

Participating Organization(s)	National Institutes of Health (NIH)
Components of Participating Organizations	National Center for Advancing Translational Sciences (NCATS)
Funding Opportunity Title	Biomedical Data Translator: Development
Activity Code	OT2 Single Component Research Project – Other Transaction Award
Announcement Type	New
Related Notices	NOT-TR-19-028
Funding Opportunity Announcement	OT-19-009
Catalog of Federal Domestic Assistance (CFDA) Number	93.350
Funding Opportunity Purpose	These awards will establish the initial Biomedical Data Translator consortium. Translator will serve as a resource for computationally-assisted exploration of knowledge and construction of new research hypotheses. The knowledge presented to the user will be a network of empirical biomedical knowledge from a variety of sources. The consortium will develop community standards for data re-use, build and disseminate common services for Translator, support the integration of existing medical and biological data sources, build and disseminate common services for Translator, and produce tools that augment human reasoning and inference for understanding the pathophysiology of human disease.
Objective Review	Objective review will be conducted in two segments. In the first segment, written applications will be reviewed by a panel convened by NCATS. A subset of those applicants will then receive the first funding segment. During the first funding segment, awardees will build prototype software, which will be evaluated via presentation to federal employee reviewers. A subset of these awardees will then be invited to continue into the second segment of the award. Applicants will not receive written feedback from the reviews.
Application Due Date	November 15, 2019; 5pm local time
Earliest Start Date	January 13, 2020
Funding Instrument	Other: An assistance mechanism that is not a grant, contract, or cooperative agreement. Other Transactions awards are subject to the requirements of the Other Transaction Award Policy Guide for the Biomedical Translator Program
Eligibility	See Eligible Applicants section of this announcement
Funds Available and Anticipated Number of Awards	NCATS intends to commit approximately \$13.5 million in FY 2020 to fund up to 20 initial awards, with up to 15 awardees receiving continued funding support. Future year support is contingent upon program success, resource sharing and collaboration, and the availability of funds.
Award Budget	Budgets for the first segment of the award will be fixed-cost.

	<p>Budgets for the second segment award are not limited but will need to reflect the actual needs of the proposed project.</p> <p>Performance will be evaluated continuously and continued support will be based on the outcome of those evaluations.</p>
Award Project Period	Up to 5 years
Funding Opportunity Expiration Date	November 16, 2019

Background and Overview

Issue/gap being addressed: In the pursuit of biomedical research, scientists often make observations that are difficult to explain. To attempt to explain such an observation, currently it falls to the researcher to manually identify potential connections or ideas by mining data and knowledge across different resources, a task that demands expertise with many different sources of data and relies upon significant recall of insights from previously published research. And what they find or don't find in those endeavors influences their next experimental steps and might in fact influence their working hypothesis. Ideally, one would mine these heterogeneous data systematically to gain insights into the relationship between molecular and cellular processes and the signs and symptoms manifested in diseases. However, there is currently no broadly-used system that gathers information from different sources and uses the aggregated knowledge as building blocks to aid in the construction of a cohesive hypothesis.

Overall goal of the Biomedical Data Translator Program: The purpose of the program is to accelerate translational research by developing a system to augment human reasoning in response to biomedical research questions. Translator will serve as a resource for computer-assisted exploration and construction of new research hypotheses by connecting and distilling existing empirical knowledge spanning all types of biomedical data, including environmental, molecular and clinical data. NCATS anticipates that this will be a multi-modal computational tool that leverages multiple types of existing data sources, including objective signs and symptoms of disease, drug effects and intervening types of biological data relevant to understanding pathophysiology. The Biomedical Data Translator, "Translator," will be designed to make networks by connecting a variety of data types using both derived knowledge and well-curated data sources and present a user with the most relevant data to help augment their own analysis of translational research problems. In doing so, we will facilitate classification of diseases based on a set of molecular and cellular abnormalities. This would enable recognition of and therapeutic development for conditions with a shared molecular etiology that might manifest differently in the clinic. The Translator must be dynamic and transparent, i.e., able to incorporate new data and information as it becomes available, and able to accommodate a variety of analytical approaches to assist the generation of hypotheses. Translator will be open source and completely publicly available for any user.

When fully operational, Translator will be capable of revealing potential relationships across a multitude of disparate data types, from clinical signs and symptoms to cellular and molecular events to environmental exposures. The scope of Translator has been left intentionally vast to leverage biomedical data of all types to help assemble information to address complex questions.

This effort requires broad teams of clinical research, basic research and data science experts to work together in a highly collaborative manner with active program management.

Feasibility assessment phase. The Translator program began with a feasibility assessment phase that generated demonstration projects focused on dismantling barriers to integrating diverse biomedical data. Cross-team working groups formed to integrate many disparate data sources which drove the adoption of the [emerging knowledge graph standards](#). As an example of the integration of underutilized data, three major academic healthcare institutions within the Translator program created open clinical knowledge sources ([COHD](#), from Columbia University; [ICEES](#), from University of North Carolina; and [JHU Clinical Profiles](#), from Johns Hopkins University) to draw on patient data from electronic health records without compromising patient privacy and enabled incorporation of clinical knowledge into basic research knowledge graphs. This is only one example of the power of removing barriers to data integration and allowing for connections between seemingly-incongruous sources of data.

As these efforts progressed, the program focused on augmenting human reasoning with Translator resources. This effort resulted in several tools which support chaining queries together, as well as accepting various Translator knowledge sources as inputs as defined by the [reasoner standard API](#), to provide the user with a dossier of the most highly relevant information gathered from multiple sources of data and knowledge. As tools were developed, they were [registered](#) in order to allow other teams to discover and access them. The reasoning and architecture teams created a feedback loop which helps to identify gaps in the data as well as integrate disparate knowledge sources to demonstrate that a system can semi-autonomously respond to queries and support exploration of important classes of diverse translational research problems.

In order to convey the breadth of the capabilities that were evaluated during the feasibility assessment phase, the cross-team working groups produced reports on specific examples called [Tidbits](#). Each Tidbit is a vignette that tells a compelling story and demonstrates a kind of insight enabled by Translator.

The feasibility assessment phase demonstrated that Translator can accelerate translational research efforts in a manner that is fully transparent and open source. The next phase will continue to fill gaps in data and knowledge used, reduce Translator's dependence on manual analysis, and increasing the breadth of data and speed with which users are able to uncover meaningful results to inform or generate hypotheses.

Intent of this FY2020 funding opportunity, Biomedical Data Translator Development: In order to realize the vision of the Biomedical Data Translator and transition from the feasibility assessment period to a working platform that serves as a resource to the translational research community, NCATS is announcing the opportunity to submit applications and participate in one of three distinct components of the Translator program. This platform, funded through NCATS's Other Transactions Authority will: help researchers understand the pathophysiology of human disease; connect clinical observations with molecular etiology; identify shared molecular etiologies underlying multiple diseases; redefine diseases through new clinical endotypes and clinical regroupings; identify new opportunities for drug repurposing; and facilitate the generation of new hypotheses for understanding and treating disease. Successful applicants will be integral parts of a community that builds software to support translational science and allow for new innovations and discoveries that could lead to incredible leaps in biomedical research. Successful applicants will work in a highly collaborative culture to build upon the work completed during the feasibility phase of the program.

FOA Timeline

Key Events	Dates	Action needed by applicants
Call for applications posted	September 23, 2019	
Project applications due	November 15, 2019	Complete application through ASSIST
Review of written applications completed	December, 2019	
Segment 1 awards anticipated	mid-January, 2020	
Presentation by awardees	March 16-19, 2020	* Prototype software will be presented
Segment 2 invitations sent	March 23, 2020	
Negotiations for Segment 2 begin	March 23, 2020	
Kick-off meeting	Mid-April, 2020	DC area
Segment 2 funding anticipated	Mid-May 2020	

*Presentation by at least one team member is required. If the awardee has not previously participated in the Translator program, the presentation must be conducted in-person in the Bethesda, MD area.

Program Components

There are three distinct program components to this FOA, which are described below. Applicants can only apply for one component in a single application. Applicants cannot submit for multiple components in the same application. Applicant institutions interested in more than one component may submit more than one application. However, an individual may be listed as a principal investigator (PI) or one of multiple principal investigators (MPI) for only one application, and each application must focus entirely on one of these three components. An Individual may be named in more than one application, but not as the application PI or MPI. See the Application Content section below for more details.

- Knowledge Providers will seek out, integrate and provide high-value AI-ready data sources within a specific scope of knowledge relevant to Translator. Of particular importance is their ability to employ extrapolation, expansion, filtering, and machine learning to create or improve upon existing sources to enhance their ability to respond to biomedical questions.
- Autonomous Relay Agents are tools used to determine which knowledge providers to invoke when a query is made of the system, identify the most relevant and robust information from their responses and help to guide further iterations within the Autonomous Relay System (ARS). The ARS will be built by NCATS staff and will relay the query from the user to the ARAs using an iterative process with the ARAs to generate the result in the form of a knowledge graph provided to the user. The goal of iterating with ARAs is to fill gaps, “clean up” a graph, enrich the graph, etc. The ARAs will be built to accept queries in a standardized format, dispatch subtasks to appropriate AI-ready knowledge providers, receive responses back from knowledge sources, and process responses using scoring metrics in order to return the most relevant and highest

quality potential responses to the ARS. It is expected that the ARAs will initially be built outside of the ARS and not integrated into the Translator system, therefore tolerance for risk in this component will be greater and innovation is strongly encouraged. As ARA releases are ready for production, they will be incorporated into the ARS.

- The Standards and Reference Implementation Component awardee will be responsible for managing the development of community-driven data and coding standards for the entire consortium, as well as developing and deploying reference implementations for essential, shared Translator infrastructure.

In addition, some production elements of Translator beyond the Autonomous Relay System will be developed directly by NCATS staff. All production elements of Translator will be hosted by NCATS and awardees will work closely with NCATS staff to transition prototype software into production use and integrate with other NCATS-hosted components.

Program Component – Translator Knowledge Providers

During the full project period, awardees are expected to seek out, integrate and provide high-value AI-ready data sources within a specific scope of knowledge relevant to Translator. Of particular importance is their ability to employ extrapolation and inference to create or improve upon data sources to enhance their ability to respond to biomedical queries. Current examples of Knowledge Providers are registered at <https://smart-api.info/registry?q=translator&tags=translator,reasoner>. Awardees should anticipate that multiple, different lines of evidence would ideally be used to identify robust relationships. Knowledge assertions should be examined routinely for internal data consistency, and Knowledge Providers should have the means to capture and log inconsistencies that may be discovered in order to pursue further curation. The incorporation of fine-grained indexing of the full text of scientific publications, commercial patents and regulatory filings, along with other web-accessible documents may address some of the shortcomings of established sources and indexes. The Knowledge Providers will be Translator's source of deep knowledge within specific domains, as defined by the Knowledge Provider researchers.

Objectives for the Knowledge Providers:

- Identify and address gaps in knowledge by finding and integrating sources of direct assertions that improve the quality or quantity of connections between translational research data or synthesizing new composite knowledge sources from data currently available to Translator.
- Integrate knowledge sources from the same or closely related domains, either directly or through the creation of novel composite knowledge sources from available data, into Translator in a dynamic and transparent way as new information becomes available, accommodating a variety of analytical approaches to support the exploration of knowledge and generation of hypotheses.
- Develop metrics and testing methods that describe the quality and validity of Knowledge Provider's returned results.
- Aid in the planning and implementation of data and software standards for Translator, as well as comply with all established standards when designing and implementing software.
- Catalog compelling use-cases developed through interactions with potential users that demonstrate the value of Translator.

Evaluation criteria for this component include all of the following:

- Viability and novelty of the applicant's strategic plan for identifying and integrating knowledge sources with a clear focus on the value said knowledge sources would provide to Translator;
- Viability and novelty of the applicant's plan for evaluating their project's contributions to the accuracy and specificity of returned results and the value to the larger Translator community;
- Value and novelty of queries that Translator will be able to address as a result of the integration of new knowledge sources, as described by the applicant.

NCATS expects to fund ten to fifteen awards during the first award segment for the Translator Knowledge Providers component of the program. Annual budgets for the second award segment for the Knowledge Provider components are expected in the range of \$150,000 to \$400,000 direct costs but need to reflect the actual needs of the proposed project.

Program Component – Translator Autonomous Relay Agents:

During the project period, awardees are expected to research and develop autonomous relay agents (ARAs) that generate, retrieve, and synthesize knowledge provided from Translator knowledge providers by employing novel analytic approaches that enable Translator to address challenging translational research questions. While the Knowledge Providers will support depth of knowledge within a limited scope of biology, the autonomous relay agents should adroitly handle the integration of knowledge from multiple Knowledge Providers and thus multiple different domains of biomedical knowledge.

Although work done during the first segment may be somewhat scientifically conservative or traditional, high risk innovation will be encouraged for the ARAs. For high risk ideas, alternative high risk or traditional approaches should also be described as part of the applicant's strategic plan.

Objectives for the Autonomous Relay Agents:

The autonomous relay agents will be focused primarily on research to develop software that can be incorporated into the Autonomous Relay System (ARS) that will be built by NCATS staff and used by the other components of Translator. Autonomous Relay Agents will:

- Research creative uses of Knowledge Providers to synthesize and distill knowledge graphs relevant to a biomedical query.
- Develop methods to compare and contrast results returned from knowledge providers to deliver more accurate and relevant results. ARAs will be expected to have the capability to warn users of a potentially spurious finding, identify internal inconsistencies in the data and surface contradicting claims or counterevidence.
- Accept input queries from the ARS which are within the agent's scope of query space, determine which Knowledge Providers should be invoked to supply relevant information, and return a standardized knowledge graph to the ARS for further iterative queries or to be returned to the user.
- Aid in the planning and implementation of data and software standards for Translator, as well as complying with all established standards when designing and implementing software.
- In consultation with potential users, catalog compelling use-cases that demonstrate the value of Translator.

Evaluation criteria for this component include the following:

- Applicant's description of how the proposed relay agent will broaden the scope of possible questions that may be asked of Translator;
- Novelty of the applicant's epistemological approach and its potential for being more generally applied to the distillation of relevant information from multiple Knowledge Providers;
- The extent to which the proposed relay agent would advance reasoning through innovative uses of knowledge sources, and the impact it would have on Translator if successfully implemented;
- Viability of the applicant's plan to create comparison methods for results, and the applicant's vision for how these methods can be used to improve returned results;

NCATS expects to fund three to seven awards during the first award segment for Autonomous Relay Agents. Annual budgets for the second award segment of the Autonomous Relay Agents are expected in the range of \$400,000 to \$650,000 direct costs but need to reflect the actual needs of the proposed project.

Program Component – Translator Standards and Reference Implementation

During the project period, awardees are expected to work with NCATS staff as well as other Translator research teams to lead a community-driven standards process that expands on [current Translator standards](#) and defines how Translator resources can be discovered, how they are invoked, and the format of data exchanged between them. Beyond capturing knowledge graphs, it will be essential to identify appropriate metadata that facilitates data interpretation, integration and refinement into a response for a user's translational research question. In collaboration with the other Translator teams and NCATS staff, the awardees will be expected to develop reference implementations of Translator services which will serve as the foundation upon which Translator will be implemented. Awardees are expected to produce enterprise-quality code, apply best-practice software development principles, and work closely with other research teams to define a path for bringing research resources into production.

This program is intensely collaborative among research partners and the NCATS ARS staff, and the successful applicants will be expected to build consensus among research teams before implementing their vision of the reference implementation.

Objectives for the Standards and Reference Implementation component

- Manage the development of community-driven data and coding standards for the entire consortium, as well as develop and deploy reference implementations for essential, shared Translator infrastructure.
- Define standards and implement functionality to determine query result provenance in order to enhance credibility and reproducibility of queries and results.
- Develop solutions for integration barriers (e.g., entity recognition, entity resolution, entity normalization, etc.) or data inclusion barriers.
- Develop and implement a protocol for long-term data quality control and data updates.
- Develop a plan to ensure the continued community-driven evolution of Translator beyond the project period.

Evaluation criteria for the component includes all of the following:

- Previous experience at developing enterprise solutions for large-scale, collaborative projects, including the incorporation of community-contributed source code;
- Previous experience at developing and implementing community-driven data and coding standards;
- Expertise in the semantic modeling of biomedical data;
- Viability of the applicant's plan for the sustained evolution of Translator.

NCATS expects to fund one award for the Translator Standards and Reference Implementation component of the program. Annual budgets for the second award segment of the Translator Standards and Reference Implementation component are expected in the range of \$600,000 to \$700,000 direct costs, but need to reflect the actual needs of the proposed project.

Additional, Shared Evaluation Criteria

Evaluation criteria considered for all applications include the following, in addition to component-specific criteria as described in the Program Components sections above:

- Viability of the applicant's plan to implement their proposed projects, including specific and realistic milestones for the entire project period;
- Scientific complementarity of the application with other applications under consideration;
- Viability of the applicant's plan to ensure the usefulness of their contributions to the Translator program to potential end-users;
- The team's history of collaborative scientific efforts as determined by references and/or letters of support;

Data and Software Sharing

Data sharing is essential for expedited translation of research results into knowledge, products, and procedures to improve human health; consequently, all software and other tools used for this project **must be open source and publicly available at the time of application, and all software created during the project period must be made publicly available** through program-directed source code repositories. The NIH expects and supports the timely release and sharing of final research data, software and tools that support the publication of these data from NIH-supported programs for use by other researchers. NCATS expects that this project will be intensely collaborative among research partners and NIH staff, and that the unrestricted exchange of source code and software tools written as part of this program will be essential to a successful outcome.

Meetings and collaboration

All awardees will be expected to collaborate with both NCATS staff and other awardees and will be expected to participate in multiple weekly and monthly conference calls in addition to periodic face-to-face meetings. Face-to-face meetings help to foster innovation and collaboration. At these meetings, participants will examine and improve upon the foundational work completed by Translator teams during the feasibility assessment phase, as well as implement new functionality and data integration in order to address the needs of the translational research community. We anticipate having three, four-day, consortium-wide, in-person working meetings per year, with additional smaller working meetings

planned as necessary to facilitate collaborations between teams as needed. The meetings will generally rotate between east coast, west coast, and central U.S. locations.

Application Content

All pages should be Arial 11pt, single space with 1" margins.

Summary Vision Statement – limited to one page

Knowledge Provider Applicants and Autonomous Relay Agent Applicants should include a single page describing:

- 1) A statement of which component you are proposing to build.
- 2) The problem that the applicant is trying to address. This should be specific to the application, not the problem Translator is trying to address.
- 3) A plan for implementation of the project, along with examples of what types of questions the proposed tools or data sources will allow Translator users to address;
- 4) How the expertise and resources that the applicant can provide will be used to collaborate with NIH staff and other awardees to address project goals and integrate new data sources into the overall Translator architecture; and
- 5) Potential challenges, gaps and barriers to implementing the goals of the proposed project, which may include barriers to integrating data sources, scoring and ranking returned results, or developing tools to make the best possible use of data sources.

Applicants for the Translator Standards and Reference Implementation component should include a single page describing:

- 1) A statement of which component you are proposing to build.
- 2) The problem that the applicant is trying to address. This should be specific to the application, not the problem Translator is trying to address.
- 3) A plan for development and implementation of Translator standards, as well as for reference implementations of Translator services which will serve as the foundation upon which Translator will be built;
- 4) How the expertise and resources that the applicant can provide will be used to collaborate with NIH staff and other awardees to create standards and a reference implementation of Translator, integrating into the current Translator infrastructure; and
- 5) Potential data and infrastructure challenges, gaps and barriers to achieving the project goals.

Project Plan

The project plan should clearly describe how the project goals will be achieved and is not to exceed 2 pages. Any graphs, pictures or data tables must be included in the body of the text and will count against the 2-page limit.

Personnel

Include a CV or NIH biosketch for each of the key personnel who have committed to participating in the project if it is awarded. In the context of this program, it is especially important to highlight contributions of personnel to existing open source projects, standards, and initiatives as well as evidence of ability to work collaboratively.

Provide a table listing all personnel, including all to be named personnel, role on the project, and percent effort to be committed. While there is no minimum effort level required for the PI or MPIs, due to the intensive nature of this program, after the first segment of the award, a minimum of two team members with a minimum of 50% effort each is expected. Do not include salaries here. For the first segment, please indicate which personnel will be involved and their level of effort during that period.

Resources

Include a 1-page description of resources available for the project.

Previous Work Examples

Applicants for the Translator Standards and Reference Implementation component only should include a detailed description of prior open-source, enterprise software developed by members of the proposed project team, including links to current versions of such software, as well as previous examples of developing and implementing software and/or data standards (such as participation in ISO or W3C standards) that is no more than 2 pages.

Data Sharing and Collaboration Plans

Applicants must include a plan for data sharing and a collaboration plan up to 1 page total, which should address the requirement for open source code deposition for the project. If data sharing will be restricted in any way, state how and why, including the potential impact of this restricted sharing on the proposed project and Translator as a whole. NIH's data sharing policy may be found at the following website: <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-032.html>.

First Segment Award Milestones and Budget

Provide a two-page description of specific milestones to be completed during the first segment in order to demonstrate the value of the project's expected contributions to Translator through prototyped software, along with all associated costs (total cost per milestone). NCATS will provide a fixed award of \$34,000 in direct cost funds for this period. Applicants whose PIs have not received funding for work related to a Translator project in the past will receive an additional \$1,500 direct costs (for a fixed total of \$35,500 in direct cost funds) to defray the expenses associated with traveling to Bethesda, MD to present their prototype software in person. Applicants who have been part of funded Translator projects before will instead present their prototype software to NCATS staff by videoconference. Candidates will be expected to make all prototype software code available through a public code repository in a timely manner following their prototype presentations.

Additionally, recipients of the first funding segment award will receive a restricted amount of \$50,000 direct cost for continuation after the prototype software presentation in March 2020. These funds may be used to support preparation and participation in the kick-off meeting in late April including travel costs and for work during milestone and budget negotiations for the second funding segment. Release of these funds will be contingent upon the success of the applicant's prototyped software presentation; awardees who do not receive invitations for the second award segment will not attend the kick-off meeting and the restricted funds will be deobligated and returned to NCATS.

Awardees who continue into the second segment of the award will submit revised detailed milestones and budget for that segment following the kick-off meeting.

Project Milestones

Provide a description of annual milestones for the proposed project period and associated costs (total cost per milestone) in up to 3 pages. This document should include a detailed description of the planned process of moving from research to implementation.

Budget (2 pages)

Provide 1 page stating the estimated breakdown for the fixed price (\$34,000) direct cost for the first award segment period: personnel, travel and other. Institutions with an established F&A rate may include the approved rate. Institutions without an established F&A rate may propose a rate for review and negotiation. Those who have not previously participated in the Translator program will be required to present in-person in Bethesda, MD and should include the additional \$1500 travel funds in their proposed budget.

Provide 1 page stating the estimated overall direct cost for the second award segment period: personnel, travel and other. Institutions with an established F&A rate may include the approved rate. Institutions without an established F&A rate may propose a rate for review and negotiation. Travel budgets should include costs for in-person attendance at Translator working meetings. It is anticipated that after segment 2 candidates are identified, and after the kick-off meeting, some originally proposed milestones might be removed and some new milestones may be added. The estimated budget should be based on the milestones proposed in the application. Please refer to the component descriptions for information on budget expectations.

Letters of Support and References

Letters of support for all collaborators/other significant contributors, consultants and sub-award sites should be provided. Letters that are written for the sole purpose of endorsement should not be included and will not be considered during review. However, a list of previous collaborators (limited to one page) who may be contacted as references as to the applicants' history of collaborative work on large-scale projects should also be included, as applicable.

How to submit the application

Applications must be submitted through NIH's ASSIST site by 5:00 p.m. local time on November 15, 2019 *[This date has been corrected as of Oct 4, 2019]* at <https://public.era.nih.gov/assist/public/login.era>. Paper applications will not be accepted. Applications from institutions must be submitted by an authorized organizational representative.

Objective review process

See component descriptions above for the specific evaluation criteria that will be used for each component type.

Applications will be evaluated in two stages. The first stage will be based on a written application. Once applications are received, external reviewers will evaluate each application based on the criteria described in each of the Program Component sections above. The outcome of the review and complementarity with other applicants will be used to select applicants who will be awarded the first funding segment to create prototype software.

The first segment awardees will be expected to create prototype software demonstrating their vision and expectations for their project moving forward. After approximately two months, awardees will present their software to NCATS staff. Awardees who have been part of a Translator feasibility project team before will present their prototypes through teleconference. Those who have not received funding through a Translator feasibility award in the past will present their prototypes to NCATS staff as part of an in-person presentation at NCATS offices in Rockville, MD. Based on these presentations, restricted funds will be released for some awardees, while others will proceed to close out. This process will ensure that Translator projects are of the highest technical and visionary quality moving into the Development phase of the program.

Written feedback about the outcome of the objective reviews will not be provided.

Eligible Applicants

Applications will be accepted from individuals and organizations as defined in the categories below:

Individuals

Applications submitted by an individual (not submitted by an institution or organization) are allowed. In these instances, by law, only U.S. citizens and permanent residents are eligible to apply. Foreign key personnel are permitted to participate in award activities but may not serve as the individual award recipient. individual(s) with the skills, knowledge and resources necessary to carry out the proposed project is invited to develop an application for support.

Individual applicants will be subject to financial analysis and risk assessment conducted by NIH staff.

Organizations

NOTE: Organizations are not limited to a single application under this FOA.

Higher Education Institutions

- Public/State Controlled Institutions of Higher Education
- Private Institutions of Higher Education
- The following types of Higher Education Institutions are always encouraged to apply for NIH support as Public or Private Institutions of Higher Education:
 - Hispanic-serving Institutions
 - Historically Black Colleges and Universities(HBCUs)
 - Tribally Controlled Colleges and Universities(TCCUs)
 - Alaska Native and Native Hawaiian Serving Institutions
 - Asian American Native American Pacific Islander Serving Institutions(AANAPISIs)

Nonprofits Other Than Institutions of Higher Education

Nonprofits with 501(c)(3) IRS Status (Other than Institutions of Higher Education)

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

For-Profit Organizations

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

Governments

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

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

Organizational applicants will be subject to financial analysis and risk assessment conducted by NIH staff.

Multiple Principal Investigators

More than one individual may be named as Principal Investigator on a single application; however, any given investigator may only be named as Principal Investigator on one application.

Foreign Institutions

Non-domestic (non-U.S.) Entities (Foreign Institutions) **are not** eligible to apply. Non-domestic (non-U.S.) components of U.S. Organizations **are** eligible to apply. Foreign components, as defined in the Other Transaction Award Policy Guide for the Biomedical Translator Program: Development Projects, **are** allowed.

Questions about this opportunity should be emailed to translator-questions@nih.gov