

This Q&A pertains only to the Pre-Release Webinars from September 19th and December 5th 2019. Provided information regarding the TRISH Radiation Program is subject to change prior to the release of the solicitation.



Human-Based Models to Study Effects of Space Radiation and Countermeasures Space Radiation Program (SRAD 2001)



Questions and Answers from Pre-Release Webinar September 19th and December 5th 2019

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Questions about TRISH

Q: *What does it mean to work with TRISH on a particular project? Does TRISH have specific facilities in which the researcher can relocate work on the project or will TRISH provide grants for researchers who will perform their work in their local institutions?*

A: We are a funding agency that focuses on innovation, and as such we focus on funding grants through different funding mechanisms. In addition, we are also a space health community, and provide a way for people to network. But if you are interested in space health research and you are faculty or an established professor that has always dreamed of doing research with space we do have a faculty exchange program. For more information on this program and others, please follow this link: <https://www.bcm.edu/centers/space-medicine/translational-research-institute/programs/scientist-program>.

Q: *If there are more questions post webinar, what is a good email or forum to reach out on?*

A: For any additional questions regarding this solicitation or any of our other programs, please contact us via Spacehealth-info@bcm.edu. You can also reach us on Orbit here: <https://trish.force.com/s/login/SelfRegister>

Q: *In what end of the Technology Readiness Level (TRL) and Countermeasure Readiness Level (CRL) spectrum is TRISH more interested?*

A: TRISH is interested in both market ready technologies that can be adapted to spaceflight and proof-of-concept risky and innovative technologies, but the focus usually depends on the topic. Specifically for those that are in industry, we are trying to tackle the later end of the spectrum for example using medical devices or methods, to help with medical and behavioral conditions that people can experience

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in deep space exploration. When it comes to technologies we are very interested in that end of the TRL/CRL. But again, the kind of science in the low end of the spectrum, such as Science Fiction to Science Fact type, innovative, ahead of the curve high-risk/high reward research, particularly in the area of space radiation, can be of great value as well.

Q: *Is there a chance for preliminary research collaboration with our European institution for development of technological approach involving oscillatory forces to overcome microgravity conditions?*

A: NASA and TRISH funding through this program may not be used to support research efforts by non-U.S. organizations at any level; however, the direct purchase of supplies and/or services that do not constitute research from non-U.S. source by U.S. award recipients is permitted. The policy of NASA and TRISH is to conduct research with non-U.S. organizations on a cooperative, no exchange-of-funds basis. See NASA FAR Supplement Part 1835.016-70 for additional information on international participation, which can be referenced at <https://www.hq.nasa.gov/office/procurement/regs/NFS.pdf>.

Q: *Can foreign students apply for these grants?*

A: Participation in this TRISH grants is open to all categories of U.S. organizations, NASA laboratories, industry, educational institutions, other non-profit organizations, and other agencies of the U.S. Government. Applicants must be U.S. citizens, permanent residents, or persons with pre-existing visas obtained through their sponsoring institutions.

Q: *On the high end TRLs do you take into consideration the quenching of potential market demand by competing medical technologies, e.g., oncological "standard of care" vs. low-cost nutritional approaches?*

A: We try to take into consideration the impact that these high end TRL technologies would have in the health care community in addition to space flight. Part of our metrics that we like to capture at TRISH for our investigators is "Thanks to TRISH funding, you were able to...": For example: get additional venture capital funding, grow your community and company, more competitive market value, maybe it helped you have a better engineered approach that is more effective or efficient to market. When it comes to the high end of TRL/CRL we are interested in how the TRISH investment can help catalyze your growth and potential in the market for your technology.

Q: *Would you be interested in a study that addresses the following:*

To design and possible study potential ways to address some of the health hazards occurring during space missions and conditions of prolonged isolation and confinement (or similarly hostile and stressful situations), to compensate for some of the limits characterizing astronauts' food rations, and to improve astronauts metabolic cardio and cognitive performance and health (BDNF deficiency) as well as those of individuals under similar conditions

A: TRISH does not comment on specific research questions. TRISH aims to mitigate all risks resulting from deep space travel, as mentioned in the [NASA Human Research Program Risks](#). We encourage you to visit our website and to stay tuned with TRISH's solicitations for any you may be eligible to apply. We also encourage you to submit your idea through our site: <http://trish.bcm.edu/l/777423/2019-07-01/7f4>

Q: *How should we respond to the \$100k small grants?*

A: Our Focused Investigator Program ("FIP") casts a wide net on innumerable projects that are not-solicited by TRISH but may be of interest to us. For applying to this program, please go to our website at <https://spacehealth.bcm.edu/prog/fip/>. We are also in the process of changing our policies for

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unsolicited proposals to cast a wider net on technologies and research, which will provide future proposers with more opportunities.

Q: *Is there any connection between TRISH, Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR), and/or NASA Innovative Advanced Concepts (NIAC)?*

A: SBIR and STTRs are programs that federal funding agencies have in place to fund small businesses and start-up companies on technologies or methods. In terms of TRISH's industry programs, we are not a SBIR/STTR but we believe that if you are successful in securing TRISH funding it may help with securing SBIR/STTR subsequent funding. As for NIAC, it is a Space Technology Mission Directorate Research and Development program that nurtures visionary ideas that could transform future NASA missions with the creation of breakthroughs — radically better or entirely new aerospace concepts — while engaging America's innovators and entrepreneurs as partners in the journey. TRISH has discussed with NIAC on how we can partner and work together to advance space technology and crew health.

Q: *One of the questions in the web page for idea submissions (<http://trish.bcm.edu/l/777423/2019-07-01/7f4>) is "What is your primary area of focus for this inquiry?". What if a study would cover more than 1 category, should we submit 2 proposals or just select one of the categories?*

A: In this case, please choose one area of focus but let us know the other areas that your idea covers. In case your proposed research would have two areas of focus of equal importance, you can also submit two separate research ideas on the online form.

Q: *As a new NASA intern who just finished his undergrad, what can I do to help, or what should I do to grow so I can help people in the future?*

A: We encourage you to visit our website and to stay tuned with TRISH's solicitations on our [website](#), [NSPIRES](#), and [Orbit](#), for any you may be eligible to apply.

Q: *Will the data standardization move across all entities within the Human Research Program?*

A: Our efforts to standardize raw data collection across projects funded through this solicitation are TRISH internal-only, at this point.

Questions about the Space Radiation Program (SRAD 2001)

Q: *How can we apply to the Space Radiation Program?*

A: You will be able to submit a proposal to the Space Radiation Program via the NASA Solicitation and Proposal Integrated Review and Evaluation System (NSPIRES) at nspires.nasaprs.com. We anticipate the release of this solicitation to occur in January 2020. We will be updating the TRISH website with more information on how to apply.

Q: *Are the listed amounts per project or per team? Is the \$1M per year inclusive of direct and indirect costs OR is it direct costs only? Is the total \$3.3M for 3 years? How many awards will be selected?*

A: \$1 million per year, per project, which includes direct and indirect costs. The program is for \$3.3M for three years and the third year is contingent on budget availability. We are looking to fund 2-4 proposals overall.

Q: *Are the work plan and budget to be stratified by year (i.e. year 1 only tissue model, year 2 only countermeasure development, and year 3 testing). Can the different project aspects work in parallel over the 3 years?*

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A: Yes, the team can work on them in parallel, even if the work plan structure is for year 1: characterizing the Human Complex Model for space radiation research for space radiation research; Year 2: countermeasure development and characterization; and Year 3: complete countermeasure testing

Q: Will TRISH cover NSRL (NASA Space Radiation Laboratory) beam time or should we add it to our budgets?

A: Yes, TRISH will cover this cost but you are still required to add it to your budget in the proposal. You will need to estimate the time and budget for the beam time you are planning to use.

Q: Where can I reach out to add and remove my name to the TRISH match list, and update information?

A: Please use this document to add your information

<https://docs.google.com/spreadsheets/d/1zcRul7YGancelUqYC6UnFCw8K2FCvTJy0Q9tYw5FLHs/edit?usp=sharing>. To remove or update your information, or you have any problems, please contact us at SpaceHealth-info@bcm.edu.

Q: Besides the general Excel file you shared with us with the list of people from all environments, do you have a specific list of university faculty members that are collaborating (or willing to) with TRISH and/or NASA for human health purposes? Does the spreadsheet you uploaded include them all?

A: We do not have specific collaborators besides what is available on the spreadsheet. The spreadsheet includes information of interested investigators that are willing to collaborate, and they added the information themselves. TRISH is not controlling, adding, or removing names from the spreadsheet, unless requested. We want this to be a resource and tools for you to help you understand and reach out to people that are interested in this type of research and help prepare your team to submit a proposal.

TRISH put together a non-exhaustive list of facilities that would be relevant for Space Radiation testing. This list is proposed as a tool to get you started. If you have a facility or know of one that is not included in our list, please do let us know and we will add it. TRISH does not endorse or affiliate with any of these facilities, and it is your responsibility as a proposer to contact the facility for further information.

We will be uploading that file to Orbit and our website, together with all the materials.

Q: Is there a limit on number of co-investigators that can be in a proposal?

A: There is no limit on the number of co-investigators. However, please keep in mind that for each proposal TRISH expects you to include a multi-disciplinary team grant, with all the expertise mentioned during the webinar as well as a thorough management approach highlighting how you will coordinate the research efforts.

Q: Can an industry partner be a member of my team?

A: Yes. TRISH encourages all US based institutions and companies to collaborate and submit a proposal. Principal Investigators (PIs) may collaborate with universities, the private sector, and federal, state, local government laboratories, and Federally Funded Research and Development Centers (FFRDCs).

Q: Are spaceflights to the International Space Station (ISS) considered within the scope of this call to test proof of concept(s) for countermeasure development?

A: There is a lot we can understand using ISS, particularly for microgravity. For radiation, and for the types of radiation that we are looking at, the big unknown of exposure to galactic cosmic rays (GCR), we

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need a different model. For this solicitation, a neutron or proton source, maybe even some initial studies at Brookhaven where they have a multi-ions accelerator GCR simulator, could be great start. A flight study could be value added in the future, but for now we want to test if we can use complex *in vitro* models as analogs, and start testing countermeasure approaches. **Hence, flight studies will not be considered for this call and will be declared non-compliant.**

Q: *Sample numbers for low dose studies need to be large - what are limitations for flight studies?*

A: **Flight studies will not be considered for this call and will be declared non-compliant.** However, National Center for Advancing Translational Sciences (NCATS) and ISS National Labs have done some work with tissue-chips in space already, called "Chips in Space" (<https://ncats.nih.gov/tissuechip/projects/space>). This will give you some information of what they have developed for tissue chips. They were able to partner with "Space Implementation Partners" to implement these; there is a lot of technologists that are trying to engineer these chips to go to the ISS, and there is a couple of tissue-chips that have returned to Earth and a couple that are currently in space: that throughput is between 6-12 chips or more. There is effort right now to see what these types of chips look like in space through the ISS-NCATS partnership, which focuses on "On Earth applications": can we get information using microgravity that would be advantageous on Earth?

Q: *Are federally funded research and development centers (FFRDCs) eligible as performers?*

A: Yes.

Q: *Are combined radiation effects in microgravity of interest?*

A: The combined effects are something of interest in a next phase. This call will focus on keeping this as simple as we can to determine if we can use these platforms as human analogs to test countermeasures for space radiation. We believe this 3 year program will be complex enough just to get it to work on the ground: to look at both the feasibility of these technologies for radiation to really do a robust characterization (which is critical here) and to test different countermeasures and approaches.

Q: *It seems that you are talking mainly about the radiations found in deep space/free space environments -- that is, galactic cosmic rays (GCR)/ solar particle events (SPE). Are environments with a different ratio of radiation types (such as a planetary surfaces) also of interest to TRISH?*

A: Studying exposures to other planetary radiation such as Mars and Lunar surfaces may be of interest in future TRISH calls since NASA has a directive to get back to the moon before we get to Mars. For this particular solicitation, we are focusing on the journey on the way to Mars.

Q: *Do you have a preconfigured general galactic cosmic ray spectra used for radiation attenuation analysis within Fluka? Or do you use multiple spectra to take different events into account?*

A: For this solicitation, TRISH leaves identification of the proper tools and radiation exposure to the PIs. A requirement of the proposal will be to justify the relevancy of your choices and why they are going to be an appropriate analog, not only for the human tissues but also for Galactic Cosmic Rays.

Q: *Two related questions about available data: 1) How we can have access to any epidemiology study reports that have been done in previous years? Is there any data bank available? 2) Is it possible to access "omics" data sets from NASA's twins study... specifically, we are interested in any RNA-seq data sets. These could be*

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mined for compelling preliminary data.

A: Researchers can request for access to data through NASA Life Sciences Data Archives (LSDA) for research data, or through Lifetime Surveillance of Astronaut Health (LSAH) for medical data. A list of available data sets can be searched at (<https://lsda.jsc.nasa.gov/>). Data requests are time consuming and lengthy, an appropriate timeline should be incorporated into the proposal. TRISH will conduct a feasibility assessment on the data request as part of the review process. It is also important to know that some data sets have embargoes after the studies are been completed.

For those unfamiliar with the Twins study, see an overview here: <https://www.nasa.gov/twins-study> and the first published article here: <https://science.sciencemag.org/content/364/6436/eaau8650>

Q: *Does a live blood cell examination, morning saliva, or urine pH produce a probative read-out information of interest?*

A: Those are more of clinical read out information. The purpose of this solicitation being to use a complex *in vitro* model as analog for radiation countermeasures, these read outs will not be appropriate for this solicitation.

Q: *Can you elaborate on the "citrulline" remark, mentioned in the tissues and readouts of interest slide?*

A: Citrulline is a biomarker that pathologies use to assess toxicity. Please refer to these papers for more information <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4127572/>
https://www.researchgate.net/publication/6145365_Citrulline_and_the_gut
<https://www.rjournal.org/doi/abs/10.1667/RR14305.1>

Q: *Will you share the reviewers' comments with the PI on the proposal irrespective of it is successful or unsuccessful?*

A: The submission is a 2 steps process. A Step-1 proposals is mandatory prior to the submission of a Step-2 proposal. Step-1 proposals will be reviewed for programmatic relevance and the proposers will receive a letter from the TRISH director inviting or declining to submit a Step-2 proposal. Invited Step-2 proposals will be peer-reviewed and a review document will be sent to the PI, regardless of the outcome.

Q: *When does SRAD 2001 release and the deadline for Step1-submission?*

A: Predicted release of SRAD 2001 is early January 2020 and a public announcement will be made on [NSPIRES](#), on [TRISH's Website](#), and on [Orbit](#). The expected Step-1 submission deadline is early March. Specific dates will be shared on the solicitation.

Questions about Space Radiation

Q: *On average how frequently do "relevant" radiation events hit a spacecraft in space involved in a long-term space exploration and the humans within?*

A: When it comes to Solar Particle Events (SPE) you may have blasts from a solar storm which may result in peaks of acute exposure to solar particles but those are usually mitigated through some levels of shielding. However, for Galactic Cosmic Rays (GCR), and the neutron energy that can occur throughout space outside Earth's magnetic field is a consistent low-dose exposure throughout the entire trip. It accounts for a small percentage of the entire energy that can be coming in, but data has shown that it

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can have high biological damage. For those that are new to radiation and more specifically space radiation, TRISH has a “red risk” school, which is a series of informative webinars for the different types of red risks that clarify what are they, and what TRISH and NASA are doing to mitigate those risks. For those who want to learn a bit more about the basics of space radiation, please follow [this link](#) to our “red risk school”, which had a couple of really informative overviews webinars on Space Radiation. You also visit [NASA HRP’s Radiation Element](#) page for more information.

Q: *If I am interested in TRISH and I want to get up to speed on the state of the art of radiation research, where should I get started?*

A: Webinar participants can refer to [NASA HRP’s Space Radiation Booklet](#) available here for a quick overview of the state of the art of space radiation research. Please keep in mind that for each proposal TRISH expects you to include a multi-disciplinary team grant, with all the expertise mentioned during the webinar.

Q: *What is the metric for “low dose” radiation?*

A: TRISH is currently working on standardizing these requirements. More details will be shared in the next pre-release webinar and in follow-up documentation for Space Radiation Program.

Q: *Regarding the impact of the high-speed radiation particles: does TRISH already have an estimate of the size of the impacted region by the radiation particles? This is important to know prior to considering the length scale of a model.*

A: TRISH will release more information and details regarding this subject in the next pre-release webinar and following documentation related to the Space Radiation Program.

Q: *Is there any interest on study in HZE weighting factors?*

A: We are interested in studying HZE weighting factors and how to take into account different doses in varied organ tissues. This is not a requirement for this solicitation but is of interest particularly in a multiple organ system model.

Q: *Hydrogen and helium ions are not HZE particles but make up 90-95% of the Galactic Cosmic Rays (GCR) spectrum. Can you clarify?*

A: This statement is correct. In fact, proton and Helium energy makes up the majority of the GCR spectrum. There has been a lot of emphasis on trying to focus on the HZE particles because of their high penetrance and tissue damage and TRISH is trying to understand what it does to the tissue. Since they are currently the unknown part of the spectrum, we are trying to understand if these particles are going to be a risk when we are in deep space exploration and trying to come up with countermeasure strategies.

However, if you can justify focusing on proton and helium particles in addition to HZE, we would consider it, but this program is primarily focusing on HZE.

Questions about Complex Human-based models

Q: *Are viral infection/reactivation and immune system alterations under radiation/microgravity conditions part of the interest areas?*

A: There is a growing interest to understand the effects of chronic inflammation and immune function in the presence of microgravity and radiation. If there is a way that you can add an immune component to

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your studies, specifically looking at immune function and inflammation and a chronic setting in response to space radiation exposure, it would be a value added to the research. Viral infection/reactivation could be considered as an endpoint. **Proposals focusing on the effects of microgravity only will not be considered under the Space Radiation Program.** Our primary focus of this solicitation is the effects of Space Radiation in human physiology during deep space missions.

Q: *Would you consider human level models, for example cancer patients as models instead of tissue level proposals?*

A: In general there are a number of different approaches to understanding radiation, and there is a large interest when it comes to carcinogenesis relating to radiation. For this particular solicitation, we are interesting only to complex *in vitro* analogs, focusing on those types of technologies and platforms. TRISH is mission focused, so when it comes to radiation, we think about it in terms of “how do we get our crew from Earth to Mars and back safely?” and how radiation impacts the overall function or the mood behavior during that mission. Cancer or other late term effects of space radiation have been a focus of NASA Human Research Program.

Q: *The cancer patient analog would be effect of low dosage radiation on cardiovascular tissue and behavioral changes. Not radiation effect to cause cancer. Could you clarify please?*

A: For this solicitation we are looking for human-based tissue for complex *in vitro* or *ex vivo* models. A study that takes patient cells for cardiovascular, central nervous system models and compares to non-irradiated to look at functional tissue damage would be within scope of this call. Effects of radiation on cancer occurrence would not be considered. Keep in mind there must also be a countermeasure piece to the solicitation.

Q: *Will well-characterized animal models of radiation exposure (predictive of the response in humans) be considered?*

A: **We are not considering animal models for this call.** What Space Radiation Program aims to do is take the next step forward translating from the more simplified *in vitro* to a more complex *in vitro* that is physiologically relevant to humans. We would like to verify these types of platforms and gain confidence so that we can increase our likelihood for adoption of this type of approach for the health of the crew.

Q: *Are central nervous system (CNS) in vitro models included or excluded from cerebro-vascular system tissues of interest? Are neural plasticity models of interest?*

A: From what we know there are two cerebral vascular models out there: lot of these have been the blood-brain barrier models and also CNS models. We have not seen them combined together. They are both of high interest. So looking at electro-physical capabilities is going to be important in a CNS model and the physiological model that you can use to characterize a CNS model in the context of radiation will be just as important as something like a blood-brain barrier. We are also interested in neural plasticity models. Overall, TRISH is interested in any CNS and blood brain barrier model that is philologically relevant to the development of countermeasures.

Q: *What type of effects are the main focus of gastrointestinal (GI) analogs?*

A: Please refer to the slide label tissues of interest [link to presentation]. GI is included and has a list of function or molecular readouts.

Q: *Are you interested in effects on the endocrine system including pancreas, things that can mediate multitude of effects on the whole body including chronic inflammation?*

A: **As mentioned above, we are interested in the effects of space radiation in chronic inflammation.**

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The incorporating of the endocrine system, may be important. We would like to include this information in the story of what happens to human tissues and the whole human body in the context of radiation. This is why we mentioned the computational biologist to help us put all the data together: Can we take into account the hormone response, sex differences so that female hormones vs male hormones responses, in addition to circadian rhythms and what that does to hormone response? And also outputs from other organs that influence other organ function.

Q: *Are 2D culture of induced pluripotent stem cells (iPSCs) derived cells acceptable?*

A: Although TRISH is interested in iPSCs, this solicitation is looking for studies beyond the traditional 2D standard culturing of iPSCs and other cell cultures.

Questions about countermeasures

Q: *No mention of nanomedicine related to space radiation. Could you shed some light?*

A: TRISH is aware that there is a lot of interest in the nanoparticles delivery and nanolipids that usually use nucleic acid therapeutics and use nanoparticles for means of drug delivery. Those belong to the nanotechnology and nanoparticles mentioned during the presentation. TRISH encourages potential proposers to come up with really interesting and “outside the box” countermeasure concepts, that has not been yet used in terms of radiation approaches.

Q: *Are we considering countermeasure for chronic injury or malignancy or both?*

A: We are focused on crew health for the mission during deep space exploration. Chronic tissue damage/function and initiation of adverse effects (such as inflammation) are of interest as that may impact crew health and performance during flight. Late-term effects such as cancer will not be considered for this solicitation.

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