

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	<p>National Institute of Biomedical Imaging and Bioengineering (NIBIB (http://www.nibib.nih.gov))</p> <p>National Institute on Aging (NIA (http://www.nia.nih.gov))</p> <p>National Institute on Alcohol Abuse and Alcoholism (NIAAA (http://www.niaaa.nih.gov))</p> <p>National Institute of Environmental Health Sciences (NIEHS (http://www.niehs.nih.gov))</p>
Funding Opportunity Title	Bioengineering Research Partnerships (U01 Clinical Trial Not Allowed)
Activity Code	U01 (//grants.nih.gov/grants/funding/ac_search_results.htm?text_curr=u01&Search.x=0&Search.y=0&Search_Type=Activity) Research Project – Cooperative Agreements
Announcement Type	Reissue of PAR-18-208 (https://grants.nih.gov/grants/guide/pa-files/PAR-18-208.html)
Related Notices	<ul style="list-style-type: none"> • NOT-EB-18-028 (https://grants.nih.gov/grants/guide/notice-files/NOT-EB-18-028.html) • January 8, 2019 - Notice of NIAID's Participation in PAR-19-156. See Notice NOT-AI-19-031 (//grants/guide/notice-files/NOT-AI-19-031.html).
Funding Opportunity Announcement (FOA) Number	PAR-19-156
Companion Funding Opportunity	PAR-19-157 (https://grants.nih.gov/grants/guide/pa-files/PAR-19-157.html) , U01 (//grants.nih.gov/grants/funding/ac_search_results.htm?text_curr=u01&Search.x=0&Search.y=0&Search_Type=Activity) Research Project – Cooperative Agreements

Number of Applications	See Section III. 3. Additional Information on Eligibility .
Catalog of Federal Domestic Assistance (CFDA) Number(s)	93.286, 93.113, 93.273, 93.866
Funding Opportunity Purpose	This Funding Opportunity Announcement (FOA) encourages bioengineering applications that will accelerate the development and adoption of promising tools and technologies that can address important biomedical problems. The objectives are to establish these tools and technologies as robust, well-characterized solutions that fulfill an unmet need and are capable of enhancing our understanding of life science processes or the practice of medicine. Awards will focus on supporting multidisciplinary teams that apply an integrative, quantitative bioengineering approach to developing technologies, and engage biomedical researchers or clinicians throughout the project. The goal of the program is to support projects that can realize meaningful solutions within 5 – 10 years.

Key Dates

Posted Date	January 8, 2019
Open Date (Earliest Submission Date)	January 8, 2019
Letter of Intent Due Date(s)	30 days prior to the application due date
Application Due Date(s)	<p>Standard dates (//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.</p> <p>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.</p>
AIDS Application Due Date(s)	<p>Standard AIDS dates (//grants.nih.gov/grants/guide/url_redirect.htm?id=11112) apply, by 5:00 PM local time of applicant organization. All types of AIDS and AIDS-related applications allowed for this funding opportunity announcement are due on these dates.</p>

The first AIDS application due date for this FOA is May 7, 2019.

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.

Scientific Merit Review

[Standard dates \(//grants.nih.gov/grants/guide/url_redirect.htm?id=11113\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11113)
(<http://grants1.nih.gov/grants/funding/submissionschedule.htm#reviewandawa>)
apply

Advisory Council Review

[Standard dates \(//grants.nih.gov/grants/guide/url_redirect.htm?id=11113\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11113)
(<http://grants1.nih.gov/grants/funding/submissionschedule.htm#reviewandawa>)
apply

Earliest Start Date

[Standard dates \(//grants.nih.gov/grants/guide/url_redirect.htm?id=11113\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11113)
apply

Expiration Date

January 8, 2022

Due Dates for E.O. 12372

Not Applicable

Required Application Instructions

It is critical that applicants follow the Research (R) Instructions in the [SF424 \(R&R\) Application Guide \(//grants.nih.gov/grants/guide/url_redirect.htm?id=12000\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=12000), except where instructed to do otherwise (in this FOA or in a Notice from the [NIH Guide for Grants and Contracts \(//grants.nih.gov/grants/guide/\)](http://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 \(http://www.grants.gov/web/grants/applicants/download-application-package.html#search=true&oppNum=PAR-19-156\)](http://www.grants.gov/web/grants/applicants/download-application-package.html#search=true&oppNum=PAR-19-156) 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.

Table of Contents

[Part 1. Overview Information](#)

[Part 2. Full Text of the Announcement](#)

[Section I. Funding Opportunity Description](#)

[Section II. Award Information](#)

[Section III. Eligibility Information](#)

[Section IV. Application and Submission Information](#)

[Section V. Application Review Information](#)

[Section VI. Award Administration Information](#)

[Section VII. Agency Contacts](#)

[Section VIII. Other Information](#)

Part 2. Full Text of Announcement

Section I. Funding Opportunity Description

Purpose

The goal of a Bioengineering Research Partnership (BRP) is to drive the development and speed the adoption of promising tools and technologies that can address important biomedical problems for which insufficient or no solutions exist. The use of engineering principles is encouraged to establish these tools and technologies as robust, well-characterized solutions that fulfill an unmet need. A synergistic partnership between engineering and the life, physical, and computational sciences is also encouraged, where the unique skills of each discipline combine to enhance our understanding of life science processes or the practice of medicine.

The purpose of this FOA is to encourage BRP applications that: 1) establish a robust engineering solution to a problem in biomedical research or the practice of medicine; 2) develop a strategic alliance of multidisciplinary partners based on a well-defined leadership plan; and 3) realize a specific endpoint within 5-10 years based on a detailed plan with a timeline and quantitative milestones.

Background

For many years, the NIH has recognized that the application of principles and techniques from physics, mathematics, chemistry, computer sciences, and engineering can be used to solve significant biomedical problems, leading in turn to new understanding of biological processes, novel products, and innovative tools to improve health. To address this, three distinct program announcements, the BRP, the Bioengineering Research Grant (BRG), and the Exploratory/Developmental Bioengineering Research Grant (EBRG), encourage and support the use of bioengineering and other physical scientific methods to solve problems in biological and biomedical research and clinical practice. These three announcements cover the spectrum of activity, from earliest stage (EBRG) to development of collaborative projects (BRG) to a team-partnership structure with a

specific timeframe and milestones (BRP). To facilitate a multidisciplinary approach, these announcements include review criteria that emphasize ways in which a project may incorporate bioengineering principles to drive new understanding or changes in clinical practice.

Objectives

The primary objective of this FOA is to encourage basic, applied, or clinical bioengineering solutions to unmet needs in biological or biomedical research and clinical practice that can enhance the capabilities of end-users to improve our understanding of life science processes or the practice of medicine within 5 – 10 years. A BRP may bring together new or existing technologies to form creative solutions that have the potential to be widely adopted and improve human health. To deliver practical solutions within this timeframe, applicants are encouraged to use a design-directed research strategy with well-defined end goal(s) and intermediate, quantitative milestones. Goals may include, but are not limited to, establishing proof of concept, pre-commercial prototype production, licensure, release of software packages, designs or models, demonstrating the biological effectiveness of engineered constructs, elucidating the structural and functional relevance of biomolecules or tissues, first-in-human testing, or starting the investigational device exemption or investigational new drug process.

A second key objective is to encourage collaborations and partnerships among allied quantitative and biomedical disciplines. The value of strategic partnerships is well supported by the literature of both economics and science and technology policy, which documents greater success at research and development by groups that work in strategic alliances, often involving multiple institutions, compared to those working separately. In addition to the benefits to be derived from the research, the collaborations and partnerships can create opportunities for trans-disciplinary communication and training of a new generation of scientists who are capable of interacting across traditional technical boundaries. A Partnership typically consists of two to six partners from multiple institutions or multiple departments from the same institution, with each partner bringing critical strengths to the project. The team may require experience in technology development, appropriate model systems for validation, human factors research, regulatory approval, project management or commercialization to realize and disseminate a robust solution. Potential beneficiaries should be active participants in the partnership from the beginning, to provide assurance that proposed solutions will meet community needs. Partnerships with companies that have relevant expertise or may eventually engage in future commercialization or with organizations that can test and disseminate technologies are encouraged under the BRP program. Each PD/PI or collaborator is expected to provide substantive contributions to the intellectual or technical aspects of the project, and should be clearly differentiated from team members who supply necessary but not unique components or services.

Scope of the Program

Funding may be requested to develop, adapt, enhance, optimize, validate, or otherwise accelerate the adoption of promising bioengineering solutions, but not for support of commercial production or later stage (Phase II or Phase III) clinical trials. The approach used does not necessarily need to be extremely novel and may be based on integrating or scaling up existing technologies in untested ways. Overall impact of these new capabilities may include but is not limited to reducing disparities in care, providing new insight into basic biological processes, promoting wellness and independent living, engineering integrated biological and physical systems, increasing access to and usability of technologies to improve quality of life, reducing cost and complexity of high-demand tools, or increasing throughput sensitivity and specificity of laboratory and clinical studies. Innovation for this program is based on a coherent plan to deliver emerging or new capabilities to end users, including through combination of proven approaches and recognizing their resources, workflow, and skills.

Developing a technology is expected to require innovation, but novelty in and of itself is not a requirement. For this FOA, it is innovative to deliver a new capability to solve an unmet need. Innovation in this case is heightened by a technology that can be easily adopted into routine practice and will give users, for example biomedical researchers, healthcare professionals, or citizens, new understanding, or will change health care practice.

Projects must clearly serve the mission of one or more of the NIH Institutes or Centers (ICs) participating in this FOA. Investigators are strongly encouraged to contact the Scientific/Research contacts identified in this FOA for individual IC policies, as well as feedback on the scope and relevance of the proposed project and guidance on the development of appropriate goals and milestones. Those investigators seeking to establish proof of concept are encouraged to respond to the EBRG FOA (PA-18-286). Investigators proposing smaller team projects, tackling problems that cannot be addressed within 5 – 10 years, or that have open-ended aims, are encouraged to respond to the BRG FOA (PAR-18-206).

Institute statements of interest:

The mission of the National Institute of Biomedical Imaging and Bioengineering ([NIBIB \(https://www.nibib.nih.gov/\)](https://www.nibib.nih.gov/)) is to improve health by leading the development and accelerating the application of biomedical technologies. The Institute is committed to integrating engineering with the physical and life sciences to advance basic research and medical care. One way that this is achieved is through the support of research and development of new biomedical imaging and bioengineering tools and technologies to improve the prevention, detection, treatment, and monitoring of disease. NIBIB scientific program areas that are appropriate for the BRP mechanism can be found at <http://www.nibib.nih.gov/Research/ProgramAreas> (<http://www.nibib.nih.gov/Research/ProgramAreas>). NIBIB supports research from early stage technology development through first in human demonstrations and early feasibility clinical studies.

Prior to funding an application, NIBIB program staff will contact the applicant to discuss the proposed timeline and go-no go milestones and any changes suggested by the review panel or program staff. A final timeline and approved milestones will be specified in the Notice of Award. Progress toward achieving the milestones will be evaluated by NIBIB program staff. If a funded project does not meet the milestones, funding for the project may be discontinued.

The mission of the National Institute on Alcohol Abuse and Alcoholism ([NIAAA \(https://www.niaaa.nih.gov/\)](https://www.niaaa.nih.gov/)) is to conduct and support biomedical and behavioral research with respect to the prevention of alcohol abuse and the treatment of alcoholism and alcohol related health effects. Development of research or clinical tools that advance the understanding of fundamental cell and molecular biological mechanism of the deleterious effects of alcohol is encouraged. Of particular interest is the development of a discreet, accurate, wearable alcohol biosensor to support NIAAA's mission in the arenas of research, treatment, and rehabilitation.

The mission of the [NIEHS \(https://www.niehs.nih.gov/index.cfm\)](https://www.niehs.nih.gov/index.cfm) is to discover the role of environmental influences in order to promote healthier lives. For the purposes of this FOA, NIEHS has particular interest in exploration of bioengineering concepts and biomaterials, stem cells, iPSCs, and Tissue Chip technologies that can lead to preventive strategies. Illustrative projects include, but are not limited to: technologies leading to identification and monitoring of early biomarkers for health and disease; high-throughput assays to determine genome integrity or DNA repair capacity in individuals and human populations; systems such as Tissue Chips that allow improved measure of the effects of chemical exposure or stressors on stem cells; in vivo or in situ tools that act as reporters of exposure – response in living organisms and can be applied to people; tools to improve determination of exposure – response and clarify the resulting short or long term physiological

consequences.

National Institute on Aging (NIA (<https://www.nia.nih.gov/>)):

NIA is interested in applying bioengineering approaches to studies of brain aging and Alzheimer's Disease and AD-Related Dementias (AD/ADRD). As described in the AD/ADRD Research Implementation Milestones based on recommendations from the NIH AD/ADRD Research Summits, NIA is interested in supporting research aimed at enabling technologies and AD/ADRD monitoring. This includes studies of wearable technologies, high frequency data capture platforms to enable continuous monitoring of research participants, and technologies for monitoring individuals at all stages of AD/ADRD progression. NIA is also interested in supporting research on standardized diagnostic screening of MCI and dementia, practical applications of innovative technologies to support people living with AD/ADRD (telemedicine GPS, robotics, and social networking), biosensors and prosthetic devices to aid age-related cognitive decline, new technologies for sleep disorders in older persons, improved imaging technology to visualize neural activity during cognitive behavior in older adults, and development of high-throughput measuring and monitoring of neural function in 3D or organoid cultures of human brain cells.

NIA is also interested in potential applications of imaging technologies to the biology of aging. Specifically, NIA seeks to promote imaging of any of the pillars or hallmarks of aging which include protein homeostasis, nuclear and DNA integrity, metabolism and mitochondrial quality control, cellular senescence, autophagy and cell death, and other major hallmarks as described in the literature. More specifically, NIA is interested in applications that compare unperturbed to altered aging, where the former is represented by the unaltered common laboratory animal in with standard animal husbandry, and the later may include any of the numerous pharmacological, genetic, dietary and exercise interventions or other experimental paradigms that alter the apparent rate of aging (measured by lifespan or healthspan or aging phenotypes (such as repair-after-injury, resilience, aging-dependent changes in cellular composition or cellular integration in organs, etc.)). This may also be considered in the context of human populations, where possible, with a special interest in health disparities, comparisons among groups within the human population covering a range of multi-morbidities, the known progeroid syndromes or existing well-controlled study cohorts where there are rigorous data on health and behaviors. NIA is also interested in the application of imaging of aging to test whether short-term manipulations can be effective surrogates for longer-term studies of aging (e.g., acute versus chronic low-level stressors).

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

Section II. Award Information

Funding Instrument

Cooperative Agreement: A support mechanism used when there will be substantial Federal scientific or programmatic involvement. Substantial involvement means that, after award, NIH scientific or program staff will assist, guide, coordinate, or participate in project activities. See Section VI.2 for additional information about the substantial involvement for this FOA.

Application Types Allowed

New
Renewal
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 not limited but need to reflect the actual needs of the proposed project.

Award Project Period

The scope of the proposed project should determine the project period. The maximum project period is 5 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

- o Public/State Controlled Institutions of Higher Education
- o 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:

- o Hispanic-serving Institutions
- o Historically Black Colleges and Universities (HBCUs)
- o Tribally Controlled Colleges and Universities (TCCUs)
- o Alaska Native and Native Hawaiian Serving Institutions
- o 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
- Non-domestic (non-U.S.) Entities (Foreign Institutions)

Foreign Institutions

Non-domestic (non-U.S.) Entities (Foreign Institutions) **are** eligible to apply.

Non-domestic (non-U.S.) components of U.S. Organizations **are** eligible to apply.

Foreign components, as [defined in the NIH Grants Policy Statement](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-039.html) ([//grants.nih.gov/grants/guide/url_redirect.htm?id=11118](https://grants.nih.gov/grants/guide/url_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](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-039.html) ([//grants.nih.gov/grants/guide/notice-files/NOT-OD-15-039.html](https://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](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11176) ([//grants.nih.gov/grants/guide/url_redirect.htm?id=11176](https://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](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)) - 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](https://grants.nih.gov/grants/guide/url_redirect.htm?id=82300) ([//grants.nih.gov/grants/guide/url_redirect.htm?id=82300](https://grants.nih.gov/grants/guide/url_redirect.htm?id=82300)) – 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 Research (R) Instructions in the [SF424 \(R&R\) Application Guide](http://grants.nih.gov/grants/guide/url_redirect.htm?id=12000) ([//grants.nih.gov/grants/guide/url_redirect.htm?id=12000](http://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](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11133) ([//grants.nih.gov/grants/guide/url_redirect.htm?id=11133](http://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.

Other Attachments: Applicants are required to include a Leadership Plan. For applications that do not utilize Multiple PDs/PIs, this item must be uploaded as a separate attachment in pdf format with a filename that corresponds to the item

(Leadership Plan). For Multiple PD/PI applications, the Leadership Plan should be uploaded using the Multiple PD/PI Leadership Plan attachment on the PHS 398 Research Plan form. Applications lacking this required item will be deemed incomplete and will not be reviewed. The Leadership Plan is limited to 6 pages.

Leadership Plan: As part of the Leadership Plan, applicants are encouraged to build collaborations and partnerships among allied quantitative and biomedical disciplines. An organizational structure that clearly defines the partnership and relationships among the various components must be described in the Leadership Plan and illustrated in an organizational chart. This plan should also describe the governance and organizational structure of the leadership team and the research project, including communication plans, processes for making decisions on scientific direction, intellectual property, and procedures for resolving conflicts. The roles and administrative, technical, and scientific responsibilities for the project or program should be delineated for the PDs/PIs and other collaborators. For publications, policies to address the ordering and recognition of authors, and decisions about what material to publish, consistent with the interests of

commercial partners (where applicable) should be presented. Under terms and procedures to be defined in the Leadership Plan, the partnership has the responsibility and authority to use BRP funds in the most productive way to achieve the goals defined at the time that the award is made. To accomplish these tasks, the PDs/PIs can adjust funding among BRP participants to support new partners or to reduce support to existing partners as needed. Plans for enhancing the abilities and opportunities for investigators to work across disciplinary boundaries should also be included.

SF424(R&R) Senior/Key Person Profile

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

Biographical Sketch. Indicate experience in project management as well as assessing and meeting stakeholder needs

R&R or 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: The problems to be addressed and the timeliness and appropriateness of the solution must be stated concisely. Key milestones, uniqueness of the team, and the expected outcomes of the project, if successful, should be described succinctly.

Research Strategy: As part of the Research Strategy, applicants are asked to address the following points:

Note for Applications Proposing the involvement of Human Subjects: Use the Research Strategy section to discuss the overall strategy, methodology, and analyses of your proposed research, but do not duplicate information collected in the PHS Human Subjects and Clinical Trial Information form. The PHS Human Subjects and Clinical Trial Information form will capture detailed study information, including eligibility criteria; inclusion of women, minorities, and children; protection and monitoring plans; and statistical design and power. You are encouraged to refer to information in the PHS Human Subjects and Clinical Trial Information form as appropriate in your discussion of the Research Strategy (e.g., see Section 2.4 Inclusion of Women, Minorities, and Children).

Significance: Briefly describe the area of bioengineering research that is the focus of the BRP. Explain why a multidisciplinary approach is needed to realize a solution. Explain how the proposed project will improve scientific knowledge, technical capability, and/or clinical practice by providing new capabilities to users. Critically evaluate existing knowledge and approaches that have been or are being applied in the area and specifically describe how the proposed BRP approach will advance the field.

Innovation: Innovation for this FOA is based on a coherent plan to deliver emerging or new capabilities to end users, including through combinations of proven approaches and recognizing their resources, workflow, and skills. Developing a technology is expected to require innovation, but novelty in and of itself is not a primary

requirement. For the purpose of this FOA it is to deliver a new capability to satisfy an unmet need. Innovation in this case is heightened by a technology that can be easily adopted into routine practice and will give users, such as biomedical researchers, healthcare professionals or citizens, new understanding, or will change healthcare-related practice. Describe any novel advanced system integration.

Approach: Technical feasibility for the approach should be clearly established by preliminary results so that any risks present can be mitigated using engineering and project management principles. Comparison of performance specifications with current practice is expected, such as sensitivity, specificity, reproducibility, reliability, portability, throughput, operability by biological researchers or healthcare workers, potential research or clinical utility and cost of acquisition and operation as applicable. An integrative systems approach or a design-driven approach and their appropriateness for the proposed project should be described, including plans for collecting, analyzing, interpreting, and archiving data. Details for making the performance of technologies sufficiently selective, sensitive, or otherwise appropriate for the identified problem should be supported with quantitative benchmarks. Potential technical challenges and possible alternative approaches to achieve the aims of the project should be discussed. If the proposed BRP research is closely related to ongoing research, explain how the research activities of the BRP will complement but not overlap with the existing research. The robustness and reproducibility of preliminary results should be described along with independent validation or replication of results if available. Alternative interpretations of preliminary data, including relevant literature in support or disagreement with the results, should be described. For projects that pursue feasibility in humans, the approach should describe contact with appropriate regulatory bodies and milestones for achieving regulatory approval.

Project Milestones and Timeline: Generate a subsection in the Approach Section that addresses Milestones and a project Timeline. Include quantitative milestones, a schedule of tasks and events including responsible personnel, and/or other evaluative criteria. Projects must identify semi-annual milestones, and provide timelines highlighting dependencies among tasks. For each milestone, provide details on methods, assumptions, experimental designs, and data analysis plans (if applicable). Quantitative criteria for success in the milestones may also be used for making go/no-go decisions and this should be specified. Applicants are encouraged to discuss impediments that could require a revision to the research plan, milestones or timeline, with a discussion of alternative approaches.

Applicants for Renewals should be aware that BRP funding will not be extended past the end of the second funding award and should describe plans for sustaining the project beyond this time.

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, with the following modification:

- All applications, regardless of the amount of direct costs requested for any one year, should address a Data Sharing Plan.
- The plan should include details for sharing raw (unreduced) data with other researchers who may wish to analyze them independently, and include plans for disseminating resources. Investigators are expected to be aware of and abide by all applicable NIH guidance for sharing of research resources and data, consistent with existing laws, regulations, and policies. Please see https://grants.nih.gov/grants/policy/data_sharing/data_sharing_faqs.htm (https://grants.nih.gov/grants/policy/data_sharing/data_sharing_faqs.htm)
- There is no prescribed sharing approach for software produced by a project. However, reviewers will be asked to comment on the adequacy and effectiveness of plans based on their likely impact. Program staff may negotiate modifications of software sharing plans with the PD/PI before making

recommendations on funding of an application.

- All applications should describe plans for disseminating the techniques and technologies to end-users. The plan should complement the research and development strategy, and may involve partnership with industry, professional organizations, or community engagement.

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 \(https://grants.nih.gov/grants/glossary.htm#DelayedOnsetHumanSubjectStudy\)](https://grants.nih.gov/grants/glossary.htm#DelayedOnsetHumanSubjectStudy) 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.

Foreign Institutions

Foreign (non-U.S.) institutions must follow policies described in the [NIH Grants Policy Statement \(//grants.nih.gov/grants/guide/url_redirect.htm?id=11137\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11137), and procedures for foreign institutions.

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 \(https://grants.nih.gov/grants/guide/url_redirect.htm?id=82380\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=82380), the application deadline is automatically extended to the next business day.

Organizations must submit applications to [Grants.gov \(//grants.nih.gov/grants/guide/url_redirect.htm?id=11128\)](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), 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). (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](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11120) (https://grants.nih.gov/grants/guide/url_redirect.htm?id=11120).

Pre-award costs are allowable only as described in the [NIH Grants Policy Statement](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11143) (https://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](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11146) (https://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, NIH. Applications that are incomplete or non-compliant will not be reviewed.

Requests of \$500,000 or more for direct costs in any year

Applicants requesting \$500,000 or more in direct costs in any year (excluding consortium F&A) must contact a [Scientific/ Research Contact](#) at least 6 weeks before submitting the application and follow the Policy on the Acceptance for Review of Unsolicited Applications that Request \$500,000 or More in Direct Costs as described in the SF424 (R&R) Application Guide.

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](https://grants.nih.gov/grants/guide/url_redirect.htm?id=82299)). Any instructions provided here are in addition to the instructions in the policy.

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](https://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:

Innovation for this FOA is based on a coherent plan to deliver new or emerging capabilities to end users, including through a combination of proven approaches and recognizing their resources, workflow, and skills. Developing a technology to solve an unmet need is expected to require this type of innovation, but novelty in and of itself is not a requirement.

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?

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?

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 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?

Are the BRP engineering, scientific, and clinical approaches and methods adequately developed, well-integrated, and appropriate to the aims of the project? Is the Leadership Plan clear, sound, appropriate, and practical? If partnership with industry or other organization is proposed, does this positively affect the research goals and technology dissemination?

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?

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.

Leadership Plan

Do the organizational structure and leadership plan of the project indicate an ability to meet the proposed goal(s) within 5 – 10 years? Does the information provided suggest an ability to effectively partner and

manage multidisciplinary projects and deal with sensitive but critical go/no-go decisions in a team-based environment?

Milestones and Timeline

Are milestones associated with clear, quantitative criteria for success that allow go/no-go decisions? Are the timelines proposed for achieving the milestones realistic and inclusive of necessary steps? Would achieving all milestones in the application allow the project to achieve the end goals for the project?

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/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/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/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

For Renewals, the committee will consider the progress made in the last funding period.

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

Reviewers will assess whether the project presents special opportunities for furthering research programs through the use of unusual talent, resources, populations, or environmental conditions that exist in other countries and either are not readily available in the United States or augment existing U.S. resources.

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.

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>); and <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>).

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 (FAPIS) requirements. FAPIS requires Federal award making officials to review and consider information about an applicant in the designated integrity and performance system (currently FAPIS) prior to making an award. An applicant, at its option, may review information in the designated integrity and performance systems accessible through FAPIS and comment on any information about itself that a Federal agency previously entered and is currently in FAPIS. The Federal awarding agency will consider any comments by the applicant, in addition to other information in FAPIS, 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.

Cooperative Agreement Terms and Conditions of Award

The following special terms of award are in addition to, and not in lieu of, otherwise applicable OMB administrative guidelines, HHS grant administration regulations at 45 CFR Parts 74 and 92 (Part 92 is applicable when State and local Governments are eligible to apply), and other HHS, PHS, and NIH grant administration policies.

The administrative and funding instrument used for this program will be the cooperative agreement an "assistance" mechanism (rather than an "acquisition" mechanism), in which substantial NIH programmatic involvement with the awardees is anticipated during the performance of the activities. Under the cooperative agreement, the NIH purpose is to support and stimulate the recipients' activities by involvement in and otherwise working jointly with the award recipients in a partnership role; it is not to assume direction, prime responsibility, or a dominant role in the activities. Consistent with this concept, the dominant role and prime responsibility resides with the awardees for the project as a whole, although specific tasks and activities may be shared among the awardees and the NIH as defined below.

The PD(s)/PI(s) will have the primary responsibility for:

The Program Director/Principal Investigator will have the primary responsibility for: defining objectives and approaches, and to plan, conduct, analyze, and publish results, interpretations, and conclusions of their studies. Awardees are responsible for identifying specific, rigorous milestones and objective success criteria, quantitative where appropriate.

Awardees will retain custody of and have primary rights to the data and software developed under these awards, subject to Government rights of access consistent with current HHS, PHS, and NIH policies.

Awardees agree to participate at least once a year in progress meetings that may be called and organized by IC staff.

Awardees are responsible for pursuing patent protection.

Awardees are responsible for providing progress reports that include experimental design, including assumptions that underlie the design of the experiments, the results of the investigations, interpretations of the results, and whether or not milestones have been met or exceeded. In cases when IC staff request raw data, awardees agree to provide those data.

Awardees agree to communicate study reports, meeting minutes, and associated data packages if applicable, letters and other forms of communications with regulatory agencies, and other authorities if applicable.

NIH staff will have substantial programmatic involvement that is above and beyond the normal stewardship role in awards, as described below:

An Institute program officer serving as Project Scientist will have substantial scientific-programmatic involvement during conduct of this activity, through technical assistance, advice and coordination above and beyond the normal program stewardship role in grant awards, as described below. The IC Project Scientist will provide input on the milestones and make decisions regarding their finalization. The program officer will be responsible for technical monitoring of the project, such as approval of changes in experimental approaches, objectives, milestones and timelines; assessing progress against specified milestones and stated project timelines, as well as for recommending if further funds should be released to the project. However, the role of the Project Scientist will be to facilitate and not to direct the activities. It is anticipated that decisions on major changes will be reached by consensus between the PD(s)/PI(s) and the Project Scientist, and that Institute staff will be given the opportunity to offer input into this process. The Project Scientist may provide assistance by

accessing Institute-supported resources and services.

Additionally, an Institute program director will be responsible for the normal scientific and programmatic stewardship of the award and will be named in the award notice.

Areas of Joint Responsibility include:

Clarifying, negotiating and finalizing the milestones and timelines as well as attending any project-specific meetings called by the Project Scientist to discuss and resolve issues that may arise during the project period, which affect project performance and/or progress.

Dispute Resolution:

Any disagreements that may arise in scientific or programmatic matters (within the scope of the award) between award recipients and the NIH may be brought to arbitration. An Arbitration Panel composed of three members will be convened. It will have three members: a designee of the award recipient(s) chosen without NIH staff voting, one NIH designee, and a third designee with expertise in the relevant area who is chosen by the other two; in the case of individual disagreement, the first member may be chosen by the individual awardee. This special arbitration procedure in no way affects the awardee's right to appeal an adverse action that is otherwise appealable in accordance with PHS regulations 42 CFR Part 50, Subpart D and HHS regulations 45 CFR Part 16.

3. Reporting

When multiple years are involved, awardees will be required to submit the [Research Performance Progress Report \(RPPR\) \(//grants.nih.gov/grants/rppr/index.htm\)](https://grants.nih.gov/grants/rppr/index.htm) annually and financial statements as required in the [NIH Grants Policy Statement. \(//grants.nih.gov/grants/guide/url_redirect.htm?id=11161\)](https://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 \(//grants.nih.gov/grants/guide/url_redirect.htm?id=11161\)](https://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.fsr.gov \(//grants.nih.gov/grants/guide/url_redirect.htm?id=11170\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11170) on all subawards over \$25,000. See the [NIH Grants Policy Statement \(//grants.nih.gov/grants/guide/url_redirect.htm?id=11171\)](https://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/> (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>) (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)

NIH scientific contacts listed at the following website should be contacted for answers to questions about scientific issues: <http://www.nibib.nih.gov/research-funding/bioengineering-contacts>
(<http://www.nibib.nih.gov/research-funding/bioengineering-contacts>)

General questions about this funding opportunity announcement can be addressed to:

Šeila Selimovic, Ph.D.

National Institute of Biomedical Imaging and Bioengineering (NIBIB)

Telephone: 301-451-4577

Email: Seila.Selimovic@nih.gov (<mailto:Seila.Selimovic@nih.gov>)

Peer Review Contact(s)

Yuanna Cheng

Center for Scientific Review

Telephone: 301-435-1195

Email: Lyuanna.cheng@nih.gov (<mailto:Lyuanna.cheng@nih.gov>)

Financial/Grants Management Contact(s)

NIH financial contacts listed at the following web site should be contacted for answers to questions about financial issues: <http://www.nibib.nih.gov/Funding/Bioengineering/Contacts>
(<http://www.nibib.nih.gov/Funding/Bioengineering/Contacts>)

Section VIII. Other Information

Recently issued trans-NIH [policy notices](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11163) ([//grants.nih.gov/grants/guide/url_redirect.htm?id=11163](http://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](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11164) ([//grants.nih.gov/grants/guide/url_redirect.htm?id=11164](http://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](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11120) ([//grants.nih.gov/grants/guide/url_redirect.htm?id=11120](http://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](http://grants/guide/WeeklyIndex.cfm?01-11-19) ([/grants/guide/WeeklyIndex.cfm?01-11-19](http://grants/guide/WeeklyIndex.cfm?01-11-19))

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



[\(/grants/oer.htm\)](http://grants/oer.htm)

Department of Health
and Human Services (HHS)



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Note: For help accessing PDF, RTF, MS Word, Excel, PowerPoint, Audio or Video files, see [Help Downloading Files](http://grants/edocs.htm) ([/grants/edocs.htm](http://grants/edocs.htm)).