

Department of Health and Human Services

Part 1. Overview Information

Participating Organization(s)	National Institutes of Health (NIH (http://www.nih.gov))
Components of Participating Organizations	National Institute of General Medical Sciences (NIGMS (https://www.nigms.nih.gov/)) National Center for Complementary and Integrative Health (NCCIH (https://nccih.nih.gov/))
Funding Opportunity Title	Exploratory Research for Technology Development (R21 - Clinical Trial Not Allowed)
Activity Code	R21 (//grants.nih.gov/grants/funding/ac_search_results.htm?text_curr=r21&Search.x=0&Search.y=0&Search_Type=Activity) Exploratory/Developmental Research Grant
Announcement Type	Reissue of PAR-17-046 (https://grants.nih.gov/grants/guide/pa-files/PAR-17-046.html)
Related Notices	None
Funding Opportunity Announcement (FOA) Number	PAR-19-254
Companion Funding Opportunity	PAR-19-253 (https://grants.nih.gov/grants/guide/pa-files/par-19-253.html) , R01 (https://grants.nih.gov/grants/funding/ac_search_results.htm?text_curr=r01&Search.x=0&Search.y=0&Search_Type=Activity) Research Project Grant
Number of Applications	See Section III. 3. Additional Information on Eligibility.

Catalog of Federal Domestic Assistance (CFDA) Number(s)

93.859: 93.213

Funding Opportunity Purpose

This Funding Opportunity Announcement (FOA) will support exploratory research leading to the development of innovative technologies for biomedical research. The program will recognize and reward high-risk approaches with potential for significant impact. Projects should entail a high degree of risk or novelty, which will be offset by a correspondingly high potential impact. However, the possible impact is likely to be far off. Application of the proposed technology to specific biomedical questions is considered beyond the scope of the program, should not be included, and would not be funded. The goal of this FOA is to support proof of concept studies for feasibility and exploratory technology development. Feasibility must not have already been developed in the literature or with preliminary data. Published data can be used to establish the current state of the art but cannot forecast or predict project outcomes. Preliminary data for any purpose might appear to forecast the likelihood of success. Therefore, no unpublished data is allowed. While unpublished data are not permitted, references and data from widely-available preprints that have a Digital Object Identifier (DOI) are acceptable.

Key Dates

Posted Date

April 12, 2019

Open Date (Earliest Submission Date)

May 16, 2019

Letter of Intent Due Date(s)

Not Applicable

Application Due Date(s)

[Standard dates \(//grants.nih.gov/grants/guide/url_redirect.htm?id=11111\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11111) apply, by 5:00 PM local time of applicant organization. All [types of non-AIDS applications](#) allowed for this funding opportunity announcement are due on these dates.

Applicants are encouraged to apply early to allow adequate time to make any corrections to errors found in the application during the submission process by the due date.

AIDS Application Due Date(s)

Not Applicable

Scientific Merit Review	Standard dates (//grants.nih.gov/grants/guide/url_redirect.htm?id=11113) apply
Advisory Council Review	Standard dates (//grants.nih.gov/grants/guide/url_redirect.htm?id=11113) apply
Earliest Start Date	Standard dates (//grants.nih.gov/grants/guide/url_redirect.htm?id=11113) apply
Expiration Date	May 08, 2022
Due Dates for E.O. 12372	Not Applicable

Required Application Instructions

It is critical that applicants follow the instructions in the Research (R) Instructions in the [SF424 \(R&R\) Application Guide \(//grants.nih.gov/grants/guide/url_redirect.htm?id=12000\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=12000), except where instructed to do otherwise (in this FOA or in a Notice from [NIH Guide for Grants and Contracts \(//grants.nih.gov/grants/guide/\)](https://grants.nih.gov/grants/guide/)).

Conformance to all requirements (both in the Application Guide and the FOA) is required and strictly enforced. Applicants must read and follow all application instructions in the Application Guide as well as any program-specific instructions noted in [Section IV](#). When the program-specific instructions deviate from those in the Application Guide, follow the program-specific instructions.

Applications that do not comply with these instructions may be delayed or not accepted for review.

There are several options available to submit your application through Grants.gov to NIH and Department of Health and Human Services partners. You **must** use one of these submission options to access the application forms for this opportunity.

1. Use the NIH ASSIST system to prepare, submit and track your application online.

Apply Online Using ASSIST

2. Use an institutional system-to-system (S2S) solution to prepare and submit your application to Grants.gov and [eRA Commons \(http://public.era.nih.gov/commons/\)](http://public.era.nih.gov/commons/) to track your application. Check with your institutional officials regarding availability.
3. Use [Grants.gov \(http://www.grants.gov/web/grants/applicants/download-application-package.html#search=true&oppNum=PAR-19-254\)](http://www.grants.gov/web/grants/applicants/download-application-package.html#search=true&oppNum=PAR-19-254) Workspace to prepare and submit your application and [eRA Commons \(http://public.era.nih.gov/commons/\)](http://public.era.nih.gov/commons/) to track your application.

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Part 2. Full Text of Announcement

Section I. Funding Opportunity Description

Support for Early-Stage Technology Development Is Critical to Advance Biomedical Research

Biomedical research is enabled and accelerated by the development of advanced technologies. Technology enables science by providing new ways to answer questions, and more importantly, allowing new types of questions to be asked that could not be anticipated in the absence of the enabling technology. New knowledge drives the imperative for new tools, and those tools open new questions, in a mutually reinforcing positive feedback loop that drives science forward.

A study by NIGMS staff in 2015, which included substantial, detailed input from the biomedical research community in response to a Request for Information ([NOT-GM-15-118](https://grants.nih.gov/grants/guide/notice-files/not-gm-15-118.html) (<https://grants.nih.gov/grants/guide/notice-files/not-gm-15-118.html>)), concluded that there is a significant unmet need for explicit support of early stage technology development, before nascent tools are ready to be applied to untested biomedical research problems. Early stage technology development can be described in two stages: (I) exploratory proof-of-concept research to determine the best approach(es) for a technology development project, and (II) the subsequent research and development that focuses exclusively on creating and validating a working prototype technology before application to untested biomedical problems is possible.

To address the immediate need for funding programs that support early stage technology development, NIGMS developed programs focusing on the two stages described above. This FOA invites projects in stage I, an early conceptual stage of the technology development process. A companion FOA [PAR-19-253](https://grants.nih.gov/grants/guide/pa-files/par-19-253.html) (<https://grants.nih.gov/grants/guide/pa-files/par-19-253.html>), (<https://grants.nih.gov/grants/guide/pa-files/par-19-253.html>) "Focused Technology Research and Development," supports projects in stage II to develop prototypes..

Defining Characteristics of Focused Technology Research and Development

- Projects must be at a **conceptual stage**, not yet supported by data. The concept should be compared to competing, state-of-the-art technology. The current state of knowledge is the project starting point. Concepts must not yet have been tested for feasibility. Project aims should focus on either: (a) exploratory research to differentiate possible technical approaches to determine the one most likely to be successful, or (b) demonstrating feasibility of a specific proposed approach.
- The **Significance** of the project could postulate a significant increment of **technical advance** over the state of the art. A favorable comparison against the state of the art should be postulated and adequately tested.
- Project **Significance** should be justified based on a strong **potential to advance biomedical research** if successful. Describe new biological questions that would be enabled by the proposed technology. The utility and inventiveness are both critical review criteria for the significance. The future utility of the technology for biomedical research should be described so biologists can evaluate its purpose and biomedical impact. The potential biological impact should be shown to affect the Institute or Center (IC) mission.
- The **Innovation** of the concept should be a significant increment of advancement over the state of the art. The technology should be a novel invention or method. Innovation could be described by a technical advance over the state of the art, an unanticipated technological advance, or the shift in current biomedical research or approaches. Project utility and inventiveness are both critical review criteria for innovation.
- The **Approach** should provide answers to Specific Aims or questions with rigorous logic, data treatment, and interpretation. The Approach should be focused on technical questions regarding the development of an innovative research tool. The **Specific Aims should be to gain new technological knowledge** and to measure quantitative advances over state-of-the-art technology. Specific Aims should be questions or hypotheses that are necessary and sufficient to connect the Approach to the overall project objectives. Project Specific Aims should identify limitations and stumbling blocks anticipated while establishing a core concept but need not integrate peripheral aspects that only later would be needed to develop a working prototype. Key obstacles and risks could be managed with reference to the literature, citation of investigator or collaborator expertise, or proposed alternate approaches, but must not be addressed by unpublished or preliminary data.
- The **objectives** at the end of the exploratory research could be a clear **proof of concept or a test of feasibility**, with quantitative performance criteria for success and for failure. There should be measurable intermediate and end point objectives and timelines (project milestones) that are used to indicate the progress of a project. The pass or fail performance criteria should be developed in the context of an acceptable technical advance over state of the art or the acceptable performance that would be required to accomplish future biomedical objectives. Projects are anticipated to have a high risk of failure with concomitant high reward.
- The **project outcome** should include an evaluation of the performance of the resulting research tool compared to state-of-the-art technology. **Validation** with well-characterized models or gold-standard biological samples is encouraged while investigation of untested biological questions should not be included. The criteria for success could include quantitative statistical end points to determine whether or not objectives have been achieved.

Appropriateness for this Program

For this FOA, technology refers to tools that enable basic research rather than directly leading to clinical diagnostics or interventions. This includes laboratory instruments and other devices, algorithms and software, chemical reagents and processes, or biological molecules or systems that have been modified by human intervention to become research tools that would find use in the biomedical community and have value for solving basic biomedical problems relevant to the IC mission.

Further, this FOA calls for innovative exploratory technology development predicated on a broad need or challenge in biomedical research that can be described explicitly. This need should be beyond the capability of current technology. The state-of-the-art technological performance defines a measurable starting point. The proposed improvement of technical performance should be compared to the state of the art which provides the rationale for developing a fundamentally different technology. The proposed technology should have the potential to address basic biomedical research needs or technical problems that are not limited to a single species of molecule, cell, tissue, organism, or other biological systems. Specific examples may be used for validation, but the systemic utility across molecules, cells, tissues, or organisms should be highlighted.

Proof of Concept: The goal of this FOA is to support proof-of-concept studies to evaluate feasibility and exploratory technology development. Feasibility for the proposed research must not have already been developed in the literature or in the application. Since proof of concept is not allowed, the project objectives must not be obvious based on the current state of the art. The expected outcome of the project should be a clear test of concept, either positive or negative. The concept should represent a significant advance over the state of the art since this FOA is designed for concepts that are highly innovative. Projects supported by this program should not be low risk, or incremental improvements to established technologies. The program is intended to support the development of highly innovative technologies that will address significant opportunities to enable biomedical research to go further. The significance of the proposed projects should be characterized in terms of innovation and novelty; that is, the effectiveness and impact of the proposed technology should be significant and the concept should be new, without published proof of concept.

No unpublished information: Since preliminary data for any purpose might appear to forecast or increase the likelihood of success, applications must not include or refer to preliminary or unpublished data, results, or conclusions. Unpublished results are not allowed, whether they support the state of the art, the expertise of the investigators, the feasibility of Specific Aims, or mitigate high-risk bottlenecks. Risk should not be resolved with data, but can be mitigated by theoretical evaluation, alternative approaches, and well-described criteria that would discriminate successful from unsuccessful project outcomes. Descriptive diagrams, conceptual charts or theoretical evaluations can be included, provided they do not contain unpublished data. Inclusion of unpublished data will make applications noncompliant with FOA instructions and will result in withdrawal without review. Determination of compliance is made after submission based on information included in the application.

Published data: Published data that establishes the current state of the art can be included. Any data that forecasts the project objectives or develops proof of concept are not allowed. Allowable data include published literature, and unreviewed preprints, protocols, and publicly available research products. However, citations in the application to unpublished sources must include Digital Object Identifier (DOI) and object type as described in [NOT-OD-17-050 \(https://grants.nih.gov/grants/guide/notice-files/not-od-17-050.html\)](https://grants.nih.gov/grants/guide/notice-files/not-od-17-050.html). Data only available in abstracts or on personal or institutional webpages without a DOI must not be included. Data must be clearly identified as published. Figures containing published data must include citations within the figure legend. Published data that is included in the research plan, biographical sketch or elsewhere in the application must be

cited adjacent to each occurrence. Data that is published must be unambiguously identified as such within the application.

No Biological Aims: Applications in response to this FOA that include biological aims will not be funded, but validation against known standards is encouraged. Biomedical relevance is an essential element of NIH research. However, this stage of technology development should not include immediate short-term application of nascent technologies to challenging biomedical research questions because an insistence on explicit linkage to a specific research problem and the immediate demonstration of an immature technology's effectiveness in that context can distort the technology development process. It can also diminish focus on development of genuinely innovative technology in favor of incremental improvements to existing technologies. In the early stages of technology development, insistence on biomedical applications is counterproductive. Therefore, in this program, application to specific biomedical questions in the time frame of the proposed project is considered beyond the scope of the program. Note that NIGMS does not participate in the Parent R21 funding announcement, so exploratory R21 projects that include biological objectives are not supported by NIGMS.

Validation: Application to synthetic models or well-characterized biological systems to assess performance can be included at this stage. To be considered for funding, applications of the technology must be limited to test systems chosen to facilitate development of the technology. The aims of the project must be focused entirely on the development of the technology.

Milestones: A milestone (or intermediate objective) is a defined event, achievement, or important stage that is used to indicate the progress of a project. Milestones should be descriptive of what will be done and when it will be completed. Milestones should lead logically to the final project objectives. The expected outcome from projects funded under this announcement will be the demonstration of feasibility, including (a) proof of concept or (b) preliminary data that indicates a promising avenue for future technology development.

Relevance of Research Topics for this FOA

Applicants are strongly advised to consult with the Scientific/Research Contact listed in this FOA for guidance on assessing the relevance of applications for this FOA. Technology development for a specific disease and/or organ system, translational research leading to disease diagnosis and intervention, or preclinical and clinical research should be matched to the appropriate Institutes or Centers (ICs). See the [List of NIH of Institutes, Centers, and Offices \(https://www.nih.gov/institutes-nih/list-nih-institutes-centers-offices\)](https://www.nih.gov/institutes-nih/list-nih-institutes-centers-offices) to learn more about specific missions. Also, as indicated in HOLD FOR NOTICE NUMBER, HIV/AIDS-related applications are no longer supported by NIGMS, and accordingly, will not be accepted for review or funding consideration.

Whether a technology is appropriate for a specific NIH IC can be evaluated by the biological significance and utility that would be enabled by the technology. Historical funding of research topics by institute can be identified with the [NIH Reporter \(https://projectreporter.nih.gov/reporter_MatchmakerResults.cfm\)](https://projectreporter.nih.gov/reporter_MatchmakerResults.cfm) to identify the historical fit to any NIH institute and study section. It is recommended that applicants contact program staff for IC eligibility. Final determination of application eligibility for this FOA will be based on the full application after submission.

Concepts should be both innovative (represent a significant advance) and novel (not publicly described). The following examples are not appropriate for this FOA: Incremental advance of technology, obvious substitution of one known element for another, technology that has incremental potential to advance biomedical research, combinations of prior elements with additive utility, technologies that are ready for advanced development and

validation.

NIGMS:

The [mission \(https://www.nigms.nih.gov/about/overview/\)](https://www.nigms.nih.gov/about/overview/) of NIGMS is to support basic research that increases our understanding of basic biological processes and lays the foundation for future advances in disease diagnosis, treatment, and prevention. NIGMS supports research and technology development that is aimed at understanding general principles, mechanisms, and processes through [Divisions with diverse interests \(https://www.nigms.nih.gov/about/Pages/contactbyarea.aspx\)](https://www.nigms.nih.gov/about/Pages/contactbyarea.aspx). NIGMS does not focus on single classes of cells, tissues, organs, or diseases unless they are used as models for elucidating basic principles. Technology development for a specific disease and/or organ system, translational research leading to disease diagnosis and intervention, or preclinical and clinical research may be more appropriate for other ICs.

NCCIH:

The [mission \(https://nccih.nih.gov/about/research/objectives\)](https://nccih.nih.gov/about/research/objectives) of NCCIH is to define, through rigorous scientific investigation, the usefulness and safety of complementary and integrative health interventions and their role in improving health and health care. NCCIH supports technologies which will help to elucidate or quantify the important components and/or mechanisms of action of complex interventions [relevant to the Center's mission \(https://nccih.nih.gov/about/offices/der\)](https://nccih.nih.gov/about/offices/der).

Choosing the Appropriate Biomedical Technology Development Program

Biomedical Technology Research and Development programs are defined by specific criteria that differentiate each stage of technology development. The process of technology research and development can be divided into three domains. The appropriate FOA in each area for applicants is listed. Further information is available at the NIGMS website "[Choosing the Appropriate Biomedical Technology Development Program](http://www.nigms.nih.gov/technologydevelopment)" (<http://www.nigms.nih.gov/technologydevelopment>).

(I) This FOA: Exploratory Research for Technology Development:

These projects evaluate high-risk concepts by exploring possible strategies to develop a potential biomedical technology. This is preliminary research that, if successful, should lead to proof of concept, or a demonstration of feasibility. These projects are characterized by a high degree of uncertainty regarding the appropriateness and performance characteristics of the technology in question, with no supporting unpublished and/or preliminary data. The project should be responsive to an unmet need or emerging opportunity in biomedical research. Projects that are ready for prototyping or have a fully defined research plan have advanced beyond a stage appropriate for the R21 mechanism and might be better matched to a three-year R01 mechanism with a reduced budget.

(II) [PAR-19-253 \(https://grants.nih.gov/grants/guide/pa-files/par-19-253.html\)](https://grants.nih.gov/grants/guide/pa-files/par-19-253.html): Focused Technology Research and Development: These projects focus on the further development of a working prototype technology with potential to enable biomedical research. Projects are characterized by innovative research and development focused on addressing technical challenges that stand in the way of creating an effective research tool. Projects are supported by preliminary data demonstrating feasibility of the approach. The challenge in these projects lies in how the technical challenges will be addressed more than whether the approach is possible. Projects that have significant remaining risk but are supported by early feasibility studies might be appropriate for a three-year R01 application with reduced budget to better manage risk and investment. Projects that are

well supported by proof of concept and propose to develop and validate fully functional prototypes might require higher budgets and a four-year duration (five years for [Early Stage Investigators](https://grants.nih.gov/grants/glossary.htm#EarlyStageInvestigatorESI) (<https://grants.nih.gov/grants/glossary.htm#EarlyStageInvestigatorESI>)). Projects that primarily focus on optimization, hardening, or obvious extrapolations of established technology might be less competitive. Focused Technology research and development projects will stop short of the application of the emerging technology to specific biomedical research problems.

(III) Parent R01: NIH Research Project Grant: These projects are characterized primarily by the iterative coupling of technology development with the application of emerging technologies to biomedical projects that serve as test-beds. These projects combine aims in technology development with challenging biomedical research aims that are positioned to benefit significantly from access to the technology as it matures. In these cases, technology developers benefit significantly from the opportunity to use biomedical research as a proving ground for robustness and for continued development of technologies. Unlike this technology-focused R01 funding announcements, the Parent R01 applications are evaluated for overall impact on the field of interest, rather than the potential utility of a technical project for future biological research.

Projects that include both technical advances and biological hypotheses or discovery are appropriate for the [Parent R01 funding announcement](https://grants.nih.gov/grants/guide/pa-files/PA-19-056.html) (<https://grants.nih.gov/grants/guide/pa-files/PA-19-056.html>). Unlike this technology-focused R01 funding announcements, the Parent R01 applications are evaluated for overall impact on the field of interest, rather than the potential utility of a technical project for future biological research.

New Investigators and Early Stage Investigators

As part of the [Next Generation Researchers Initiative](https://grants.nih.gov/ngri.htm) (<https://grants.nih.gov/ngri.htm>), investigators who have not yet received substantial support from the NIH (<https://grants.nih.gov/policy/early-investigators/list-smaller-grants.htm>) are encouraged to apply for technology development FOAs and are given extra consideration during review and funding decisions. Among investigators new to the NIH, many meritorious, innovative technologies have been proposed but not all have generated sufficient enthusiasm in review. NIH provides [general guidance](https://grants.nih.gov/grants/how-to-apply-application-guide/format-and-write/write-your-application.htm) (<https://grants.nih.gov/grants/how-to-apply-application-guide/format-and-write/write-your-application.htm>) on how to write your application to allow reviewers to better evaluate the science and merit of your application. In addition, guidance provided in this FOA on grant logic and strategy is based on reviewer critiques of technology development applications.

- [New Investigators](https://grants.nih.gov/grants/glossary.htm#NewInvestigator) (<https://grants.nih.gov/grants/glossary.htm#NewInvestigator>)(NI) are those who have not yet received substantial funding from the NIH, including well established investigators from research areas focused on technology development that historically have not yet enabled biomedical research. While this FOA is intended for these investigators, a clear description of future biomedical utility is required for compliance with the FOA. Consulting with biomedical consultants and future adopters about the utility of the proposed technology might strengthen the project significance that is perceived by reviewers.
- [Early Stage Investigators](https://grants.nih.gov/grants/glossary.htm#EarlyStageInvestigatorESI) (<https://grants.nih.gov/grants/glossary.htm#EarlyStageInvestigatorESI>) (ESIs) are [New Investigators](https://grants.nih.gov/grants/glossary.htm#NewInvestigator) (<https://grants.nih.gov/grants/glossary.htm#NewInvestigator>) who are less than 10 years out from their terminal degree, may be prioritized for funding. ESIs that are awarded an R21 do not lose their ESI status for future R01 applications. Technology development R21s are competitive and should not be considered a starter grant for new laboratories or a substitute for an R01 application. The intent of the Exploratory Research for Technology Development (R21) is to develop a proof of concept, not to establish or sustain a full research program. ESIs can apply for a 5-year R01

See [Section VIII. Other Information](#) for award authorities and regulations.

Section II. Award Information

Funding Instrument

Grant: A support mechanism providing money, property, or both to an eligible entity to carry out an approved project or activity.

Application Types Allowed

New
Resubmission
Revision
The [OER Glossary \(//grants.nih.gov/grants/guide/url_redirect.htm?id=11116\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11116) and the SF424 (R&R) Application Guide provide details on these application types.

Clinical Trial?

Not Allowed: Only accepting applications that do not propose clinical trials
[Need help determining whether you are doing a clinical trial? \(https://grants.nih.gov/grants/guide/url_redirect.htm?id=82370\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=82370)

Funds Available and Anticipated Number of Awards

The number of awards is contingent upon NIH appropriations and the submission of a sufficient number of meritorious applications.

Award Budget

Application budgets are limited to a total of \$275,000 Direct Costs over the two-year project period. No more than \$200,000 Direct Costs may be requested in any single year. The budget must be well justified and reflect the actual needs of the proposed project.

Award Project Period

The maximum project period is 2 years.

NIH grants policies as described in the [NIH Grants Policy Statement \(//grants.nih.gov/grants/guide/url_redirect.htm?id=11120\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11120) will apply to the applications submitted and awards made from this FOA.

Section III. Eligibility Information

1. Eligible Applicants

Eligible Organizations

Higher Education Institutions

- Public/State Controlled Institutions of Higher Education

- Private Institutions of Higher Education

The following types of Higher Education Institutions are always encouraged to apply for NIH support as Public or Private Institutions of Higher Education:

- Hispanic-serving Institutions
- Historically Black Colleges and Universities (HBCUs)
- Tribally Controlled Colleges and Universities (TCCUs)
- Alaska Native and Native Hawaiian Serving Institutions
- Asian American Native American Pacific Islander Serving Institutions (AANAPISIs)

Nonprofits Other Than Institutions of Higher Education

- Nonprofits with 501(c)(3) IRS Status (Other than Institutions of Higher Education)
- Nonprofits without 501(c)(3) IRS Status (Other than Institutions of Higher Education)

For-Profit Organizations

- Small Businesses
- For-Profit Organizations (Other than Small Businesses)

Governments

- State Governments
- County Governments
- City or Township Governments
- Special District Governments
- Indian/Native American Tribal Governments (Federally Recognized)
- Indian/Native American Tribal Governments (Other than Federally Recognized)
- Eligible Agencies of the Federal Government
- U.S. Territory or Possession

Other

- Independent School Districts
- Public Housing Authorities/Indian Housing Authorities
- Native American Tribal Organizations (other than Federally recognized tribal governments)
- Faith-based or Community-based Organizations
- Regional Organizations

Foreign Institutions

Non-domestic (non-U.S.) Entities (Foreign Institutions) **are not** eligible to apply

Non-domestic (non-U.S.) components of U.S. Organizations **are not** eligible to apply.

Foreign components, as [defined in the NIH Grants Policy Statement \(//grants.nih.gov/grants/guide/uri_redirect.htm?id=11118\)](https://grants.nih.gov/grants/guide/uri_redirect.htm?id=11118), **are** allowed.

Required Registrations

Applicant organizations

Applicant organizations must complete and maintain the following registrations as described in the SF 424 (R&R) Application Guide to be eligible to apply for or receive an award. All registrations must be completed prior to the application being submitted. Registration can take 6 weeks or more, so applicants should begin the registration process as soon as possible. The [NIH Policy on Late Submission of Grant Applications](http://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-039.html) ([//grants.nih.gov/grants/guide/notice-files/NOT-OD-15-039.html](http://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-039.html)) states that failure to complete registrations in advance of a due date is not a valid reason for a late submission.

- [Dun and Bradstreet Universal Numbering System \(DUNS\)](http://fedgov.dnb.com/webform) (<http://fedgov.dnb.com/webform>) - All registrations require that applicants be issued a DUNS number. After obtaining a DUNS number, applicants can begin both SAM and eRA Commons registrations. The same DUNS number must be used for all registrations, as well as on the grant application.
- [System for Award Management \(SAM\)](https://www.sam.gov/portal/public/SAM/) (<https://www.sam.gov/portal/public/SAM/>) – Applicants must complete and maintain an active registration, which requires renewal at least annually. The renewal process may require as much time as the initial registration. SAM registration includes the assignment of a Commercial and Government Entity (CAGE) Code for domestic organizations which have not already been assigned a CAGE Code.
 - [NATO Commercial and Government Entity \(NCAGE\) Code](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11176) ([//grants.nih.gov/grants/guide/url_redirect.htm?id=11176](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11176)) – Foreign organizations must obtain an NCAGE code (in lieu of a CAGE code) in order to register in SAM.
- [eRA Commons](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11123) ([//grants.nih.gov/grants/guide/url_redirect.htm?id=11123](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11123)) - Applicants must have an active DUNS number to register in eRA Commons. Organizations can register with the eRA Commons as they are working through their SAM or Grants.gov registration, but all registrations must be in place by time of submission. eRA Commons requires organizations to identify at least one Signing Official (SO) and at least one Program Director/Principal Investigator (PD/PI) account in order to submit an application.
- Grants.gov – Applicants must have an active DUNS number and SAM registration in order to complete the Grants.gov registration.

Program Directors/Principal Investigators (PD(s)/PI(s))

All PD(s)/PI(s) must have an eRA Commons account. PD(s)/PI(s) should work with their organizational officials to either create a new account or to affiliate their existing account with the applicant organization in eRA Commons. If the PD/PI is also the organizational Signing Official, they must have two distinct eRA Commons accounts, one for each role. Obtaining an eRA Commons account can take up to 2 weeks.

Eligible Individuals (Program Director/Principal Investigator)

Any individual(s) with the skills, knowledge, and resources necessary to carry out the proposed research as the Program Director(s)/Principal Investigator(s) (PD(s)/PI(s)) is invited to work with his/her organization to develop an application for support. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply for NIH support.

For institutions/organizations proposing multiple PDs/Pis, visit the Multiple Program Director/Principal Investigator Policy and submission details in the Senior/Key Person Profile (Expanded) Component of the SF424 (R&R) Application Guide.

2. Cost Sharing

This FOA does not require cost sharing as defined in the [NIH Grants Policy Statement](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11126). ([//grants.nih.gov/grants/guide/url_redirect.htm?id=11126](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11126))

3. Additional Information on Eligibility

Number of Applications

Applicant organizations may submit more than one application, provided that each application is scientifically distinct.

The NIH will not accept duplicate or highly overlapping applications under review at the same time. This means that the NIH will not accept:

- A new (A0) application that is submitted before issuance of the summary statement from the review of an overlapping new (A0) or resubmission (A1) application.
- A resubmission (A1) application that is submitted before issuance of the summary statement from the review of the previous new (A0) application.
- An application that has substantial overlap with another application pending appeal of initial peer review (see [NOT-OD-11-101](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-11-101.html) ([//grants.nih.gov/grants/guide/notice-files/NOT-OD-11-101.html](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-11-101.html)))

Section IV. Application and Submission Information

1. Requesting an Application Package

The application forms package specific to this opportunity must be accessed through ASSIST, Grants.gov Workspace or an institutional system-to-system solution. Links to apply using ASSIST or Grants.gov Workspace are available in [Part 1](#) of this FOA. See your administrative office for instructions if you plan to use an institutional system-to-system solution.

2. Content and Form of Application Submission

It is critical that applicants follow the instructions in the Research (R) Instructions in the [SF424 \(R&R\) Application Guide](https://grants.nih.gov/grants/guide/url_redirect.htm?id=12000) ([//grants.nih.gov/grants/guide/url_redirect.htm?id=12000](https://grants.nih.gov/grants/guide/url_redirect.htm?id=12000)) except where instructed in this funding opportunity announcement to do otherwise. Conformance to the requirements in the Application Guide is required and strictly enforced. Applications that are out of compliance with these instructions may be delayed or not accepted for review.

Page Limitations

All page limitations described in the SF424 Application Guide and the [Table of Page Limits](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11133) ([//grants.nih.gov/grants/guide/url_redirect.htm?id=11133](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11133)) must be followed

Instructions for Application Submission

The following section supplements the instructions found in the SF424 (R&R) Application Guide and should be used for preparing an application to this FOA.

SF424(R&R) Cover

All instructions in the SF424 (R&R) Application Guide must be followed.

SF424(R&R) Project/Performance Site Locations

All instructions in the SF424 (R&R) Application Guide must be followed.

SF424(R&R) Other Project Information

All instructions in the SF424 (R&R) Application Guide must be followed.

SF424(R&R) Senior/Key Person Profile

All instructions in the SF424 (R&R) Application Guide must be followed.

Modular Budget

All instructions in the SF424 (R&R) Application Guide must be followed.

R&R Subaward Budget

All instructions in the SF424 (R&R) Application Guide must be followed.

PHS 398 Cover Page Supplement

All instructions in the SF424 (R&R) Application Guide must be followed.

PHS 398 Research Plan

All instructions in the SF424 (R&R) Application Guide must be followed, with the following additional instructions:

Specific Aims:

Specific Aims should be focused on the objective of developing an innovative research tool. The project objectives should be to gain new technological knowledge and measure quantitative advances over state-of-the-art technology. Specific Aims should be questions or hypotheses that are necessary and sufficient to connect the work to be performed to the project objectives.

Specific Aims should advance the technical knowledge required to investigate or manipulate biological systems in the service of furthering basic biomedical research that is supported by each IC. Technical advances should be novel, inventive entities or methods that have future utility to broadly advance biomedical research. Examples would include instruments, devices, processes, algorithms, software, chemicals, biomolecules, or cells that have potential value for generating new basic biomedical research. Biomedical knowledge by itself would not be considered a technological advance. Applications submitted under this FOA that include pursuit of a biomedical hypothesis will not be considered for funding. Applications that are outside the mission of the Institute and would therefore not have utility for future research supported by the appropriate IC will be withdrawn.

Research Strategy:*Significance*

In addition to the topics outlined in the SF424 (R&R) Application Guide, the application should describe the potential impact of the tool that will be developed. The Significance should describe both the proposed technical advance over the state-of-the-art, and the future biological applications that would be enabled by the new technology. The state-of-the-art technological performance is defined by all available data and provides a quantitative starting point for the proposed technological improvement. Limitations of the state-of-the-art provide the rationale for developing a fundamentally different technology. Because this is very early stage exploratory technology development, the impact is not likely to be immediate. Nonetheless, the possible future impact of the proposed technology must be compelling and clearly articulated. The Significance should clearly define the unmet need or emerging research opportunity that will be addressed by the proposed technology and describe its anticipated use for acquisition of biomedical knowledge. The application should explain the potential impact of the technology in the context of biomedical research. The proposed technology must have a well-articulated potential to address both basic biomedical research needs and technical problems that occur broadly

across multiple biological systems or diseases. The rationale for the proposed technology development should be explained and should incorporate discussion of the broad opportunity or need that the new technology will address, as well as a discussion of why the approach or approaches to be explored have been selected.

Innovation

In addition to the topics outlined in the SF424 (R&R) Application Guide, the application should describe the nature of the technical opportunity to be exploited and obstacles to be overcome. If the relative merits of multiple technological pathways will be explored, provide the rationale for why that broad approach is likely to lead to an innovative solution. If one specific approach is to be explored, explain the rationale for the proposed solution.

The project should be highly innovative. The technology concept should be novel, inventive entities or methods with potential utility for biomedical research. Innovation could be evaluated by the increment of technical advance over the state-of-the-art, unanticipated technological advance, and the potential shift in current biomedical research or approaches.

The application should describe uncertainties underlying the proposed technology research and development, including risk of failure. A high degree of uncertainty and risk are appropriate in early-stage technology development and should be described realistically. Avoid unrealistic, overly optimistic descriptions of the possible outcomes. Straightforward discussion of the challenges and risks inherent in the research plan is encouraged. Describe the desired performance characteristics of the proposed technology and specific measures that will be used to evaluate progress towards achieving those objectives. Objectives and performance measures should be commensurate with the stage of development of the technology and may be very early in the process.

Approach

In addition to the topics outlined in the SF424 (R&R) Application Guide, the application should describe those aspects of the experimental approach that are specific to exploratory technology development. These include the uncertainties underlying the proposed technology research and development, including the risk of failure.

The Approach should establish feasibility or proof of concept of substantially improved technical capacities not provided by current tools. The Approach should describe how data will be obtained, analyzed, and interpreted with sufficient rigor to quantitatively assess project outcomes. The project performance that would be required to achieve high reward should be identified in the objectives and milestones. While inclusion of untested biological hypotheses will not be funded, validation of technology with well characterized models or gold standard biological samples is encouraged.

Project objectives should be novel and not obvious compared to the current state of the art. Evidence that the concept is achievable would demonstrate positive proof of concept which is not allowed in this FOA. To ensure that feasibility or proof of concept has not been evaluated, applications must not include or refer to unpublished and/or preliminary data, results, or conclusions since these forecast an increased likelihood of success. Proof of concept or feasibility must not already be developed by published or unpublished studies. For this program, any data demonstrating feasibility of the proposed approach indicates that the project has advanced beyond the scope of the program. Applications that have been evaluated by proof-of-concept or feasibility studies will be considered noncompliant with the FOA instructions and will be withdrawn without review. Projects that are ready

for prototyping or have a fully defined research plan has advanced beyond a stage appropriate for the R21 mechanism might be better matched to a three-year R01 mechanism with a reduced budget.

Published data that describes the current state of the art can be included. All instances of published data must cite the publication, preprint, or interim research product from which they are taken. Citations to preprints and interim research products must include a DOI and object type as described in [NOT-OD-17-050 \(https://grants.nih.gov/grants/guide/notice-files/not-od-17-050.html\)](https://grants.nih.gov/grants/guide/notice-files/not-od-17-050.html). Figures containing published data must include a citation within the figure legend and data elsewhere in the application must be cited at each occurrence. Data that cannot be unambiguously attributed to a publication or interim research product with a DOI will be considered noncompliant with the FOA instructions, and the application will be withdrawn without review. The criteria for withdrawal are based on unambiguous citation, not whether the data exists in published literature. Applications can include descriptive diagrams, conceptual charts or theoretical evaluations that do not contain unpublished data. Determination of compliance will be made after submission, based on information within the application. Post-submission information will not be used to determine compliance.

Objectives and Milestones: The desired characteristics of the technology at the conclusion of the project should be described as end-point objectives, and intermediate objectives or milestones towards that goal should be presented. The milestones should be directed towards answering the fundamental questions regarding the selection of an appropriate way forward for continued development. The end-point milestones and objectives are measurable project performance criteria that, if achieved, would be a significant increment of technical advance over the state-of-the-art. For exploratory research, high risk is expected, and milestones might not be reached on a predictable timetable. Nonetheless, measurable milestones should be defined, and it should be stated whether intermediate or end-point project performance would be adequate for further technical development of working prototypes and adequate for testing future biological hypotheses. For exploratory research, it is expected that further technical improvement would be necessary to achieve biomedical utility. Describe the desired performance characteristics of the proposed technology and specific measures that will be used to evaluate progress toward achieving those goals. Applications of the technology should be limited to test systems. The Research Strategy should explain the rationale for the choice of test systems in terms of the desired performance of the technology and how a test system will facilitate development of the technology.

Resource Sharing Plan: Individuals are required to comply with the instructions for the Resource Sharing Plans as provided in the SF424 (R&R) Application Guide.

The following modifications also apply:

- All applications, regardless of the amount of direct costs requested for any one year, should address a Data Sharing Plan.

Appendix:

Only limited Appendix materials are allowed. Follow all instructions for the Appendix as described in the SF424 (R&R) Application Guide.

PHS Human Subjects and Clinical Trials Information

When involving NIH-defined human subjects research, clinical research, and/or clinical trials (and when applicable, clinical trials research experience) follow all instructions for the PHS Human Subjects and Clinical Trials Information form in the SF424 (R&R) Application Guide, with the following additional instructions:

If you answered “Yes” to the question “Are Human Subjects Involved?” on the R&R Other Project Information form, you must include at least one human subjects study record using the **Study Record: PHS Human**

Subjects and Clinical Trials Information form or **Delayed Onset Study** record.

Study Record: PHS Human Subjects and Clinical Trials Information

All instructions in the SF424 (R&R) Application Guide must be followed.

Delayed Onset Study

Note: Delayed onset does NOT apply to a study that can be described but will not start immediately (i.e., delayed start). All instructions in the SF424 (R&R) Application Guide must be followed.

PHS Assignment Request Form

All instructions in the SF424 (R&R) Application Guide must be followed.

3. Unique Entity Identifier and System for Award Management (SAM)

See Part 1. Section III.1 for information regarding the requirement for obtaining a unique entity identifier and for completing and maintaining active registrations in System for Award Management (SAM), NATO Commercial and Government Entity (NCAGE) Code (if applicable), eRA Commons, and Grants.gov

4. Submission Dates and Times

[Part I. Overview Information](#) contains information about Key Dates and times. Applicants are encouraged to submit applications before the due date to ensure they have time to make any application corrections that might be necessary for successful submission. When a submission date falls on a weekend or [Federal holiday](#) (https://grants.nih.gov/grants/guide/url_redirect.html?id=82380), the application deadline is automatically extended to the next business day.

Organizations must submit applications to [Grants.gov](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11128) ([//grants.nih.gov/grants/guide/url_redirect.htm?id=11128](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11128)) (the online portal to find and apply for grants across all Federal agencies). Applicants must then complete the submission process by tracking the status of the application in the [eRA Commons](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11123) ([//grants.nih.gov/grants/guide/url_redirect.htm?id=11123](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11123)), NIH's electronic system for grants administration. NIH and Grants.gov systems check the application against many of the application instructions upon submission. Errors must be corrected and a changed/corrected application must be submitted to Grants.gov on or before the application due date and time. If a Changed/Corrected application is submitted after the deadline, the application will be considered late. Applications that miss the due date and time are subjected to the NIH Policy on Late Application Submission.

Applicants are responsible for viewing their application before the due date in the eRA Commons to ensure accurate and successful submission.

Information on the submission process and a definition of on-time submission are provided in the SF424 (R&R) Application Guide.

5. Intergovernmental Review (E.O. 12372)

This initiative is not subject to [intergovernmental review](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11142). ([//grants.nih.gov/grants/guide/url_redirect.htm?id=11142](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11142))

6. Funding Restrictions

All NIH awards are subject to the terms and conditions, cost principles, and other considerations described in

the [NIH Grants Policy Statement \(//grants.nih.gov/grants/guide/url_redirect.htm?id=11120\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11120) .

Pre-award costs are allowable only as described in the [NIH Grants Policy Statement \(//grants.nih.gov/grants/guide/url_redirect.htm?id=11143\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11143).

7. Other Submission Requirements and Information

Applications must be submitted electronically following the instructions described in the SF424 (R&R) Application Guide. Paper applications will not be accepted.

Applicants must complete all required registrations before the application due date. [Section III. Eligibility Information](#) contains information about registration.

For assistance with your electronic application or for more information on the electronic submission process, visit [How to Apply – Application Guide \(https://grants.nih.gov/grants/how-to-apply-application-guide.html\)](https://grants.nih.gov/grants/how-to-apply-application-guide.html). If you encounter a system issue beyond your control that threatens your ability to complete the submission process on-time, you must follow the [Dealing with System Issues \(https://grants.nih.gov/grants/how-to-apply-application-guide/due-dates-and-submission-policies/dealing-with-system-issues.htm\)](https://grants.nih.gov/grants/how-to-apply-application-guide/due-dates-and-submission-policies/dealing-with-system-issues.htm) guidance. For assistance with application submission, contact the Application Submission Contacts in [Section VII](#).

Important reminders:

All PD(s)/PI(s) must include their eRA Commons ID in the Credential field of the Senior/Key Person Profile Component of the SF424(R&R) Application Package. Failure to register in the Commons and to include a valid PD/PI Commons ID in the credential field will prevent the successful submission of an electronic application to NIH. See [Section III](#) of this FOA for information on registration requirements.

The applicant organization must ensure that the DUNS number it provides on the application is the same number used in the organization's profile in the eRA Commons and for the System for Award Management. Additional information may be found in the SF424 (R&R) Application Guide.

See [more tips \(//grants.nih.gov/grants/guide/url_redirect.htm?id=11146\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11146) for avoiding common errors.

Upon receipt, applications will be evaluated for completeness and compliance with application instructions by the Center for Scientific Review and/or the appropriate IC. Applications that are incomplete or non-compliant will not be reviewed.

Post Submission Materials

Applicants are required to follow the instructions for post-submission materials, as described in [the policy \(//grants.nih.gov/grants/guide/url_redirect.htm?id=82299\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=82299).

Section V. Application Review Information

1. Criteria

Only the review criteria described below will be considered in the review process. Applications submitted to the NIH in support of the [NIH mission \(//grants.nih.gov/grants/guide/url_redirect.htm?id=11149\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11149) are evaluated for scientific and technical merit through the NIH peer review system.

For this particular announcement, note the following:

The Exploratory Research for Technology Development program uses the R21 activity code but is distinguished from the NIH Parent R21 in several important respects. Projects should be justified with a strong potential to enable biomedical research if successful. However, projects should focus exclusively on technology development that is initially at the concept stage and has not yet been proven. Because projects will not yet have been evaluated for feasibility, it should be expected that they might have a high risk of failure. Appropriate justification for the proposed work can be provided through literature citations, published data from other sources including preprints with a DOI number, or theoretical principles. The project should focus on exploratory research that at its conclusion would evaluate the feasibility of one or more technical approaches. Projects referring to unpublished or preliminary data are not appropriate for this program. Unpublished data must not be included and proof of concept or feasibility must not have been established. Any preexisting data would be part of the state of the art, which serves as the baseline for innovative advances. Significant projects should have both innovative technical advances and compelling utility for future biological research. Biological validation with known samples is encouraged, but untested biomedical research aims are inappropriate for this program and will not be funded.

Overall Impact

Reviewers will provide an overall impact score to reflect their assessment of the likelihood for the project to exert a sustained, powerful influence on the research field(s) involved, in consideration of the following review criteria and additional review criteria (as applicable for the project proposed).

Scored Review Criteria

Reviewers will consider each of the review criteria below in the determination of scientific merit, and give a separate score for each. An application does not need to be strong in all categories to be judged likely to have major scientific impact. For example, a project that by its nature is not innovative may be essential to advance a field.

Significance

Does the project address an important problem or a critical barrier to progress in the field? Is the prior research that serves as the key support for the proposed project rigorous? 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?

For this FOA: Is the proposed technology inventive and a significant advance over state-of-the-art technology? Does the proposed technology development have the potential to address a significant unmet need in biomedical research or open significant new avenues for investigation? Does the proposed technology propose an unanticipated increment of technical advance, or does it solve a longstanding technical problem in an established technology area? Is the potential effect of the technology for biomedical research appropriately broad, beyond a single molecule, tissue, organism, system, or disease?

Regardless of the inherent risk of the project, assuming that continued development of the technology is successful, would its availability significantly facilitate current research or enable testing of biological hypotheses that cannot be tested with existing technology?

If the technology is fully developed subsequently, is it likely to have practical effect on the research community? Does the proposed technology have the potential to be widely adopted by the relevant research community?

Investigator(s)

Are the PD(s)/PI(s), collaborators, and other researchers well suited to the project? If Early Stage Investigators or those 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?

For this FOA: Do the investigators have a record of significant technological innovation? Do the investigators demonstrate a willingness to recognize risks, and take risks to solve challenging problems?

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?

For this FOA:

Is the proposed technology fundamentally novel, non-obvious, and inventive compared to the technical state-of-the-art, including all published data? Does the application propose a proof-of-concept or a feasibility study that has not already been developed in published or unpublished results? Are the project milestones and final objectives a significant advance over the technical state-of-the-art? If successful, would the future utility of the technology enable tests of novel or inventive biomedical hypotheses?

Is the application ambitious, with well identified risk, rather than incremental? Does the proposed project go beyond the current technology development regime in a given area? Will the project take a fundamentally new approach?

Approach

Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project? Have the investigators included plans to address weaknesses in the rigor of prior research that serves as the key support for the proposed 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?

If the project involves human subjects and/or NIH-defined clinical research, are the plans to address 1) the

protection of human subjects from research risks, and 2) inclusion (or exclusion) of individuals on the basis of sex/gender, race, and ethnicity, as well as the inclusion or exclusion of individuals of all ages (including children and older adults), justified in terms of the scientific goals and research strategy proposed?

For this FOA: Is the project focused on demonstrating proof of concept for an unproven idea? Does the project involve a high level of uncertainty or risk, as expected for exploratory research that must not have prior proof of concept? Is the application designed to obtain preliminary data, proof of concept or determine feasibility of the proposed technology that is non-obvious compared to previously obtained published or unpublished results? Would the utility of the technology have well described utility for acquisition of biomedical knowledge?

Does the application appropriately focus on exploratory research to determine technological feasibility rather than propose biological, hypothesis-driven research? Is the technology performance validated with well-characterized synthetic models or biological samples appropriate for early stage research? If the project is intended to test technological hypotheses by selecting the most appropriate technological approach among multiple alternatives, would completion of the proposed research plan be likely to result in necessary and sufficient preliminary data to make that determination?

If development of a specific technology is proposed, are the intermediate and end-point objectives or milestones well defined? Would accomplishment of the specific aims provide quantitative evaluation of the objectives and milestones? Are the scientific rigor, data analysis, and interpretation adequate to evaluate whether objectives or milestones have or have not been met? Would meeting the proposed objectives or milestones be sufficient to establish the feasibility of a subsequent project and serve as a foundation for future working prototypes of the technology? Would experimental results from the exploratory project serve as a foundation for next phase development efforts such as a future Focused Technology Development R01 project or equivalent?

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?

Additional Review Criteria

As applicable for the project proposed, reviewers will evaluate the following additional items while determining scientific and technical merit, and in providing an overall impact score, but will not give separate scores for these items.

Protections for Human Subjects

For research that involves human subjects but does not involve one of the categories of research that are exempt under 45 CFR Part 46, the committee will evaluate the justification for involvement of human subjects and the proposed protections from research risk relating to their participation according to the following five review criteria: 1) risk to subjects, 2) adequacy of protection against risks, 3) potential benefits to the subjects and others, 4) importance of the knowledge to be gained, and 5) data and safety monitoring for clinical trials.

For research that involves human subjects and meets the criteria for one or more of the categories of research that are exempt under 45 CFR Part 46, the committee will evaluate: 1) the justification for the exemption, 2) human subjects involvement and characteristics, and 3) sources of materials. For additional information on review of the Human Subjects section, please refer to the [Guidelines for the Review of Human Subjects \(//grants.nih.gov/grants/guide/url_redirect.htm?id=11175\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11175).

Inclusion of Women, Minorities, and Individuals Across the Lifespan

When the proposed project involves human subjects and/or NIH-defined clinical research, the committee will evaluate the proposed plans for the inclusion (or exclusion) of individuals on the basis of sex/gender, race, and ethnicity, as well as the inclusion (or exclusion) of individuals of all ages (including children and older adults) to determine if it is justified in terms of the scientific goals and research strategy proposed. For additional information on review of the Inclusion section, please refer to the [Guidelines for the Review of Inclusion in Clinical Research \(//grants.nih.gov/grants/guide/url_redirect.htm?id=11174\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11174).

Vertebrate Animals

The committee will evaluate the involvement of live vertebrate animals as part of the scientific assessment according to the following criteria: (1) description of proposed procedures involving animals, including species, strains, ages, sex, and total number to be used; (2) justifications for the use of animals versus alternative models and for the appropriateness of the species proposed; (3) interventions to minimize discomfort, distress, pain and injury; and (4) justification for euthanasia method if NOT consistent with the AVMA Guidelines for the Euthanasia of Animals. Reviewers will assess the use of chimpanzees as they would any other application proposing the use of vertebrate animals. For additional information on review of the Vertebrate Animals section, please refer to the [Worksheet for Review of the Vertebrate Animal Section \(//grants.nih.gov/grants/guide/url_redirect.htm?id=11150\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11150).

Biohazards

Reviewers will assess whether materials or procedures proposed are potentially hazardous to research personnel and/or the environment, and if needed, determine whether adequate protection is proposed.

Resubmissions

For Resubmissions, the committee will evaluate the application as now presented, taking into consideration the responses to comments from the previous scientific review group and changes made to the project.

Renewals

Not Applicable

Revisions

For Revisions, the committee will consider the appropriateness of the proposed expansion of the scope of the project. If the Revision application relates to a specific line of investigation presented in the original application that was not recommended for approval by the committee, then the committee will consider whether the responses to comments from the previous scientific review group are adequate and whether

substantial changes are clearly evident.

Additional Review Considerations

As applicable for the project proposed, reviewers will consider each of the following items, but will not give scores for these items, and should not consider them in providing an overall impact score.

Applications from Foreign Organizations

Not Applicable

Select Agent Research

Reviewers will assess the information provided in this section of the application, including 1) the Select Agent(s) to be used in the proposed research, 2) the registration status of all entities where Select Agent(s) will be used, 3) the procedures that will be used to monitor possession use and transfer of Select Agent(s), and 4) plans for appropriate biosafety, biocontainment, and security of the Select Agent(s).

Resource Sharing Plans

Reviewers will comment on whether the following Resource Sharing Plans, or the rationale for not sharing the following types of resources, are reasonable: (1) [Data Sharing Plan](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11151) ([//grants.nih.gov/grants/guide/url_redirect.htm?id=11151](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11151)); (2) [Sharing Model Organisms](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11152) ([//grants.nih.gov/grants/guide/url_redirect.htm?id=11152](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11152)); and (3) [Genomic Data Sharing Plan \(GDS\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11153) ([//grants.nih.gov/grants/guide/url_redirect.htm?id=11153](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11153)).

Authentication of Key Biological and/or Chemical Resources:

For projects involving key biological and/or chemical resources, reviewers will comment on the brief plans proposed for identifying and ensuring the validity of those resources.

Budget and Period of Support

Reviewers will consider whether the budget and the requested period of support are fully justified and reasonable in relation to the proposed research.

2. Review and Selection Process

Applications will be evaluated for scientific and technical merit by (an) appropriate Scientific Review Group(s), convened by the Center for Scientific Review in accordance with [NIH peer review policy and procedures](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11154) ([//grants.nih.gov/grants/guide/url_redirect.htm?id=11154](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11154)), using the stated [review criteria](#). Assignment to a Scientific Review Group will be shown in the eRA Commons.

As part of the scientific peer review, all applications:

- May undergo a selection process in which only those applications deemed to have the highest scientific and technical merit (generally the top half of applications under review) will be discussed and assigned an overall impact score.
- Will receive a written critique.

Applications will be assigned on the basis of established PHS referral guidelines to the appropriate NIH Institute

or Center. Applications will compete for available funds with all other recommended applications. Following initial peer review, recommended applications will receive a second level of review by the appropriate national Advisory Council or Board. The following will be considered in making funding decisions:

- Scientific and technical merit of the proposed project as determined by scientific peer review.
- Availability of funds.
- Relevance of the proposed project to program priorities.

3. Anticipated Announcement and Award Dates

After the peer review of the application is completed, the PD/PI will be able to access his or her Summary Statement (written critique) via the [eRA Commons \(//grants.nih.gov/grants/guide/url_redirect.htm?id=11123\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11123). Refer to Part 1 for dates for peer review, advisory council review, and earliest start date. Information regarding the disposition of applications is available in the [NIH Grants Policy Statement \(//grants.nih.gov/grants/guide/url_redirect.htm?id=11156\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11156).

Section VI. Award Administration Information

1. Award Notices

If the application is under consideration for funding, NIH will request "just-in-time" information from the applicant as described in the [NIH Grants Policy Statement \(//grants.nih.gov/grants/guide/url_redirect.htm?id=11157\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11157). A formal notification in the form of a Notice of Award (NoA) will be provided to the applicant organization for successful applications. The NoA signed by the grants management officer is the authorizing document and will be sent via email to the grantee's business official.

Awardees must comply with any funding restrictions described in [Section IV.5. Funding Restrictions](#). Selection of an application for award is not an authorization to begin performance. Any costs incurred before receipt of the NoA are at the recipient's risk. These costs may be reimbursed only to the extent considered allowable pre-award costs.

Any application awarded in response to this FOA will be subject to terms and conditions found on the [Award Conditions and Information for NIH Grants \(//grants.nih.gov/grants/guide/url_redirect.htm?id=11158\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11158) website. This includes any recent legislation and policy applicable to awards that is highlighted on this website.

2. Administrative and National Policy Requirements

All NIH grant and cooperative agreement awards include the [NIH Grants Policy Statement \(//grants.nih.gov/grants/guide/url_redirect.htm?id=11120\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11120) as part of the NoA. For these terms of award, see the [NIH Grants Policy Statement Part II: Terms and Conditions of NIH Grant Awards, Subpart A: General \(//grants.nih.gov/grants/guide/url_redirect.htm?id=11157\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11157) and [Part II: Terms and Conditions of NIH Grant Awards, Subpart B: Terms and Conditions for Specific Types of Grants, Grantees, and Activities \(//grants.nih.gov/grants/guide/url_redirect.htm?id=11159\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11159). More information is provided at [Award Conditions and Information for NIH Grants \(//grants.nih.gov/grants/guide/url_redirect.htm?id=11158\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11158).

Recipients of federal financial assistance (FFA) from HHS must administer their programs in compliance with federal civil rights law. This means that recipients of HHS funds must ensure equal access to their programs without regard to a person's race, color, national origin, disability, age and, in some circumstances, sex and religion. This includes ensuring your programs are accessible to persons with limited English proficiency. HHS

recognizes that research projects are often limited in scope for many reasons that are nondiscriminatory, such as the principal investigator's scientific interest, funding limitations, recruitment requirements, and other considerations. Thus, criteria in research protocols that target or exclude certain populations are warranted where nondiscriminatory justifications establish that such criteria are appropriate with respect to the health or safety of the subjects, the scientific study design, or the purpose of the research.

In accordance with the statutory provisions contained in Section 872 of the Duncan Hunter National Defense Authorization Act of Fiscal Year 2009 (Public Law 110-417), NIH awards will be subject to the Federal Awardee Performance and Integrity Information System (FAPIIS) requirements. FAPIIS requires Federal award making officials to review and consider information about an applicant in the designated integrity and performance system (currently FAPIIS) prior to making an award. An applicant, at its option, may review information in the designated integrity and performance systems accessible through FAPIIS and comment on any information about itself that a Federal agency previously entered and is currently in FAPIIS. The Federal awarding agency will consider any comments by the applicant, in addition to other information in FAPIIS, in making a judgement about the applicant's integrity, business ethics, and record of performance under Federal awards when completing the review of risk posed by applicants as described in 45 CFR Part 75.205 "Federal awarding agency review of risk posed by applicants." This provision will apply to all NIH grants and cooperative agreements except fellowships.

For additional guidance regarding how the provisions apply to NIH grant programs, please contact the Scientific/Research Contact that is identified in Section VII under Agency Contacts of this FOA. HHS provides general guidance to recipients of FFA on meeting their legal obligation to take reasonable steps to provide meaningful access to their programs by persons with limited English proficiency. Please see <https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/index.html> (<https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/index.html>). The HHS Office for Civil Rights also provides guidance on complying with civil rights laws enforced by HHS. Please see <https://www.hhs.gov/civil-rights/for-individuals/section-1557/index.html> (<https://www.hhs.gov/civil-rights/for-individuals/section-1557/index.html>)<https://www.hhs.gov/civil-rights/for-providers/laws-regulations-guidance/index.html> (<https://www.hhs.gov/civil-rights/for-providers/laws-regulations-guidance/index.html>). Recipients of FFA also have specific legal obligations for serving qualified individuals with disabilities. Please see <https://www.hhs.gov/civil-rights/for-individuals/disability/index.html> (<https://www.hhs.gov/civil-rights/for-individuals/disability/index.html>). Please contact the HHS Office for Civil Rights for more information about obligations and prohibitions under federal civil rights laws at <https://www.hhs.gov/ocr/about-us/contact-us/index.html> (<https://www.hhs.gov/ocr/about-us/contact-us/index.html>) or call 1-800-368-1019 or TDD 1-800-537-7697. Also note it is an HHS Departmental goal to ensure access to quality, culturally competent care, including long-term services and supports, for vulnerable populations. For further guidance on providing culturally and linguistically appropriate services, recipients should review the National Standards for Culturally and Linguistically Appropriate Services in Health and Health Care at <http://minorityhealth.hhs.gov/omh/browse.aspx?lvl=2&lvlid=53> (<http://minorityhealth.hhs.gov/omh/browse.aspx?lvl=2&lvlid=53>).

Cooperative Agreement Terms and Conditions of Award

Not Applicable

3. Reporting

When multiple years are involved, awardees will be required to submit the [Research Performance Progress Report \(RPPR\) \(//grants.nih.gov/grants/rppr/index.htm\)](http://grants.nih.gov/grants/rppr/index.htm) annually and financial statements as required in the [NIH Grants Policy Statement. \(//grants.nih.gov/grants/guide/url_redirect.htm?id=11161\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11161)

A final RPPR, invention statement, and the expenditure data portion of the Federal Financial Report are required for closeout of an award, as described in the [NIH Grants Policy Statement \(//grants.nih.gov/grants/guide/url_redirect.htm?id=11161\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11161).

The Federal Funding Accountability and Transparency Act of 2006 (Transparency Act), includes a requirement for awardees of Federal grants to report information about first-tier subawards and executive compensation under Federal assistance awards issued in FY2011 or later. All awardees of applicable NIH grants and cooperative agreements are required to report to the Federal Subaward Reporting System (FSRS) available at [www.fsrs.gov \(//grants.nih.gov/grants/guide/url_redirect.htm?id=11170\)](http://www.fsrs.gov) on all subawards over \$25,000. See the [NIH Grants Policy Statement \(//grants.nih.gov/grants/guide/url_redirect.htm?id=11171\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11171) for additional information on this reporting requirement.

In accordance with the regulatory requirements provided at 45 CFR 75.113 and Appendix XII to 45 CFR Part 75, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts from all Federal awarding agencies with a cumulative total value greater than \$10,000,000 for any period of time during the period of performance of a Federal award, must report and maintain the currency of information reported in the System for Award Management (SAM) about civil, criminal, and administrative proceedings in connection with the award or performance of a Federal award that reached final disposition within the most recent five-year period. The recipient must also make semiannual disclosures regarding such proceedings. Proceedings information will be made publicly available in the designated integrity and performance system (currently FAPIIS). This is a statutory requirement under section 872 of Public Law 110-417, as amended (41 U.S.C. 2313). As required by section 3010 of Public Law 111-212, all information posted in the designated integrity and performance system on or after April 15, 2011, except past performance reviews required for Federal procurement contracts, will be publicly available. Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75 – Award Term and Conditions for Recipient Integrity and Performance Matters.

Section VII. Agency Contacts

We encourage inquiries concerning this funding opportunity and welcome the opportunity to answer questions from potential applicants.

Application Submission Contacts

eRA Service Desk (Questions regarding ASSIST, eRA Commons, application errors and warnings, documenting system problems that threaten submission by the due date, and post-submission issues)

Finding Help Online: [http://grants.nih.gov/support/ \(//grants.nih.gov/support/\)](http://grants.nih.gov/support/) (preferred method of contact)

Telephone: 301-402-7469 or 866-504-9552 (Toll Free)

General Grants Information (Questions regarding application instructions, application processes, and NIH grant resources)

Email: [GrantsInfo@nih.gov \(mailto:GrantsInfo@nih.gov\)](mailto:GrantsInfo@nih.gov) (preferred method of contact)

Telephone: 301-945-7573

Grants.gov Customer Support (Questions regarding Grants.gov registration and Workspace)

Contact Center Telephone: 800-518-4726

Email: support@grants.gov (<mailto:support@grants.gov>)

Scientific/Research Contact(s)

Paul Sammak, Ph.D.

Division of Biophysics, Biomedical Technology and Computational Biosciences

National Institute of General Medical Sciences (NIGMS)

Email: paul.sammak@nih.gov (<mailto:paul.sammak@nih.gov>)

Miles Fabian, Ph.D.

Division of Pharmacology, Physiology, and Biological Chemistry

National Institute of General Medical Sciences (NIGMS)

Email: fabianm@nigms.nih.gov (<mailto:fabianm@nigms.nih.gov>)

D. Craig Hopp, Ph.D.

Division of Extramural Research

National Center for Complementary and Integrative Health (NCCIH)

Email: hoppdc@mail.nih.gov (<mailto:hoppdc@mail.nih.gov>)

Peer Review Contact(s)

Examine your eRA Commons account for review assignment and contact information (information appears two weeks after the submission due date).

Financial/Grants Management Contact(s)

Jennifer Billington

National Institute of General Medical Sciences (NIGMS)

Email: billingj@mail.nih.gov (<mailto:billingj@mail.nih.gov>)

Shelley Carow

National Center for Complementary and Integrative Health (NCCIH)

Email: scarow@mail.nih.gov (<mailto:scarow@mail.nih.gov>)

Section VIII. Other Information

Recently issued trans-NIH [policy notices](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11163) (https://grants.nih.gov/grants/guide/url_redirect.htm?id=11163) may affect your application submission. A full list of policy notices published by NIH is provided in the [NIH Guide for Grants and Contracts](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11164) (https://grants.nih.gov/grants/guide/url_redirect.htm?id=11164). All awards are subject to the terms and conditions, cost principles, and other considerations described in the [NIH Grants Policy Statement](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11120) (https://grants.nih.gov/grants/guide/url_redirect.htm?id=11120).

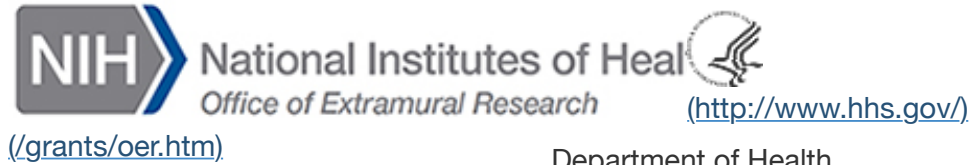
Authority and Regulations

Awards are made under the authorization of Sections 301 and 405 of the Public Health Service Act as amended

(42 USC 241 and 284) and under Federal Regulations 42 CFR Part 52 and 45 CFR Part 75.

[Weekly TOC for this Announcement \(/grants/guide/WeeklyIndex.cfm?04-12-19\)](/grants/guide/WeeklyIndex.cfm?04-12-19)

[NIH Funding Opportunities and Notices \(/grants/guide/index.html\)](/grants/guide/index.html)



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