

Submission and Review of Applications

NIH-CASIS Coordinated MPS Program for Translational Research in Space (UH2/UH3)

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SUBMISSION

- START EARLY!
- Read & follow all instructions in Funding Opportunity Announcement (FOA), which includes links to relevant sites (e.g., SF424 instructions, Grants.gov, registration sites and helpful software (i.e., ASSIST and SciENCv)
- Pay close attention to Key Dates, particularly submission deadline – START EARLY
- Letter of Intent may be requested for special initiative
- Key registrations are required and these may take 6 weeks – START EARLY
 - ✓ Dun and Bradstreet Universal Numbering System (DUNS) – *this no. is needed for SAM and eRA Commons registration*
 - ✓ System for Award Management (SAM)
 - ✓ NIH's eRA Commons (required for both institution & Principal Investigator(s))
 - ✓ Grants.gov
- Download application package – START EARLY
- Follow all instructions in FOA regarding page limitations, budget, required sections
 - ✓ e.g., for UH2/UH3: 1 pg.–Specific Aims, 12 pg.–Research Strategy, 5 pg.-Biosketches
- Submit through Grants.gov portal (or via ASSIST) START EARLY!

CHECKING & TRACKING APPLICATION AFTER SUBMISSION

- Submit application through Grants.gov portal (link in FOA) or use ASSIST – submitted by your institution
- Application will be submitted as multiple pdf documents, which will be assembled to form your completed application
- It is your responsibility to check the assembled application to make sure it is complete, via eRA Commons
- If there are error messages, or you find errors in what you have submitted, they must be corrected prior to the application deadline
- Track the progress of your application, from submission through review and funding decision – via eRA Commons – NIH’s electronic system for research grant administration

NIH Peer Review Process

- NIH Peer Review: Two stages
- First, Scientific / Merit review by study section or initial review group (IRG); study section does not make funding recommendation / decision; provides merit review based on criteria defined by NIH (stated in FOA)
- Upon receipt, NIH assigns application to study section; panel of experts with relevant expertise (i.e., study section) is assembled to evaluate scientific merit of application
- Panel discusses competitive applications and provide written comments, core criterion & overall impact scores (reported on scale of 10-90)
- Scores typically appear in eRA Commons within 1-48 hours
- Final Summary Statement, including summary of discussion & written comments from assigned reviewers, is available several days to weeks, after study section has met
- Second stage of review - Consideration by NCATS Advisory Council based on
 - ✓ Scientific & technical merit of the proposed project as determined by study section
 - ✓ Availability of funds
 - ✓ Relevance of the proposed project to program priorities

UH2/UH3 - Standard Review Criteria

Overall Impact: likelihood for the project to exert a sustained, powerful influence on the research field(s) involved

Significance: Does the project address an important problem or a critical barrier to progress in the field? Is there a strong scientific premise for the project? If the aims of the project are achieved, how will scientific knowledge, technical capability, and/or clinical practice be improved? How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?

Investigator(s): Are the PD(s)/PI(s), collaborators, and other researchers well suited to the project? If Early Stage Investigators or New Investigators, or in the early stages of independent careers, do they have appropriate experience and training? If established, have they demonstrated an ongoing record of accomplishments that have advanced their field(s)? If the project is collaborative or multi-PD/PI, do the investigators have complementary and integrated expertise; are their leadership approach, governance and organizational structure appropriate for the project?

Review Criteria – Cont'd

Innovation: Does the application challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions? Are the concepts, approaches or methodologies, instrumentation, or interventions novel to one field of research or novel in a broad sense? Is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions proposed ?

Approach: Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project? Have the investigators presented strategies to ensure a robust and unbiased approach, as appropriate for the work proposed? Are potential problems, alternative strategies, and benchmarks for success presented? If the project is in the early stages of development, will the strategy establish feasibility and will particularly risky aspects be managed? Have the investigators presented adequate plans to address relevant biological variables, such as sex, for studies in vertebrate animals or human subjects?

Environment: Will the scientific environment in which the work will be done contribute to the probability of success? Are the institutional support, equipment and other physical resources available to the investigators adequate for the project proposed? Will the project benefit from unique features of the scientific environment, subject populations, or collaborative arrangements

Special Initiative – May Include FOA-specific Criteria for Review

“Only the review criteria described below will be considered in the review process.”
But

For UH2/UH3, FOA-specific criteria are likely to be included

Importantly, FOA will include extensive section (I) describing the objectives for the FOA, background information, examples of topics relevant to the FOA

While this does not define review criteria, it does inform reviewers of how to apply defined criteria

Read the FOA!!!! The stated objectives, goals, background, examples of relevant topics will help you to formulate your application so that it addresses the criteria relevant to this FOA

Additional Review Criteria and Considerations

The following Additional Review Criteria will not be assigned a numerical score, but may influence the Overall Impact Score:

- Protections for Human Subjects
- Inclusion of Women, Minorities, and Children
- Vertebrate Animals
- Biohazards

The following Additional Review Considerations, if relevant, must be addressed in the application; however, reviewers' evaluation of them will not influence the Overall Impact Score:

- Select Agent Research
- Resource Sharing Plans
- Authentication of Key Biological and/or Chemical Resources
- Budget and Period of Support

Attention!

You may be inclined to focus on sections of the FOA, but repeating,
Read the entire announcement!

Key Dates (recall, that you will START EARLY)

Section I – Funding Opportunity Description (program objectives, goals, etc.; these are relevant to what you propose/submit and to review of your application)

Section II – Award Information (budget & duration of support)

Section III – Eligibility Information (includes info. regarding required registrations & related links)

Section IV – Application and Submission Information (relevant links for submission; SF424 & FOA-specific instructions)

Section V – Application Review Information (UH2/UH3 standard review criteria and FOA-specific criteria)

Section VII – Agency contacts (e.g., programmatic, review, grants management)

General Recommendations (i.e., Do's / Don'ts)

UH2/UH3 FOAs typically require that aims, research plan, milestones for both phases be included in application (remember this as you formulate specific aims/milestones, timelines, the research plan, etc.)

Common mistakes:

- ✓ Rationale is not presented clearly
- ✓ Convincing case for feasibility
- ✓ Failure to address potential roadblocks and alternative approaches
- ✓ Inadequate plans for analysis & interpretation