoral Fellowship Committee will consider whether or not 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 Fellows candidate (Approximately 20%).** Specifically, the TRI 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 or not the candidate has demonstrated the ability to learn and/or develop new strategies or procedures. The Committee will also consider whether or not the candidate has demonstrated teaching and educational outreach activities that qualify him/her to be an effective communicator to peers and diverse public audiences.

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

**Deficiencies in any of these three criteria may prevent selection of an application.** The development of selection recommendations will be based on the findings of the TRI Postdoctoral Fellowship Committee and considerations of TRI programmatic needs and goals. Final selections for funding of proposals will be made by the TRI Selection Official. Only grants will be awarded as a result of this TRI-RFA.

## **VI. Award Requirements**

### **Travel Requirements**

Annually, Postdoctoral Fellows selected in response to the TRI-RFA will be expected to attend the following meetings: a mandatory meeting of Postdoctoral Fellows at the annual NASA Human Research Program Investigators’ Workshop in the Houston/Galveston area, and one or more scientific meetings of the Postdoctoral Fellow’s choice. Limited funding, as available, will be provided to cover the costs associated with these meetings.

### **Peer-Reviewed Publications, Poster Presentations and Abstracts**

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It is expected that results from funded research will be published in peer-reviewed journals as the work is completed. **Published papers, as well as posters, abstracts, invention disclosures, copyrights, and patents must acknowledge TRI support** by inclusion of the following phrase: “This work is supported by the Translational Research Institute through Cooperative Agreement NNX16A069A.”

Please 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 Lifetime Surveillance of Astronaut Health (LSAH; [https://lsda.jsc.nasa.gov/lisah\\_home1.aspx](https://lsda.jsc.nasa.gov/lisah_home1.aspx)) 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.

TRI-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, both NASA HRP and TRI request but do not require in all cases that scientific manuscripts prepared under HRP or TRI support be sent to the offices of both the TRI Interim Director ([donoviel@bcm.edu](mailto:donoviel@bcm.edu)) and HRP Chief Scientist ([john.b.charles@nasa.gov](mailto:john.b.charles@nasa.gov)) before submission for publication. Scientific papers that report operationally relevant data or particularly controversial findings should however always be reported to the TRI 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, to identify synergies between projects, and to track program status. It will not be used to otherwise control the content of such manuscripts.

### **Annual Report**

TRI 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 TRI Headquarters 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.

### **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 TRI-supported work. This report must be submitted to TRI headquarters within 60 days after the end of the fellowship. Postdoctoral Fellows will also be requested and required to deliver a virtual, oral presentation to TRI scientific leadership, as well as to NASA stakeholders within 60 days following submission of their final Annual Progress Reports.

### **Outreach**

TRI 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

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should plan some public outreach activities. Examples include:

- Creating a lesson plan for K-12 teachers for posting on TRI's website.
- Recording a video of an experiment for posting on TRI's website.
- Collaborating with a museum to create a display.
- Delivering a talk in a local school system or museum about the Post-Doctoral Fellow's TRI-funded research.

### **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, TRI will request brief, periodic updates on the career status and accomplishments of TRI Postdoctoral Fellows throughout their careers. Requests for updates will be facilitated mainly by TRI management and may include interviews or requested current CVs from participants.

### **Formative Assessment**

TRI 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 TRI management. It is expected that both the Postdoctoral Fellow and the Mentor cooperate with these assessments.

**SECTION C**

**General Instructions For Responding To TRI Requests For Applications**

**(a) General.**

- 1) Proposals received in response to a TRI RFA will be used only for evaluation purposes. TRI does not allow a proposal, the contents of which are not available without restriction from another source, or any unique ideas submitted in response to a TRI-RFA to be used as the basis of a solicitation nor in negotiation with other organizations, nor will a synopsis be pre-award.
- 2) A solicited proposal that results in a TRI award becomes part of the record of that transaction and may be available to the public on specific request; however, information or material that TRI and the awardee mutually agree to be of a privileged nature will be held in confidence to the extent permitted by law, including the Freedom of Information Act.
- 3) TRI-RFAs contain programmatic information and certain requirements which apply only to proposals prepared in response to that particular announcement. These instructions contain the general proposal preparation information which applies to responses to all TRI-RFAs.
- 4) A cooperative sub-agreement will be used to accomplish an effort funded in response to a TRI-RFA. TRI will coordinate the implementation of the award instrument. Contracts resulting from TRI-RFAs 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).
- 5) TRI has a mandatory format for responses to this TRI-RFA. All applications must be submitted utilizing the NSPIRES System [nspires.nasaprs.com](https://nspires.nasaprs.com). For further information, please see [Section B, Part IV.B](#).
- 6) To be considered for award, a submission must, at a minimum, present a specific project which proposes to mitigate one or more of the risks detailed on NASA's Human Research Roadmap (<https://humanresearchroadmap.nasa.gov/>); contain sufficient technical information to permit a meaningful evaluation; be signed by an official authorized to legally bind the submitting organization; not merely offer to perform standard services or to just provide computer facilities or services; and not significantly duplicate a more specific current or pending NASA or TRI solicitation.

**(b) TRI-RFA-Specific Items.** Several proposal submission items appear in the TRI-RFA itself: the unique TRI-RFA identifier; dates for proposal deadlines; instructions for submission of proposals; electronic submission format; and sources for more information. Items included in these instructions may be supplemented by the TRI-RFA.

**(c)** The following information is needed to permit consideration in an objective manner. TRI RFAs will generally specify topics for which additional information or greater detail is desirable.

## **TRI-RFA-17-01: TRI Request for Applications Soliciting Postdoctoral Fellows**

### **(1) Proposal Cover Page**

- i. The legal name of the organization and specific division or campus identification if part of a larger organization;
- ii. A brief, scientifically valid project title intelligible to a scientifically literate reader and suitable for use in the public press;
- iii. Type of organization: e.g., profit, non-profit, small business, woman-owned, socially and economically disadvantaged, etc.;
- iv. Name and telephone number of the Mentor (PI) and business personnel who may be contacted during evaluation or negotiation;
- v. Identification of the TRI-RFA, by number and title, to which the proposer is responding;
- vi. Desired starting date, and duration of project;
- vii. Date of submission;
- viii. Signature of a responsible official or authorized representative of the organization, or any other person authorized to legally bind the organization (unless the signature appears on the proposal itself); and
- ix. Signature of a Mentor for Postdoctoral Fellowship Program applications.

### **(2) Restriction on Use and Disclosure of Proposal Information.**

Information contained in proposals is used for evaluation purposes only. Offerors or quoters should, in order to maximize protection of trade secrets or other information that is confidential or privileged, place the following notice at the beginning of the Research Plan (which is not included in the page limit) and specify the information subject to the notice by inserting an appropriate identification in the notice. In any event, information contained in proposals will be protected to the extent permitted by law, but TRI assumes no liability for use and disclosure of information not made subject to the notice.

#### **Notice**

##### **Restriction on Use and Disclosure of Proposal Information**

The information (data) contained in this proposal constitutes a trade secret and/or information that is commercial or financial and confidential or privileged (“Information”). It is furnished to TRI in confidence with the understanding that it will not, without permission of the Offeror, be used or disclosed other than for evaluation purposes; provided, however, that in the event a contract (or other agreement) is awarded on the basis of this proposal the Government shall have the right to use and disclose this Information to the extent provided in the contract (or other agreement). This restriction does not limit the Government’s right to use or disclose this Information if obtained from another source without restriction. The obligations in this Section shall not apply with respect to any Information which:

- (a) is disclosed in a printed publication available to the public, is described in a patent anywhere in the world, is otherwise in the public domain at the time of disclosure, or becomes publicly known through no wrongful act on the part of TRI;
- (b) is known to TRI or becomes known to TRI through disclosure by sources other than the Offeror having the right to disclose such Information;
- (c) is disclosed pursuant to the requirement of a governmental agency or any law requiring disclosure thereof;
- (d) is generally disclosed to third parties by the Offeror without similar restriction on such third parties; or
- (e) is approved for release by written authorization of the Offeror.

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**(3) Proposal Summary.** Include a concise 100-300 word abstract describing the objectives and the methods of approach and written for the lay reader.

**(4) Project Description (Research Plan).** The main body of the proposal shall be a detailed statement of the work 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. The project description (Research Plan) cannot exceed 12, 8½- by 11-inch pages using a standard 12-point font and 1-inch margins. 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 project description, other than to review this section and provide editorial comments. The project description should also address the evaluation factors in these instructions and any specific factors in the TRI-RFA. Any substantial collaboration with individuals other than the Mentor, or use of consultants, should be described. Subcontracting significant portions of a research project is discouraged.

**(5) Personnel.** The Mentor is responsible for supervision of the work. Short biographical sketches for both the Postdoctoral Fellow and the Mentor, a list of principal publications and any exceptional qualifications should be included. Omit social security numbers and other personal items which do not merit consideration in evaluation of the proposal.

**(6) 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.

**(7) Security.** Proposals should not contain security-classified material. If the research requires access to, or may generate, security-classified information, the submitter will be required to comply with Government security regulations.

**(8) 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 ending dates. Please include a brief description of any potential overlap with the work described in this TRI Postdoctoral Fellowship Program application.

**(9) Special Matters.** Include any required statements of environmental impact of the research, human subject or animal care provisions, conflicts of interest, or such other topics as may be required by the nature of the effort and current statutes, executive orders, or other current Government-wide guidelines.

**(10) Length.** Unless otherwise specified in the TRI-RFA, effort should be made to keep proposals as brief as possible, concentrating on substantive material. Necessary detailed information, such as reprints, should be included as attachments.

**(11) Withdrawal.** Applications may be withdrawn at any time before award. Applicants are requested to notify TRI if the proposal is funded by another organization or of other changed circumstances which dictate termination of evaluation.

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### **(12) Selection for Award.**

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

(12.2) When an application is selected for award, negotiation and award will be handled by TRI 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.

**(13) Cancellation of TRI-RFA.** TRI reserves the right to make no awards under this TRI-RFA and to cancel this TRI-RFA. TRI assumes no liability for canceling the TRI-RFA or for anyone's failure to receive notice of cancellation.

**SECTION D**

**Vertebrate Animal Scientific Review (VASR)**

**A. 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," TRI 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 TRI may release information contained in specific funded proposals pursuant to Freedom of Information Act requests.

**B. 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

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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 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 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 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

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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 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.

### **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>).

NASA Policy and Requirements

<https://nodis3.gsfc.nasa.gov/displayDir.cfm?t=NPR&c=8910&s=1B>

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](http://www.nap.edu/openbook.php?record_id=5140)

AVMA Guidelines on Euthanasia

<https://www.avma.org/KB/Policies/Documents/euthanasia.pdf>

### **C. Worksheet to Assist in Addressing the Required Five Points of the VASR**

#### **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?

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### **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 - Provide justifications for:**

- The use of animals
- Choice of species
- Number of animals to be used (cite power calculations, if appropriate)

### **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 - 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 - 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

## **D. 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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- 1) 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 antivirals. 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; 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. 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.

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- 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*.