

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/))
Note: Not all NIH Institutes, Centers, and Offices (ICOs) participate in Announcements. Applicants should carefully note which ICOs participate in this announcement and view their respective areas of research interest at the ICO-Specific Scientific Interests website (https://grants.nih.gov/funding/find-a-fit-for-your-research/nih-institutes-centers-offices) . ICOs that do not participate in this announcement will not consider applications for funding.
Funding Opportunity Title
Biomedical Technology Optimization and Dissemination Center (BTOD) (RM1 - Clinical Trial Not Allowed)
Activity Code
RM1 (http://grants.nih.gov/grants/funding/ac_search_results.htm?text_curr=RM1&Search_Type=Activity&Search.x=0&Search.y=0) Research Project with Complex Structure
Announcement Type
Reissue of PAR-23-110
Related Notices
Check for any recent Notices of NIH Policy Changes (https://grants.nih.gov/grants/guide/url_redirect.php?id=11163) that may impact application requirements.
Funding Opportunity Number (FON)
PAR-27-024
Companion Funding Opportunity
None
Number of Applications
See Section III. 3. Additional Information on Eligibility.
Assistance Listing Number(s)
93.859
Funding Opportunity Purpose
This Notice of Funding Opportunity (NOFO) encourages applications for NIGMS Biomedical Technology Optimization and Dissemination (BTOD) Centers to support late-stage technology optimization and sustainable dissemination of the technologies to the wider biomedical research community. A BTOD Center should be at the leading edge of its field with respect to both technology optimization and engagement with relevant research communities. BTOD projects must address biomedical research areas within the NIGMS mission (https://www.grants.nih.gov/funding/find-a-fit-for-your-research/nih-institutes-centers-offices/NIGMS). Potential applicants are strongly encouraged to consult with NIGMS staff about adherence of their proposed research strategy to the Institute's goals and mission and its responsiveness to this NOFO.
Funding Opportunity Goal(s)
The National Institute of General Medical Sciences (NIGMS) supports basic research that increases our understanding of biological processes and lays the foundation for advances in disease diagnosis, treatment, and prevention. NIGMS also supports research in specific clinical areas that affect multiple organ systems: anesthesiology and peri-operative pain; clinical pharmacology common to multiple drugs and treatments; and injury, critical illness, sepsis, and wound healing. NIGMS-funded scientists investigate how living systems work at a range of levels—from molecules and cells to tissues and organs—in research organisms, humans, and populations. Additionally, to ensure the vitality and continued productivity of the research enterprise, NIGMS provides leadership in supporting the training of future scientists and developing research capacity throughout the country.
Key Dates
Posted Date
June 08, 2026
Open Date (Earliest Submission Date)

Application Due Dates			Review and Award Cycles		
New	Renewal / Resubmission / Revision (as allowed)	AIDS - New/Renewal/Resubmission/Revision, as allowed	Scientific Merit Review	Advisory Council Review	Earliest Start Date
September 29, 2026	September 29, 2026	Not Applicable	March 2027	May 2027	July 2027
January 28, 2027	January 28, 2027	Not Applicable	July 2027	October 2027	December 2027
May 28, 2027	May 28, 2027	Not Applicable	November 2027	January 2028	April 2028
January 28, 2028	January 28, 2028	Not Applicable	July 2028	October 2028	December 2028
May 26, 2028	May 26, 2028	Not Applicable	November 2028	January 2029	April 2029
January 29, 2029	January 29, 2029	Not Applicable	July 2029	October 2029	December 2029

All applications are due by 5:00 PM local time of applicant organization.

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.

Expiration Date

January 30, 2029

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 [How to Apply - Application Guide \(https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400), except where instructed to do otherwise (in this NOFO or in a Notice from [NIH Guide for Grants and Contracts \(http://grants.nih.gov/grants/guide/url_redirect.htm?id=11164\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11164)).

Conformance to all requirements (both in the [How to Apply - Application Guide \(https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400) and the NOFO) is required and strictly enforced. Applicants must read and follow all application instructions in the [How to Apply - Application Guide \(https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400) as well as any program-specific instructions noted in Section IV. When the program-specific instructions deviate from those in the [How to Apply - Application Guide \(https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400), 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 \(https://public.era.nih.gov/assist/public/login.era\)](https://public.era.nih.gov/assist/public/login.era) to prepare, submit and track your application online.
2. Use an institutional system-to-system (S2S) solution to prepare and submit your application to Grants.gov and [eRA Commons \(https://public.era.nih.gov/commons/\)](https://public.era.nih.gov/commons/) to track your application. Check with your institutional officials regarding availability.
3. Use [Grants.gov \(https://grants.gov/search-grants?oppStatuses=closed|archived|posted|forecasted&fon=PA-25-301\)](https://grants.gov/search-grants?oppStatuses=closed|archived|posted|forecasted&fon=PA-25-301) 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. Notice of Funding Opportunity Description

This Notice of Funding Opportunity Announcement (NOFO) encourages applications for support of Biomedical Technology Optimization and Dissemination (BTOD) Centers in any of the basic or clinical research areas within the [NIGMS mission \(https://www.grants.nih.gov/funding/find-a-fit-for-your-research/nih-institutes-centers-offices/NIGMS\)](https://www.grants.nih.gov/funding/find-a-fit-for-your-research/nih-institutes-centers-offices/NIGMS). This program supports optimization of late-stage technologies that have demonstrated laboratory feasibility and dissemination of the optimized technologies to the broad biomedical research community. A BTOD Center may focus on a specific technology, or it may integrate multiple technologies to create a transformative approach to solving a class of research problems.

Background and Overview

The NIGMS technology research and development pipeline supports technology development from its earliest stages to broad dissemination of products to the research community. The Technology Development R21/R01 Program supports early-stage proof of concept and prototype development. The BTOD Center program supports the optimization of late-stage technologies, defined as functional technologies that, while readily employed by investigators with specialized expertise, require further optimization and dissemination for use by the general research community.

Technologies of interest include, but are not limited to: analytical biochemistry and chemical biology tools, high throughput biochemical methods, chemistry, advanced spatial omics, structural biology and imaging methods, molecular biology, cell manipulation, computational methods, and modeling of molecular and biological systems.

BTOD Center Structure

BTOD Centers are comprised of three integrated components: Technology Optimization Projects (TOPs), Driving Biomedical Projects (DBPs), and Community Engagement (CE). The Center optimizes technologies through synergistic collaborations between TOPs and DBPs and disseminates them through CE activities. The latter promote and distribute the technologies to the wider research community using multiple strategies including training, commercialization, and public outreach.

Technology Optimization Projects (TOPs): TOPs are the central focus of the BTOD Center and serve as the foundation for all other Center activities.

TOPs Characteristics:

- *State-of-the-art, late-stage technologies:* The BTOD Centers program supports optimization of specialized and unique technologies that are fully operational in experts' laboratories but are not yet sufficiently robust for broad use by non-experts.
- *NIGMS mission fit:* TOPs should broaden the utility of technologies for mechanistic understanding of fundamental biological processes or for specific clinical areas within the Institute's scientific mission.
- *Synergy:* TOPs may consist of multiple applications of a common underlying technology or complementary technologies supporting a common goal.
- *TOPs should not be solely focused on data collection:* Modest projects designed to generate data for use in technology development or testing may be included as a part of a TOP. Such projects do not substitute for DBPs and should be included only when data to test tools, devices, or software are not available elsewhere.

Technology Partnership Projects (TPPs): BTOD centers have the option to collaborate with industrial partners to accelerate technology optimization over a short time window (1-2 yrs), however, no funds from this project can support the activity.

If applicable, applicants should describe TPPs in the application. TPPs may also be initiated at any time during the grant period at the discretion of the PD(s)/PI(s).

Driving Biomedical Projects (DBPs): DBPs are biomedical research projects that the Center pursues in collaboration with outside investigators to serve as test beds for refinement of its technologies. This collection of projects and their collaboration with TOPs are core components of a BTOD Center and should represent a significant investment of its time and effort.

DBPs Characteristics:

- *NIGMS mission fit:* DBPs should focus on performing mechanistic biological, chemical, physical or related fundamental studies. For Centers focused on technologies related to NIGMS-supported clinical areas (e.g., sepsis, wound healing, etc), DBPs may include translational research to optimize technologies for disease diagnosis or treatment.
- *Dynamic:* To provide new challenging test beds for the TOPs, DBPs should change throughout the award period. A lack of DBP turnover will be considered a negative outcome for Center renewals.
- *Independently funded:* DBPs should, in most cases, stem from ongoing peer reviewed biomedical research projects.
 - DBP investigators should not receive financial support from the Center for ongoing on- or off-site collaborations.
 - Collaborations with resource-limited institutions may be enabled through BTOD Center funds via a subcontract only if such collaborations increase the breadth of research questions addressed by the technology or facilitate dissemination of the technology to a variety of institution types or geographical regions.
- *Broad in scientific scope, geographic, and institutional distribution:* A majority of collaborating DBPs should be external to the award institution. Only in exceptional circumstances with strong scientific justification may the majority of DBPs be at the award institution.
 - DBPs should represent the intended reach of the optimized technologies including scientific scope and research communities in terms of career stage, geography, and institutional type.
 - Centers are strongly encouraged to include investigators from lesser-resourced or Institutional Development Award (IDeA) state institutions.
 - A maximum of 10 DBPs may be included; the number of collaborating DBPs in practice should be tuned to achieve the desired scientific scope, geographic reach and institutional types.
- *DBP/TOP Interactions:* Although each TOP must have a relationship with at least one DBP, it is preferred that each DBP drives more than one TOP and that each TOP interacts with multiple DBPs.

Community Engagement (CE): A BTOD Center should develop a plan to engage with a variety of biomedical research community segments to facilitate adoption of its technologies.

- The CE plan may include engagement with different types of organizations (e.g., research-intensive, undergraduate-focused, community-based) and should include engagement with investigators at different career stages.
- The CE approaches do not need to be novel, and applicants are encouraged to look to currently funded Biomedical Technology Development and Dissemination (BTDD) and BTOD Centers for example activities.
- The Center should commit substantial financial and personnel resources to ensure broad dissemination of optimized technologies and methods beyond the Center's primary research focus.

CE Characteristics:

- *Sustainable Dissemination of Center technologies:* The long-term goal of the Center's dissemination activities is to enable the broad research community to use the technologies independent of the Center itself. Activities can include but are not limited to the following:
 - Publish research articles, books, newsletters, annual reports, or special issues of technical journals; issue press releases; and present research results and Center technologies at scientific conferences; and
 - Host workshops and produce web-based training modules and tutorials.

Acknowledgment of NIGMS grant support and citation of NIGMS grant number are required (see [Communicating and Acknowledging Federal Funding](https://grants.nih.gov/policy-and-compliance/policy-topics/federal-funding) (<https://grants.nih.gov/policy-and-compliance/policy-topics/federal-funding>)).

- *Robust web presence:* A Center should create and maintain a robust website that provides current information about its research focus and capabilities for both researchers and the public. It should promote technology user training activities and provide information about how to contact the Center to establish DBP collaborations.
- *Technology Training for the Scientific Community:* A Center should work to build technical competencies in both experts and non-experts to enable BTOD technology adoption in their own research programs. Examples of training activities include:
 - External investigator consultation with Center staff on DBP suitability for TOPs;
 - On-site, hands-on laboratory experience, or off-site visits by Center personnel;
 - Seminars and lectures at academic institutions or scientific conferences; and
 - Train-the-trainer programs that educate core directors in Center technologies.

Academic courses, research, and training activities that are not available to the biomedical research community external to the Center's institution are not considered community engagement.

- *Clear path toward commercialization:* When applicable, a Center should engage in mechanisms to disseminate technologies through commercialization. Examples may include:
 - Collaborate with vendors or disseminate through creation of new businesses, for example, with assistance of small business (SBIR/STTR) grants;
 - Patent inventions and license technologies to industry; and
 - Provide reagents, tools, and maintenance directly through commercial arrangements.

External Advisory Committee: Each BTOD Center must have an External Advisory Committee (EAC) that meets at least annually and prepares a written report of its recommendations.

- EAC members are appointed by the PD(s)/PI(s) to advise them on future Center directions, particularly in setting priorities for the Center.
- EAC membership should be rotated periodically. The committee chair should be knowledgeable of the Center's technologies and the science it serves but should not be a member of the Center staff or a DBP or TPP collaborator.
- Other committee memberships should be distributed among scientists with knowledge of the Center's technologies, experts in its application to biomedical research problems, and Center technology users.
- DBP PI membership in the EAC is not prohibited but should constitute a minority of members.
- Members should represent a balance of perspectives, and at least one member should be from a lesser-resourced institution, IDeA state, or Primarily Undergraduate Institution (PUI).

Center Expectations

- BTOD Centers describing specialized technologies that would only be useful for small communities of researchers will not be supported by this funding opportunity.
- Applications that propose transitioning from a previously funded P41 Biomedical Technology Research and Resource (BTRR) award to a BTOD Center should focus on optimizing late-stage technologies for their broad utility and dissemination in a self-sustaining fashion.
- A BTOD Center will be supported for a maximum of 15 years, inclusive of previously funded years through the BTRR or BTDD programs. An application for a new BTOD Center that would extend NIGMS support for an existing center beyond 15 years should not simply propose a change in PD/PI. Rather, the application must include a substantial change in the focus of technology optimization efforts.
- BTOD Centers are not intended to be user facilities. NIGMS supports user resources for community access to state of the art, mature technologies through the National and Regional Resource (R24), the Mature Synchrotron Resources for Structural Biology (P30), (<https://nigms.nih.gov/grants/Pages/Mature-Synchrotron-Resources>), and the National Centers for Cryoelectron Microscopy (R24) programs.
- Incorporation of students, postdoctoral fellows and other trainees in Center operations requires an institutional letter describing how these activities are integral to their overall training goals.

Prior Consultation with Institute Staff

- Potential applicants are strongly encouraged to consult with NIGMS staff at least 8 weeks prior to the application due date about alignment of the proposed research strategy with the goals and mission of the Institute.
- Institute staff will not evaluate the technical and scientific merits of the proposed program in advance; technical and scientific merit will be determined during peer review using the review criteria described in this NOFO.
- During the consultation phase, if the proposed research strategy does not include the necessary components, meet NIGMS programmatic needs, or is not appropriate as a BTOD Center for other reasons, applicants will be advised to consider other funding opportunities.

Non-Responsiveness Criteria

The following types of BTOD Center applications are non-responsive to this NOFO and will not be reviewed:

- Those that optimize and disseminate technologies primarily for translational or clinical research communities outside the scope of NIGMS-supported clinical areas.
- Those that propose user access to mature technologies.

Applications that propose technologies of limited utility to the biomedical research community will be low priority for funding.

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

Section II. Award Information

Funding Instrument

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

Application Types Allowed

New
Renewal
Revision

The [OER Glossary \(http://grants.nih.gov/grants/guide/url_redirect.htm?id=11116\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11116) and the [How to Apply - Application Guide \(https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400) provide details on these application types. Only those application types listed here are allowed for this NOFO.

Clinical Trial?

Not Allowed: Only accepting applications that do not propose clinical trials. Note: Applications may propose activities involving human subjects that are not deemed 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 number of meritorious applications.

Award Budget

The maximum budget that may be requested is \$850,000 in direct costs per year, excluding equipment and consortium F&A costs. Applications requesting more than this amount will not be reviewed. Because of the technology-intensive nature of these Centers, there may be a need to acquire specialized equipment. Equipment requests are expected to vary with the nature of the technology optimization projects proposed. Funds for such specialized equipment may be requested in excess of the \$850,000 operating limit but should be well justified.

Award Project Period

The scope of the proposed project should determine the project period. The maximum project period is 5 years. NIGMS will not support a BTOD Center for more than 15 total years (2 renewals), including support for previous P41 BTRR and RM1 BTDD Centers.

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

Section III. Eligibility Information

1. Eligible Applicants

Eligible Organizations

Higher Education Institutions - Includes all types

- Public/State Controlled Institutions of Higher Education
- Private Institutions of Higher Education

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)

Local 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)

Federal Governments

- 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 Organizations/Foreign Collaborations

Non-domestic (non-U.S.) Entities (Foreign Organizations) **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 \(http://grants.nih.gov/grants/guide/url_redirect.htm?id=11118\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11118), **are** allowed.

NIH will no longer issue awards (i.e., new, renewal, or non-competing continuation) to domestic or foreign entities that involve foreign subawards/subcontracts. All NIH-funded research involving foreign subawards/subcontracts must be submitted in response to a NOFO that is specifically designated for funded international collaborations. See [NIH Grants Policy Statement 16.8 Collaborative International Research Awards \(https://grants.nih.gov/grants/policy/nihgps/HTML5/section_16/16.8_collab_int_res_awards.htm\)](https://grants.nih.gov/grants/policy/nihgps/HTML5/section_16/16.8_collab_int_res_awards.htm).

Applications involving foreign subawards/subcontracts submitted in response to this NOFO will be deemed noncompliant and will not be considered for funding. This policy applies to all monetary international collaborations resulting in foreign subawards/subcontracts, however, it does not preclude unfunded international collaborations or [foreign components \(https://grants.nih.gov/grants/policy/nihgps/HTML5/section_1/1.2_definition_of_terms.htm\)](https://grants.nih.gov/grants/policy/nihgps/HTML5/section_1/1.2_definition_of_terms.htm), funding for foreign consultants, or procurement of unique equipment or supplies from foreign vendors.

Required Registrations

Applicant Organizations

Applicant organizations must complete and maintain the following registrations as described in the [How to Apply - Application Guide \(https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400) 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. Failure to complete registrations in advance of a due date is not a valid reason for a late submission, please reference [NIH Grants Policy Statement Section 2.3.9.2 Electronically Submitted Applications \(http://grants.nih.gov/grants/guide/url_redirect.htm?id=82423\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=82423) for additional information

- [System for Award Management \(SAM\) \(https://grants.nih.gov/grants/guide/url_redirect.htm?id=82390\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=82390) – 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. Foreign organizations must obtain a [NATO Commercial and Government Entity \(NCAGE\) Code \(http://grants.nih.gov/grants/guide/url_redirect.htm?id=11176\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11176) (in lieu of a CAGE code) in order to register in SAM.

- Unique Entity Identifier (UEI)- A UEI is issued as part of the SAM.gov registration process. The same UEI must be used for all registrations, as well as on the grant application.
- [eRA Commons \(https://grants.nih.gov/grants/guide/url_redirect.htm?id=11123\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11123) - Once the unique organization identifier is established, organizations can register with eRA Commons in tandem with completing their Grants.gov registrations; 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 \(http://grants.nih.gov/grants/guide/url_redirect.htm?id=82300\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=82300) – Applicants must have an active 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.

All PD(s)/PI(s) must be registered with [ORCID \(https://orcid.org/\)](https://orcid.org/). The personal profile associated with the PD(s)/PI(s) eRA Commons account must be linked to a valid ORCID ID. For more information on linking an ORCID ID to an eRA Commons personal profile see the [ORCID topic in our eRA Commons online help \(https://era.nih.gov/erahelp/Commons/default.htm#orcid.htm%3FTocPath%3D29\)](https://era.nih.gov/erahelp/Commons/default.htm#orcid.htm%3FTocPath%3D29).

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 their organization to develop an application for 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 [How to Apply - Application Guide \(https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400).

PD(s)/PI(s) must each provide a minimum of 3 person months effort to the Center project.

PDs/PIs with a Maximizing Investigators' Research Award (MIRA, Early Stage or Established Investigator) are eligible to apply, but must maintain the minimum required research effort toward their MIRA, and 3 person months effort toward the BTOD Center. While a MIRA can support a PD/PI's laboratory for early-stage technology development, a BTOD Center can only support late-stage technology optimization and dissemination efforts.

2. Cost Sharing

This NOFO does not require cost sharing as defined in the [NIH Grants Policy Statement NIH Grants Policy Statement Section 1.2 Definition of Terms. \(http://grants.nih.gov/grants/guide/url_redirect.htm?id=11126\)](http://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, per [NIH Grants Policy Statement Section 2.3.7.4 Submission of Resubmission Application \(http://grants.nih.gov/grants/guide/url_redirect.htm?id=82415\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=82415). 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 [NIH Grants Policy Statement 2.3.9.4 Similar, Essentially Identical, or Identical Applications \(http://grants.nih.gov/grants/guide/url_redirect.htm?id=82423\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=82423)).

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 NOFO. 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 [How to Apply - Application Guide \(https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400) except where instructed in this notice of funding opportunity to do otherwise (in this NOFO, in a [policy notice \(https://grants.nih.gov/grants/guide/url_redirect.php?id=11163\)](https://grants.nih.gov/grants/guide/url_redirect.php?id=11163), or other notice from [NIH Guide for Grants and Contracts \(https://grants.nih.gov/grants/guide/url_redirect.php?id=11164\)](https://grants.nih.gov/grants/guide/url_redirect.php?id=11164)). Conformance to the requirements in the [How to Apply - Application Guide \(https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400) 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 [How to Apply - Application Guide \(https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400) and the [Table of Page Limits \(https://grants.nih.gov/grants/guide/url_redirect.htm?id=61134\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=61134) must be followed.

The Research Strategy section must consist of the following subsections, with each adhering to the following page limits:

Subsection	Page Limits
Overview	12
Administration and Management	6
Technology Optimization Projects (TOPs) (3 maximum)	12 each
Driving Biomedical Projects (DBPs) (10 maximum)	12 total
Community Engagement (CE)	12 total

Instructions for Application Submission

The following section supplements the instructions found in the [How to Apply – Application Guide \(https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400) and should be used for preparing an application to this NOFO.

SF424(R&R) Cover

All instructions in the [How to Apply - Application Guide \(https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400) must be followed.

SF424(R&R) Project/Performance Site Locations

All instructions in the [How to Apply - Application Guide \(https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400) must be followed.

SF424(R&R) Other Project Information

All instructions in the [How to Apply - Application Guide \(https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400) must be followed.

Facilities & Other Resources: For projects with more than one performance site, provide any plans to mitigate adverse effects of geographic separation of Center activities.

Other Attachments: For renewal applications, applications from existing Centers, or applications transitioning from a BTRR to a BTOD Center, the following attachments are required.

Attachment 1. Title "EAC Report": Include the most recent report as an attachment in this section.

Attachment 2: Title: "Indirectly Supported Publications": List the publications indirectly resulting from Center efforts.

SF424(R&R) Senior/Key Person Profile

All instructions in the [How to Apply - Application Guide \(https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400) must be followed.

Include TOP and CE lead investigators as key personnel.

Biographical Sketch: PD(s)/PI(s) and other key personnel should describe the following in the Personal Statement of the NIH Biographical Sketch Supplement:

- Suitability for their roles in leading Center activities including training experience and accomplishments in collaborative basic research, technology development, and its dissemination.

R&R Budget

All instructions in the [How to Apply - Application Guide \(https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400) must be followed.

- The PD/PI is required to dedicate a minimum of 3 person months effort to the Center. For multi-PD/PI applications, each PD/PI is required to dedicate a minimum of 3 person months effort. Subsection leads for TOPs and CE should be identified and provide a minimum of 1 person month effort to the project.
- In the budget justification, provide names (if available), person months effort, and the role on the project for all contributing personnel. Total effort for each person cannot exceed 100%. If effort proposed is greater than support requested, then this should be noted.
- Equipment may be requested. A justification should be supplied for the equipment requested for the Center and organized by project usage (indicate which TOP will utilize the equipment). Price quotes should be included for equipment costing more than \$25,000. The budget justification section should include an evaluation of alternative instruments or manufacturers along with a discussion of the proposed procurement plan.
- Funds may be requested in the Consultant Services category for support of EAC member travel expenses for the annual EAC meeting.
- Other than BTOD Center staff salary support, no support may be requested for DBP research that is conducted outside of the BTOD Center (i.e., laboratory work undertaken by any personnel associated with the collaborating laboratories cannot be supported through the BTOD Center grant).
- No funds may be requested to support travel or accommodations for training course registrants.
- Trainee stipends are also not allowed and may not be requested.

R&R Subaward Budget

All instructions in the [How to Apply - Application Guide \(https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400) must be followed.

PHS 398 Cover Page Supplement

All instructions in the [How to Apply - Application Guide \(https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400) must be followed.

PHS 398 Research Plan

All instructions in the [How to Apply - Application Guide \(https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400) must be followed, with the following additional instructions:

Specific Aims: Describe the overall aims of the proposed Center.

Research Strategy: The Research Strategy must consist of the following subsections, in the order listed below, and uploaded as a single PDF attachment. See page limits above.

- Overview
- Administration and Management
- Technology Optimization Projects (TOPs)
- Driving Biomedical Projects (DBPs)
- Community Engagement (CE)

Note: A BTOD Center may not be supported beyond a combined total of 15 years as a BTRR, BTDD, or BTOD if the same technology for optimization and dissemination is proposed. Applicants submitting for the final project period should be aware that BTOD Center funding will not be extended beyond the final project period and should propose a Research Strategy and a sustainable technology dissemination plan that takes this limit into account.

Overview

- Provide an overview of the proposed BTOD Center and describe its long-term goals.
- Describe the current state-of-the-art in the field and the project objectives as they relate to the TOPs, which should significantly advance the field.
- Justify the need for optimizing and disseminating the proposed technologies and explain how these technologies can be broadly applicable across different biomedical research fields.
- Describe how the Center will address the research community's needs in general and how collaborating DBPs will benefit from the existing technologies and resources provided by the Center.
- Describe competing or similar existing technologies and centers. Highlight the proposed Center's unique features.
- As appropriate, outline the Technology Partnership Projects (TPPs) and associated TOPs highlighting their synergy and complementarity.
- Describe plans to ensure geographic and institutional distribution of DBP collaborators and broad geographic reach of technology dissemination. Collaborations are encouraged with institutions in Institutional Development Award (IDeA)-eligible states, Historically Black Colleges and Universities (HBCUs), Tribal Colleges and Universities (TCUs), and Resource Limited Institutions.

- Describe the BTOD Center's CE strategies and explain how those plans will promote widespread and sustainable technological use beyond the Center's lifetime.

Annotated Timeline: Include an annotated timeline that indicates the interconnection between TOPs, DBPs (and TPPs if applicable), and target dates that illustrate the proposed project's milestones.

Existing Center or BTRR transition (if applicable):

- Include a brief summary of progress in the current project period, highlighting progress in technology optimization and dissemination.
- Include relevant metrics for any research products (publications, software, videos, tutorials, etc.) that demonstrate impact through dissemination alone and through collaborative interactions.
- Highlight both commercial and non-commercial dissemination of optimized technologies and tools (reagents, instruments, methods, software).

Administration and Management

Under Administration and Management, include the following sections with headings:

- Organizational Structure and Staff Responsibilities
- Center Operating Procedures
- External Advisory Committee (EAC)
- Technology Dissemination Plan
- Resiliency Plan

Organizational Structure and Staff Responsibilities:

- Outline how the PD(s)/PI(s) will manage the administrative functions of the Center and provide leadership and direction to the key Center components, including directing and coordinating the TOP leaders, overseeing DBP progress and turnover, and overseeing CE activities.
- Describe how the institutional environment will contribute to the probability of the Center success in providing resources (e.g., financial, physical and human resources) and facilitating the TOP, DBP, and CE projects it serves. Describe how Center staff will be organized with respect to the Center components and Administration and Management functions.
- If students or trainees are involved in BTOD Center operations, an institutional letter must be provided that justifies integration of their Center activities with the training goals (See Letters of Support below).

Center Operating Procedures:

- Describe operating procedures and policies planned for the Center.
- Include criteria and mechanisms to: a) review and approve requests to collaborate with the Center through DBPs, b) provide feedback to both successful and unsuccessful applicants, and c) schedule interactions once approved.
- Outline how the Center will ensure that DBP collaborators acknowledge Center support in any resulting publications and adhere to NIH data sharing policies.

External Advisory Committee (EAC):

- Describe the EAC's role in advising on instrument purchases, evaluating the progress of current DBPs (and TPPs, if applicable), reviewing new DBPs for merit and appropriateness, monitoring adherence to approaches, and providing feedback on proposed plans for the BTOD Center renewal (if appropriate).
- If an EAC has not been established, then describe the scientific disciplines of anticipated committee members that will be represented on the EAC and how a variety of expertise, institutions and regions will be represented. Do not name in the application, contact, or appoint potential EAC members prior to completion of the grant submission, review, and funding process.
- Additional advisory committees are allowed. Describe the function and meeting schedule for any local executive committee or other local committee appointed as an adjunct to the EAC to deal with specialized topics.

Technology Dissemination Plan:

- Describe plans for achieving the goal of wide-spread access to and adoption of Center-optimized technologies and related resources beyond the life of the BTOD Center.
- Include metrics for determining the success of these plans. For renewal applications, BTDD or BTOD Centers, provide progress toward achieving these goals.

Resiliency Plan:

- Describe plans for continuing the Center's operations if the PD(s)/PI(s) or other key personnel cannot fulfill their assigned roles.

Technology Optimization Projects (TOPs)

- A maximum of three TOPs may be included.
- Each TOP description should begin on a new page with TOP# followed by a short descriptive title as a heading.
- Immediately after the TOP heading, list the TOP lead investigator(s) and describe the TOP goals.
- List the DBPs associated with the TOP, by number and title.
- The first page of each TOP Research Strategy subsection should describe its Specific Aims.
- Present the Research Strategy in sufficient detail for critical evaluation of the individual TOP's potential impact, technology optimization's quality, and project's role in the overall Center.
- Describe why the TOP is at the forefront of its technological field and how optimization will meet the goal of increasing the technology's impact on biomedical research.
- Address the background and rationale for the TOP, its significance, and methods. Benchmark the technology's performance against existing techniques that address similar research needs.
- Describe plans for technology optimization to realistically enable broad dissemination. As appropriate, relate TOP optimization plans to dissemination plans.
- Present alternative approaches to solving technological problems if the main conceptual thrust(s) should prove infeasible.
- Include plans for prototype and method validation and reagent and biological authentication that ensure the technologies can achieve the intended biological aims.
- For an existing Center or a BTRR transitioning to a BTOD Center, please denote TOPs that are new to this application in bold font.

Include the following under the specific subheadings in the TOP subsection:

- *Technology Partnership Projects:* If one or more TPPs is proposed, explain plans for the TPP and provide supporting evidence that they are dynamic, short-term collaborations that will enable the Center to adopt and incorporate emerging capabilities in rapidly evolving fields.
- *Technology Integration:* Describe the relationship of this TOP to the overall technology optimization program of the BTOD Center. Discuss the complementarity between this TOP and the other proposed TOPs.
- *DBP/TOP Interactions:* Describe how the TOP is responsive to the emerging needs of the biomedical research community. Describe how each associated DBP will serve as a test bed for the TOP. Describe how each DBP, led by an expert or non-expert user, is enabled by the TOP.

Driving Biomedical Projects (DBPs)

All applications must provide the following (suggested page limits provided as guidance): table of proposed DBPs (1 page), summary of DBPs (1 page), and descriptions of a maximum of 10 DBPs (1 page per DBP including references).

Table of Proposed DBPs: Provide a 1-page table of up to 10 DBPs. Format the table to include the following columns:

1. DBP#: (existing BTRRs and BTDD Centers should indicate in a separate column if the DBP proposed is new) and title of the project.
2. TOPs with which the DBP interacts.
3. Name(s) of the primary collaborating investigator(s) for the DBP.
4. Collaborating investigator(s)' institution(s).
5. External funding source and status (end date) of the project, including NIH grant number, where applicable.
6. Human subject and/or vertebrate animal involvement in the project.
7. For existing Centers or BTRR transitions: number of publications that have resulted from the continuing DBP.

Summary of DBPs: Provide a 1-page summary of all DBPs with a succinct description of the overall goals. Provide a description of criteria used for including new DBPs and rotating existing DBPs out of the BTOD Center during the award period.

Descriptions of a maximum of 10 DBPs (1 page per DBP including references). Begin each on a new page with the following information:

- DBP#, title of the project, primary collaborating investigator(s) and institution(s).
- Describe the overarching goal of the DBP and its research aims that are relevant to the BTOD Center application.
- Describe how the DBP will be a test bed to demonstrate, integrate, and refine Center technologies.
- Describe the potential impact of the proposed technology optimization on the DBP, and when appropriate, provide challenges to this DBP and how the TOP(s) will address them.
- Existing Centers: Include a progress report for continuing DBPs.

Community Engagement (CE)

- Describe strategies for engaging the community to promote dissemination and adoption of the Center's technologies.
- Outline plans for obtaining feedback from the research community on how the technology could be further optimized to make it more useful for different research areas and in different settings.
- If applicable, provide plans to mitigate any obstacles to dissemination, promotion, and adoption of developed technologies. For example, if replication of a technology outside the Center is not feasible, state how this might be overcome to make the technology portable through TPPs and industrial partnerships to ensure widespread access.
- Current Centers:
 - Compare the dissemination efforts for the proposed center to those for the current resource or center.
 - For current BTRRs, the proposed CE plans should place a greater emphasis on technology dissemination.
 - Applications from current Centers should detail new CE activities.
 - A progress report on CE activities from the previous project period should be included in this section.

Technology Training for the Scientific Community:

- Describe plans for providing training to the scientific community in the technical capabilities and accomplishments of the BTOD Center technologies and how these tools can be applied to their research problems.
- Describe how successful training activities will enable researchers to fully utilize the technologies and resources optimized by the BTOD Center. Training should be well-thought-out, accessible, and effective, but does not need to be innovative. Individuals who will benefit from training may not be paid a salary nor may the training experience be a requirement for receipt of an academic degree.

Technology Dissemination:

- Provide plans to disseminate the BTOD Center's technologies to both experts and non-experts at a variety of institution types and geographic regions. Approaches can include, but are not limited to, distributing and supporting software products; transferring technologies to other laboratories directly; patenting inventions and licensing technologies to industry, including partnerships with small businesses and support from the SBIR and STTR programs.
- Provide plans for measuring the success of dissemination efforts, including demand for and utilization of resources provided directly by the BTOD Center.
- Centers developing software should emphasize portability, adequate documentation, code efficiency, user-friendliness, availability to the user community, and user support. NIGMS encourages sharing of source code.
 - Although software is not required to be open source, if the Center plans to distribute software using a restrictive license, the application must include a justification.

Website:

Outline plans to maintain an effective and current website and describe how the Center will monitor its impact.

Websites should include:

- The Center's research focus and capabilities
- A section for the general public describing technologies being optimized and how it will benefit biomedical research
- Contact information
- How to apply for DBPs
- How Center collaborators should cite the BTOD Center grant.
- A section on current newsworthy items directed to the general public.
- An image gallery that features data and results generated by the technologies, as applicable.
- Links to online tutorials.
- Availability of software, reagents, and other resources that are accessible to both expert and non-expert users, as applicable.
- Acknowledgment of NIGMS grant support for the BTOD Center.

Multiple PD/PI Leadership Plan: If multiple PD(s)/PI(s) are proposed, describe in general the structural and procedural elements that will ensure their integration and prevent fragmentation of the Center, ensuring that it is not simply a collection of individual projects with a common technological theme. Refer to the Multiple PD/PI (MPI) Leadership Plan for additional details, where details may be fully elaborated.

Letters of Support: Provide a table of contents for Letters of Support. Include the names of signatories and their institutions. Letters expressing institutional support should be presented first. Letters of support from investigators specifically collaborating with Center investigators on any TOP, DBP, or other projects described specifically in the application should be included next. The purpose of collaborative letters of support is to describe the nature of the collaborative relationship, including its scope, and any special circumstances (e.g., materials or technology transfer, or intellectual property agreements). If students or trainees are involved in BTOD Center operations, institutional letters documenting that these activities are integral to their overall training goals must be included. Do not include letters of support from users whose interactions are limited to activities described in the CE component.

Resource Sharing Plan: Individuals are required to comply with the instructions for the Resource Sharing Plans as provided in the [How to Apply - Application Guide \(https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400).

Other Plan(s):

All instructions in the [How to Apply - Application Guide \(https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400) must be followed, with the following additional instructions:

- A Data Management and Sharing Plan (DMS Plan) is required for any NIH-funded or conducted research that will generate scientific data. Applicants must submit the DMS Plan at the time of application using the [NIH DMS Plan Format Page \(https://grants.nih.gov/grants-process/write-application/forms-directory/data-management-and-sharing-plan-format-page\)](https://grants.nih.gov/grants-process/write-application/forms-directory/data-management-and-sharing-plan-format-page). The DMS Plan must address the elements in the structured format. Where the DMS Plan Format Page requires a "Yes or No" response, no additional narrative is allowed. The Data Management and Sharing (DMS) Plan must be provided in the Overall component.

Appendix: Only limited Appendix materials are allowed. Follow all instructions for the Appendix as described in the [How to Apply - Application Guide \(https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400).

- No publications or other material, with the exception of blank questionnaires or blank surveys, may be included in the Appendix.

PHS Human Subjects and Clinical Trials Information

When involving human subjects research, clinical research, and/or NIH-defined clinical trials (and when applicable, clinical trials research experience) follow all instructions for the PHS Human Subjects and Clinical Trials Information form in the [How to Apply - Application Guide \(https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400), 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 [How to Apply - Application Guide \(https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400) must be followed.

Delayed Onset Study

Note: [Delayed onset \(https://grants.nih.gov/grants/glossary.htm#DelayedOnsetStudy\)](https://grants.nih.gov/grants/glossary.htm#DelayedOnsetStudy) does NOT apply to a study that can be described but will not start immediately (i.e., delayed start). All instructions in the [How to Apply - Application Guide \(https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400) must be followed.

PHS Assignment Request Form

All instructions in the [How to Apply - Application Guide \(https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400) must be followed.

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

See Part 2. 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](#) 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 \(https://grants.nih.gov/grants/guide/url_redirect.html?id=82380\)](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 \(http://grants.nih.gov/grants/guide/url_redirect.htm?id=11128\)](http://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 \(http://grants.nih.gov/grants/guide/url_redirect.htm?id=11123\)](http://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 Grants Policy Statement Section 2.3.9.2 Electronically Submitted Applications \(http://grants.nih.gov/grants/guide/url_redirect.htm?id=82423\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=82423).

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 [How to Apply - Application Guide \(https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400).

5. Intergovernmental Review (E.O. 12372)

This initiative is not subject to [intergovernmental review. \(https://grants.nih.gov/grants/policy/nihgps/html5/section_10/10.10.1_executive_orders.htm\)](https://grants.nih.gov/grants/policy/nihgps/html5/section_10/10.10.1_executive_orders.htm)

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 \(http://grants.nih.gov/grants/guide/url_redirect.htm?id=11120\)](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 Section 7.9.1 Selected Items of Cost \(http://grants.nih.gov/grants/guide/url_redirect.htm?id=11143\)](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 [How to Apply - Application Guide \(https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400). 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 \(https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400). 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 form. 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 NOFO for information on registration requirements.

The applicant organization must ensure that the unique entity identifier provided on the application is the same identifier used in the organization's profile in the eRA Commons and for the System for Award Management. Additional information may be found in the [How to Apply - Application Guide \(https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400).

See [more tips \(http://grants.nih.gov/grants/guide/url_redirect.htm?id=11146\)](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 responsiveness by components of participating organizations, NIH. Applications that are incomplete, non-compliant and/or nonresponsive will not be reviewed.

Mandatory Disclosure

Recipients or subrecipients must submit any information related to violations of federal criminal law involving fraud, bribery, or gratuity violations potentially affecting the federal award. See Mandatory Disclosures, [2 CFR 200.113 \(https://www.ecfr.gov/current/title-2/subtitle-A/chapter-II/part-200/subpart-B/section-200.113\)](https://www.ecfr.gov/current/title-2/subtitle-A/chapter-II/part-200/subpart-B/section-200.113), and [NIH Grants Policy Statement Section 4.1.35 \(https://grants.nih.gov/policy-and-compliance/nihgps\)](https://grants.nih.gov/policy-and-compliance/nihgps).

Send written disclosures to the NIH Chief Grants Management Officer listed on the Notice of Award for the IC that funded the award and to the [HHS Office of Inspector Grant Self Disclosure Program \(https://oig.hhs.gov/compliance/self-disclosure-info/hhs-oig-grant-self-disclosure-program/\)](https://oig.hhs.gov/compliance/self-disclosure-info/hhs-oig-grant-self-disclosure-program/) at [grantdisclosures@oig.hhs.gov \(mailto:grantdisclosures@oig.hhs.gov\)](mailto:grantdisclosures@oig.hhs.gov).

Post Submission Materials

Applicants are required to follow the instructions for post-submission materials, as described in [the policy \(http://grants.nih.gov/grants/guide/url_redirect.htm?id=82299\)](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 \(http://grants.nih.gov/grants/guide/url_redirect.htm?id=11149\)](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 objectives of the BTOD Centers program are to: (1) optimize technologies that, while readily employed by investigators with specialized expertise, require further optimization; and (2) disseminate these technologies for use by the biomedical research community. The technologies described in the Technology Optimization Projects (TOPs) should potentially be of broad utility for biomedical research. Their optimization through iterative interactions with the Driving Biomedical Projects (DBPs) should yield technologies that are readily usable by both experts and non-experts. Sustainable dissemination of the optimized technologies through Community Engagement (CE) strategies should eliminate the need for continuous funding of the Center. Therefore, Center support is limited to a total of 15 years, inclusive of previous BTRRs and BTDD Center funding.

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?

Specific to this NOFO:

- To what extent will the proposed Center have national significance and wide geographical reach?

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?

Specific to this NOFO:

- If students and trainees are involved in the Center, are their contributions integral to the overall training goals as described in an institutional letter of support?
- Do the TOP, DBP and CE lead investigators have demonstrated experience in managing collaborative research and technology training? Are they aligned with BTOD mission of technology optimization, testing through collaborative DBPs, and CE training and dissemination activities?
- Is the Resiliency Plan adequate for continued Center operation in the event that PD(s)/PI(s) or key personnel cannot perform their duties?

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?

Specific to this NOFO:

- Do the technology projects enable biomedical research that cannot be accomplished with current technologies? If applicable, relative to existing technologies, will the proposed technology projects significantly advance biomedical research?

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, 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?

Specific to this NOFO:

- Will the proposed plans likely succeed in disseminating Center technologies for adoption by the user community beyond the life of the BTOD Center?
- Are the proposed metrics to evaluate the success of dissemination plans adequate?
- Will DBPs benefit from collaborations with the Center's technologies and resources? Specifically,
 - Will they increase the technologies' utility for the targeted scientific areas and engage researchers with different experience levels?
 - Do they serve as appropriate test beds for the specific associated TOP?
 - Is the TOP applicable to the proposed collaborative DBPs and will it advance the science associated with each?
- Are the proposed Center's milestones achievable in the specified timeline as they relate to the interaction among TOPs, DBPs and TPPs?
- Are criteria for accepting or declining DBP collaborations appropriate? Are plans suitable for providing feedback to successful and unsuccessful applications? Are the plans to rotate DBPs adequate, particularly with respect to recruitment and termination processes?
- For existing Centers or BTRR transition applications, are the described activities and responsibilities of the External Advisory Committee (EAC) appropriate? For new applications, is the described role of the EAC and its proposed composition including its size, breadth, research experience, leadership experience, and length of service appropriate?

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?

Specific to this NOFO:

- For Centers with more than one performance site, are the plans mitigating geographic separation of Center activities reasonable and adequate?

Additional Review Criteria

As applicable for the Center 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.

Technology Optimization Projects (TOPs)

Each TOP will receive merit descriptors (Exceptional, Excellent, Good, Fair or Marginal) based upon the following criteria:

Quality of Research:

- Will successful completion of aims enhance biomedical research or improve technical capabilities of research communities served?
- Are the TOPs at a stage suitable for optimization and dissemination?
- Are suitable strategies included to mitigate technological challenges, thus enhancing the probability of the project's success?
- Are plans for prototype and method validation, including strategies for managing reagents and biological authentication, adequate to ensure success of the proposed biological aims?

Technology Integration:

- Is the overall technology optimization of the BTOD Center a coherent program rather than a collection of individual but related projects?
- Are the TOPs synergistic?

DBP/TOP Interaction:

- Will the proposed DBPs serve as appropriate test beds for the specific associated TOP?
- Is the TOP appropriate for the proposed collaborative DBPs and will it advance the science associated with each?

For existing Center or BTRR transition applications:

- Are new DBPs (in important biomedical fields and from a range of institutions) actively sought to optimize Center technologies for general utility? Are the DBPs effective in leveraging and enhancing the TOP's technological advances? Is there evidence of significant progress in technology optimization and dissemination during the previous project period?

Technology Partnership Projects (if applicable):

- Will plans to incorporate dynamic and short-term collaborations enable the Center to adopt and integrate emerging capabilities in rapidly evolving fields?

Community Engagement

The Community Engagement component will receive merit descriptors (Exceptional, Excellent, Good, Fair or Marginal) based upon the following criteria:

- Are CE plans responsive to community needs? Do the plans use multiple strategies to engage broad segments of the biomedical research community? Are CE plans effective for adoption of Center technologies by both experts and non-experts?

Current Centers:

- Does the Center website provide information that enables the public to understand and appreciate the technologies that it is optimizing?
- Does the Center website provide useful information about its activities to biomedical research community?

For Centers developing software:

- Will software be portable, well documented, efficient, user-friendly, readily available to a broad user community with adequate user support, and, if applicable, open source?

For Center website:

- Are website plans effective in conveying the Center's research focus and capabilities, technologies being developed, the availability of contact information, and how to establish DBP collaborations?
- Are plans to measure website traffic adequate?

Technology Training for the Scientific Community:

- Are plans suitable for providing training to the scientific community on BTOD technologies, including their utility for a breadth of research problems?

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 \(http://grants.nih.gov/grants/guide/url_redirect.htm?id=11175\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11175).

This NOFO only accepts applications that do not propose clinical trials. Note: Applications may propose activities involving human subjects that are not deemed clinical trials.

Inclusion of Human Subjects Policies

When the proposed project involves human subjects and/or NIH-defined clinical research, the committee will evaluate the proposed plans for inclusion. For additional information on review of the Inclusion section, please refer to the [Guidelines for the Review of Inclusion in Clinical Research \(http://grants.nih.gov/grants/guide/url_redirect.htm?id=11174\)](http://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 three points: (1) a complete description of all proposed procedures including the species, strains, ages, sex, and total numbers of animals to be used; (2) justifications that the species is appropriate for the proposed research and why the research goals cannot be accomplished using an alternative non-animal model; and (3) interventions including analgesia, anesthesia, sedation, palliative care, and humane endpoints that will be used to limit any unavoidable discomfort, distress, pain and injury in the conduct of scientifically valuable research. Methods of euthanasia and justification for selected methods, if NOT consistent with the American Veterinary Medical Association (AVMA) Guidelines for the Euthanasia of Animals, is also required but is found in a separate section of the application. For additional information on review of the Vertebrate Animals Section, please refer to the [Worksheet for Review of the Vertebrate Animals Section \(http://grants.nih.gov/grants/guide/url_redirect.htm?id=11150\)](http://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 (as applicable), 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 (as applicable), the committee will consider the progress made in the last funding period.

Revisions

For Revisions (as applicable), 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 Resource Sharing Plan(s) (e.g., [Sharing Model Organisms \(https://sharing.nih.gov/other-sharing-policies/model-organism-sharing-policy#policy-overview\)](https://sharing.nih.gov/other-sharing-policies/model-organism-sharing-policy#policy-overview)) or the rationale for not sharing the resources, is reasonable.

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 \(http://grants.nih.gov/grants/guide/uri_redirect.htm?id=11154\)](http://grants.nih.gov/grants/guide/uri_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 will receive a written critique.

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.

Applications will be assigned to the National Institute of General Medical Sciences (NIGMS). 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 National Advisory General Medical Sciences Council. The following will be considered in making funding decisions, consistent with applicable law:

- Scientific and technical merit of the proposed Center, as determined by scientific peer review;
- Availability of funds;
- Relevance of the proposed Center to program priorities;
- Portfolio balance;
- Geographic and institutional distribution.

NIGMS will give priority to areas of technology development not already supported in current NIGMS-funded Centers.

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 Section 2.5.1. Just-in-Time Procedures \(http://grants.nih.gov/grants/guide/uri_redirect.htm?id=82418\)](http://grants.nih.gov/grants/guide/uri_redirect.htm?id=82418). This request is not a Notice of Award nor should it be construed to be an indicator of possible funding.

Prior to making an award, NIH reviews an applicant's federal award history in SAM.gov to ensure sound business practices. An applicant can review and comment on any information in the Responsibility/Qualification records available in SAM.gov. NIH will consider any comments by the applicant in the Responsibility/Qualification records in SAM.gov to ascertain the applicant's integrity, business ethics, and performance record of managing Federal awards per 2 CFR Part 200.206 "Federal awarding agency review of risk posed by applicants." This provision will apply to all NIH grants and cooperative agreements except fellowships.

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 \(http://grants.nih.gov/grants/guide/uri_redirect.htm?id=11123\)](http://grants.nih.gov/grants/guide/uri_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 Section 2.4.4 Disposition of Applications \(http://grants.nih.gov/grants/guide/uri_redirect.htm?id=82416\)](http://grants.nih.gov/grants/guide/uri_redirect.htm?id=82416).

Section VI. Award Administration Information

1. Award Notices

A Notice of Award (NoA) is the official authorizing document notifying the applicant that an award has been made and that funds may be requested from the designated HHS payment system or office. The NoA is signed by the Grants Management Officer and emailed to the recipient's business official.

In accepting the award, the recipient agrees that any activities under the award are subject to all provisions currently in effect or implemented during the period of the award, other Department regulations and policies in effect at the time of the award, and applicable statutory provisions.

Recipients must comply with any funding restrictions described in [Section IV.6. Funding Restrictions](#). Any pre-award costs incurred before receipt of the NoA are at the applicant's own risk. For more information on the Notice of Award, please refer to the [NIH Grants Policy Statement Section 5. The Notice of Award \(https://grants.nih.gov/grants/policy/nihgps/HTML5/section_5/5_the_notice_of_award.htm\)](https://grants.nih.gov/grants/policy/nihgps/HTML5/section_5/5_the_notice_of_award.htm) and NIH Grants & Funding website, see [Award Process. \(https://grants.nih.gov/grants/pre-award-process.htm#award\)](https://grants.nih.gov/grants/pre-award-process.htm#award)

Institutional Review Board or Independent Ethics Committee Approval: Recipient institutions must ensure that protocols are reviewed by their IRB or IEC. To help ensure the safety of participants enrolled in NIH-funded studies, the recipient must provide NIH copies of documents related to all major changes in the status of ongoing protocols.

2. Administrative and National Policy Requirements

The following Federal wide and HHS-specific policy requirements apply to awards funded through NIH:

- The rules listed at [2 CFR Part 200 \(https://www.ecfr.gov/current/title-2/subtitle-A/chapter-II/part-200\)](https://www.ecfr.gov/current/title-2/subtitle-A/chapter-II/part-200), Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards.
- All NIH grant and cooperative agreement awards include the [NIH Grants Policy Statement \(http://grants.nih.gov/grants/guide/uri_redirect.htm?id=11120\)](http://grants.nih.gov/grants/guide/uri_redirect.htm?id=11120) as part of the terms and conditions in the Notice of Award (NoA). The NoA includes the requirements of this NOFO. For these terms of award, see the [NIH Grants Policy Statement Part II: Terms and Conditions of NIH Grant Awards, Subpart A: General \(https://grants.nih.gov/grants/policy/nihgps/HTML5/part_ii_terms_and_conditions_of_nih_grant_awards.htm\)](https://grants.nih.gov/grants/policy/nihgps/HTML5/part_ii_terms_and_conditions_of_nih_grant_awards.htm) and [Part II: Terms and Conditions of NIH Grant Awards, Subpart B: Terms and Conditions for Specific Types of Grants, Recipients, and Activities \(http://grants.nih.gov/grants/guide/uri_redirect.htm?id=11159\)](http://grants.nih.gov/grants/guide/uri_redirect.htm?id=11159).

All federal statutes and regulations relevant to federal financial assistance, including those highlighted in [NIH Grants Policy Statement Section 4 Public Policy Requirements, Objectives and Other Appropriation Mandates. \(https://grants.nih.gov/grants/policy/nihgps/HTML5/section_4/4_public_policy_requirements_objectives_and_other_appropriation_mandates.htm\)](https://grants.nih.gov/grants/policy/nihgps/HTML5/section_4/4_public_policy_requirements_objectives_and_other_appropriation_mandates.htm)

By applying for or accepting federal funds from HHS, recipients certify compliance with all federal antidiscrimination laws and these requirements and that complying with those laws is a material condition of receiving federal funding streams. Recipients are responsible for ensuring subrecipients, contractors, and partners also comply.

Applicants and recipients are strongly encouraged to refer to the [NIH Director's Statement of Priorities \(https://www.nih.gov/about-nih/nih-director/statements/advancing-nih-mission-through-unified-strategy\)](https://www.nih.gov/about-nih/nih-director/statements/advancing-nih-mission-through-unified-strategy), entitled "Advancing NIH's Mission Through a Unified Strategy."

Recipients are responsible for ensuring that their activities comply with all applicable federal regulations. Pursuant to 2 CFR 200.340, by accepting an NIH award, the recipient agrees that continued funding for the award is contingent upon the availability of appropriated funds, recipient satisfactory performance, compliance with the Terms and Conditions of the award, and may also otherwise be terminated, to the extent authorized by law, if the agency determines that the award no longer effectuates the program goals or agency priorities, in line with 2 CFR 200.340(a)(4).

Pursuant to the Cybersecurity Act of 2015, Div. N, § 405, Pub. Law 114-113, 6 USC § 1533(d), the HHS Secretary has established a common set of voluntary, consensus-based, and industry-led guidelines, best practices, methodologies, procedures, and processes.

Successful recipients under this NOFO agree that:

When recipients, subrecipients, or third-party entities have:

- ongoing and consistent access to HHS owned or operated information or operational technology systems; and
- receive, maintain, transmit, store, access, exchange, process, or utilize personal identifiable information (PII) or personal health information (PHI) obtained from the awarding HHS agency for the purposes of executing the award.

Cybersecurity plans and procedures **must** at minimum include the following:

- Develop cybersecurity plans and procedures, modeled after the [NIST Cybersecurity framework \(https://www.nist.gov/cyberframework\)](https://www.nist.gov/cyberframework), to protect HHS systems and data:
 - **Identify:**
 - Develop an inventory of all assets and accounts with access to HHS owned and operated information or operational technology systems or which obtain PII or PHI for the purposes of the award.
 - **Protect:**
 - Limit access to HHS owned and operated systems to only those in need of access to complete reward activities.
 - Require all staff to complete annual cybersecurity and privacy awareness training. Visit [405\(d\): Knowledge on Demand \(hhs.gov\) \(https://405d.hhs.gov/kod/five-threats\)](https://405d.hhs.gov/kod/five-threats) to obtain free trainings, if needed.
 - Enable multifactor authentication for all employees, subrecipients, and third-party entities to access HHS owned and operated information or operational technology systems.
 - Regularly backup sensitive data and test backups.
 - **Detect:**
 - Install anti-virus or anti-malware software on all devices, servers, and accounts used to connect to HHS owned and operated systems.
 - **Respond:**
 - Develop an incident response plan. See [Incident-Response-Plan-Basics_508c.pdf \(cisa.gov\) \(https://www.cisa.gov/sites/default/files/publications/Incident-Response-Plan-Basics_508c.pdf\)](https://www.cisa.gov/sites/default/files/publications/Incident-Response-Plan-Basics_508c.pdf) to learn about developing incident response plans.
 - Have cybersecurity incident reporting procedures that ensure the relevant HHS awarding agencies are notified of a cybersecurity incident within 48 hours of discovery. A cybersecurity incident is defined as an unplanned interruption to a technology service or reduction in the quality of a technology service, or an occurrence that actually or potentially jeopardizes the confidentiality, integrity, or availability of an information system or the information the system processes, stores, or transmits.
 - **Recover:**
 - Investigate incidents and plug any security gaps identified.

All activities proposed in your application and budget narrative must align with applicable law, including but not limited to statutes, executive orders, federal regulations and applicable judicial holdings. Accordingly, discretionary awards shall not be used to fund, promote, encourage, subsidize, or facilitate; racial preferences or other forms of racial discrimination by the recipient, including activities where race or intentional proxies for race will be used as a selection criterion for employment or program participation; denial by the recipient of the sex binary in humans, or the belief that sex is a chosen or mutable characteristic; illegal immigration; or any other initiatives that compromise public safety. If an application does not align, the application will not receive funding to the extent permitted by law and applicable court orders.

For applications involving substance abuse, the application must not support harm reduction. Please see [Updated Funding Guidance for Recipients on Supplies and Services \(https://www.samhsa.gov/sites/default/files/dear-colleague-letter-updated-hr-funding-guidance.pdf\)](https://www.samhsa.gov/sites/default/files/dear-colleague-letter-updated-hr-funding-guidance.pdf).

For applications involving funding Medication-Assisted Treatment (MAT) or medications for opioid use disorder (MOUD), this funding should be used to provide comprehensive treatment and recovery support services rather than medication-only models for opioid use disorder. Services should include medications, where clinically indicated, in conjunction with psychosocial and other treatment and recovery support services. Funding can also be used to support individualized tapering and discontinuation of medications when clinically indicated. Please see [Updated Funding Guidance for Recipients on MAT/MOUD. \(https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.samhsa.gov%2Fsites%2Fdefault%2Ffiles%2Fdear-colleague-letter-mat-moud-guidance.pdf&data=05%7C02%7COPERAFOAREVIEW%40mail.nih.gov%7Ced5aa4e77f6e415bd90208dec0b96fa9%7C14b77578977342d58507251ca2dc2b06%7C0%7C0%7C6391601001983](https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.samhsa.gov%2Fsites%2Fdefault%2Ffiles%2Fdear-colleague-letter-mat-moud-guidance.pdf&data=05%7C02%7COPERAFOAREVIEW%40mail.nih.gov%7Ced5aa4e77f6e415bd90208dec0b96fa9%7C14b77578977342d58507251ca2dc2b06%7C0%7C0%7C6391601001983)
[As of October 1, 2025, HHS has adopted 2 CFR Part 200, with some modifications included in 2 CFR Part 300. These regulations replace those in 45 CFR Part 75. However, for NIH, under the Consolidated Appropriations Act for FY 2026, \(P.L. 119-75, Division B, Title II, Sec. 224\), the provisions relating to indirect costs in 45 CFR 75 continue to apply to NIH awards. Consistent with the statute, NIH will not apply updated thresholds outlined within 2 CFR Part 200, at this time. \(https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.samhsa.gov%2Fsites%2Fdefault%2Ffiles%2Fdear-colleague-letter-mat-moud-guidance.pdf&data=05%7C02%7Cmichele.walters%40nih.gov%7Ced5aa4e77f6e415bd90208dec0b96fa9%7C14b77578977342d58507251ca2dc2b06%7C0%7C0%7C6391601001983](https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.samhsa.gov%2Fsites%2Fdefault%2Ffiles%2Fdear-colleague-letter-mat-moud-guidance.pdf&data=05%7C02%7Cmichele.walters%40nih.gov%7Ced5aa4e77f6e415bd90208dec0b96fa9%7C14b77578977342d58507251ca2dc2b06%7C0%7C0%7C6391601001983)

Cooperative Agreement Terms and Conditions of Award

Not Applicable

3. Data Management and Sharing

A Data Management and Sharing Plan (DMS Plan) is required for any NIH-funded or conducted research that will generate scientific data. Applicants must submit the DMS Plan at the time of application using the [NIH DMS Plan Format Page \(https://grants.nih.gov/grants-process/write-application/forms-directory/data-management-and-sharing-plan-format-page\)](https://grants.nih.gov/grants-process/write-application/forms-directory/data-management-and-sharing-plan-format-page). The DMS Plan must address the elements in the structured format. Where the DMS Plan Format Page requires a "Yes or No" response, no additional narrative is allowed.

4. Reporting

When multiple years are involved, recipients will be required to submit the [Research Performance Progress Report \(RPPR\) \(http://grants.nih.gov/grants/rppr/index.htm\)](http://grants.nih.gov/grants/rppr/index.htm) annually and financial statements as required in the [NIH Grants Policy Statement Section 8.4.1 Reporting. \(https://grants.nih.gov/grants/policy/nihgps/HTML5/section_8/8.4.1_reporting.htm\)](https://grants.nih.gov/grants/policy/nihgps/HTML5/section_8/8.4.1_reporting.htm) To learn more about post-award monitoring and reporting, see the NIH Grants & Funding website, see [Post-Award Monitoring and Reporting \(https://grants.nih.gov/grants/guide/url_redirect.php?id=82428\)](https://grants.nih.gov/grants/guide/url_redirect.php?id=82428).

A reporting plan tailored to evaluate the progress in technology optimization and dissemination is required in the RPPR. Report data on an annual basis to track optimization, demand, utilization, training, and dissemination of Center technologies under TOPs, DBPs, and CEs. Sample data may include the following.

- Research publications enabled directly and indirectly by the Center technologies;
- Other successes such as patents, grant awards, license transfers, or spin-off companies;
- Breadth and geographical reach of DBPs and trainees;
- Other outcomes from Community Engagement activities including website traffic.

The report of recommendations prepared by the EAC must be included under G.1 of the annual RPPR.

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 Section 8.6 Closeout \(http://grants.nih.gov/grants/guide/uri_redirect.htm?id=82420\)](http://grants.nih.gov/grants/guide/uri_redirect.htm?id=82420). NIH NOFOs outline intended research goals and objectives. Post award, NIH will review and measure performance based on the details and outcomes that are shared within the RPPR, as described at 2 CFR Part 200.301.

5. Evaluation

In carrying out stewardship of grant programs, NIGMS will periodically evaluate the BTOD program, employing representative measures identified below. In assessing the effectiveness of technology development investments, NIGMS may use information from progress reports and public databases, PDs/PIs, and from participants themselves. Where necessary, PDs/PIs and participants may be appropriately contacted after completion of the grant period for updates on participants' subsequent outcomes. The overall program evaluation will be based on metrics that include, but are not limited to, the following:

- Aggregate types of materials, tools, and technologies provided by the Center;
- Grant awards enabled by the Center materials, tools, and technologies;
- Dissemination of Center materials, tools, and technologies through commercial agreements, licensing, and direct transfer to research laboratories;
- Training activities for outside users: the range of types and geographical reach of institutions that trainees represent and the breadth of trainees' professional career stages;
- Patent applications;
- Publications from Center technologies or enabled by Center technologies.

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 \(https://www.era.nih.gov/need-help\)](https://www.era.nih.gov/need-help) - Questions regarding ASSIST, eRA Commons, application errors and warnings, documenting system problems that threaten submission by the due date, and post-submission issues.

[Grants.gov Support Center \(https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fgrants.gov%2Fsupport&data=05%7C02%7Cantoine.caliman%40nih.gov%7Caf6dde64d644478d4e8b08dde6700581%7C14b77578977342d58507251ca2dc2b\)](https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fgrants.gov%2Fsupport&data=05%7C02%7Cantoine.caliman%40nih.gov%7Caf6dde64d644478d4e8b08dde6700581%7C14b77578977342d58507251ca2dc2b)

- Questions regarding Grants.gov registration and services (e.g., Workspace, subscriptions).

Scientific/Research Contact(s)

NIGMS BTOD Mailbox

National Institute of General Medical Sciences (NIGMS)

Email: NIGMS_BTODMailbox@nigms.nih.gov (mailto:NIGMS_BTODMailbox@nigms.nih.gov)

Peer Review Contact(s)

Center for Scientific Review (CSR)

Email: NOFORReviewContact@csr.nih.gov (<mailto:NOFORReviewContact@csr.nih.gov>)

Financial/Grants Management Contact(s)

NIGMS BBCB GAB NOFO

National Institute of General Medical Sciences (NIGMS)

Email: NIGMSBBCBGABNOFO@nih.gov (<mailto:NIGMSBBCBGABNOFO@nih.gov>)

Section VIII. Other Information

Recently issued trans-NIH [policy notices \(http://grants.nih.gov/grants/guide/uri_redirect.htm?id=11163\)](http://grants.nih.gov/grants/guide/uri_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 \(http://grants.nih.gov/grants/guide/uri_redirect.htm?id=11164\)](http://grants.nih.gov/grants/guide/uri_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 \(http://grants.nih.gov/grants/guide/uri_redirect.htm?id=11120\)](http://grants.nih.gov/grants/guide/uri_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 2 CFR Part 200.