Research Opportunity Announcement

Research Opportunity Title: NIH Common Fund Data Ecosystem (CFDE) Data Resource Center and Knowledge Center (OT2)

OTA-23-004

Participating Organization(s): National Institutes of Health

Components: This Other Transactions Research Opportunity Announcement (OT ROA) is to support the *NIH Common Fund Data Ecosystem* (CFDE) program. This research opportunity will be administered by the NIH DPSPCI Office of Strategic Coordination (OSC), also known as the Common Fund.

Funding Instrument: The funding instrument is the Other Transaction (OT) Award mechanism. OT awards are not grants, cooperative agreements, or contracts, and use an Other Transactions Authority provided by law. Terms and conditions may vary between awards. Each award is therefore issued with a specific Agreement, which is negotiated with the recipient and details the agreed-upon terms and conditions for that award.

Related Notices:

NOT-OD-22-189 Implementation Details for the NIH Data Management and Sharing Policy

NOT-OD-22-198 Implementation Changes for Genomic Data Sharing Plans Included with Applications Due on or after January 25, 2023

Research Opportunity Purpose:

The purpose of this announcement is to invite applications from eligible organizations to establish the Data Resource Center (DRC) and Knowledge Center (KC) for the Common Fund Data Ecosystem (CFDE). Center award(s) made through this announcement will support CFDE by providing technical and administrative coordination and support to enable broad use of, respectively, the data sets and knowledge generated by the Common Fund (CF) programs. The recipient(s) will work collaboratively with each other and other participating components of the CFDE to integrate and coordinate activities across the ecosystem. The end products of CFDE will constitute a thriving ecosystem that enables the research community to (re)use the CF generated data, knowledge and other digital resources for discoveries and new purposes.

This initiative is funded through the NIH Common Fund, which supports cross-cutting programs that are expected to have an exceptionally high impact. All Common Fund initiatives invite investigators to develop bold, innovative, and often risky approaches to address problems that may seem intractable or to seize new opportunities that offer the potential for rapid progress.

Applicants responding to this ROA are expected to familiarize themselves with the other components of the CFDE listed below, as the Data Resource and Knowledge Centers will be expected to communicate, coordinate, and collaborate with these components.

Background:

The NIH Common Fund supports bold scientific programs that catalyze discovery across all biomedical and behavioral research. Common Fund programs create a space where investigators and multiple NIH Institutes and Centers (ICs) collaborate on innovative research addressing high-priority challenges for the NIH as a whole and make a broader impact in the scientific community.

Approximately two-thirds of CF programs generate large-scale data resources and digital tools that are intended to be used by researchers across the entire spectrum of biomedical research. These resources provide unprecedented opportunities to understand biological mechanisms, interrogate complex biological systems, deliver new types of discoveries, and rapidly advance novel treatments and cures for many diseases. However, as a federated collection of CF programs, these resources reside in different locations and are made accessible via different platforms, formats, and mechanisms. This federated setup creates unique challenges in working with CF resources in an easily accessible, integrated, and user-friendly manner. Multiple challenges in data collection, curation, storage, management, and sharing must be addressed to realize the full potential of the "big data" revolution in biomedical research. NIH is taking steps to modernize the NIH-funded biomedical data-resource ecosystem, as described in the NIH Strategic Plan for Data Science. In alignment with this plan, the CF addresses data science opportunities and challenges related to CF programs.

The Common Fund Data Ecosystem (CFDE) is an infrastructure investment made by the CF to address the growing challenges facing scientific programs that leverage data-intensive strategies. To support these programs and downstream data users, the CFDE is helping to ensure that all Common Fund data sets are Findable, Accessible, Interoperable, and Reusable (FAIR), providing training for users to operate on the data in a cloud environment, and ensuring that CF data continue to be available after individual programs are completed. The CFDE will amplify the impact of many CF programs by enabling researchers to interrogate disparate data sets, thereby making new kinds of scientific discoveries that are otherwise unattainable. The CFDE is also being designed in parallel with NIH IC data platforms to enable crosstalk between CF and IC data sets and address NIH-wide data management objectives described in the NIH Strategic Plan for Data Science.

The CFDE program addresses an emerging scientific opportunity, namely the removal of barriers to enable the reuse of CF resources for new discoveries and purposes. The CFDE is working towards fostering scientific discovery through the (re)use of the CF generated data and digital resources by achieving its three aims: 1) Enable users to query across and use multiple CF data sets; 2) Provide training and outreach to bring people to CF data and train them to work in the cloud; and 3) Coordinate and integrate infrastructure and activities into a cohesive ecosystem. Unlocking the full potential of CF resources through expanded (re)use will require expertise from multiple scientific domains, including biomedicine, data science, data management, and cloud workspace training.

Structure of CFDE:

Currently the CFDE program is in the third and final year of its pilot phase. During this three-year pilot phase, a Common Fund Data Ecosystem Coordination Center (CFDE-CC) was established to provide technical and logistical coordination of the CFDE consortium activities. The primary task of the CFDE-CC during the pilot phase was to engage with the Data Coordination Centers (DCCs) of ongoing CF programs as partners to establish an ecosystem of data sets and other digital resources generated by the DCCs that is FAIR. Further information about CFDE and its accomplishments in the first phase as well as the resources made available through the CFDE portal and other platforms can be found at https://nih-

cfde.github.io/2022-CoC-Videos/appendix/.

Building on the successful first phase, CFDE will be expanding its scope in increasing the (re)use of CF generated data, knowledge, and tools, and significantly ramp up the skills development and training efforts. CFDE will establish data resource and knowledge portals and cloud workspaces that will enable users to query across and use multiple CF resources. CFDE will increase (re)use by expanding outreach and training efforts that bring biomedical researchers to CF resources and to work in the cloud. To accommodate these changes in the scope and better address the needs, CFDE will be structured as five tightly integrated Centers. In general, these are:

Data Resource Center (DRC): This center will be responsible for creating and maintaining the CFDE Portal, which is the landing page/front end for CFDE. The CFDE Portal will integrate information, digital resources and products from the CFDE centers and DCCs and will disseminate them to the wider scientific community and provide usage help as needed. Another major responsibility of this center will be creating the Data Resource Portal that enables users to query and use the data sets from across CF programs.

Knowledge Center (KC): This center will be responsible for creating a knowledge network to integrate knowledge generated by CF programs and coordinate knowledge generation and handling. The KC will also create the Knowledge Portal that will enable users to query and access the integrated knowledge provided across the network of CF programs.

Cloud Workspace Implementation Center (CWIC): This center will be responsible for creating a CFDE designated cloud workspace that enables users to import their data and co-analyze them together with other CF data sets and/or utilize CFDE constructed analysis pipelines, workflows and other analysis and visualization resources. The cloud workspace will meet the needs of both novice and expert users.

Center for Training (CT): This center will be responsible for performing a landscape analysis to identify the training opportunities and needs of the CFDE community. It will also develop and help other CFDE Centers develop and administer targeted training to address gaps in the training landscape.

Integration and Coordination Center (ICC)**:** This center will focus on ensuring internal cohesion within CFDE and implementing a structured evaluation process to ensure a continuous improvement cycle. It will have three major responsibilities: (1) Integration and coordination across the CFDE Centers and CFDE-related activities among participating CF programs; (2) Sustainability services; and (3) Leading an annual program evaluation.

In addition to the CFDE Centers, ***Data Coordinating Centers (DCCs) of the engaged CF Programs*** are critical components of CFDE. Participating CF program DCCs will work closely with the DRC and KC to ensure their digital resources are available through the CFDE portal(s), collaborate with the CWIC to make their resources available to the broader user community in designated cloud workspaces, and coordinate their training and outreach activities with the CT. The participating CF program DCCs will also be required to perform regular FAIRness assessments to monitor changes in the FAIRness of their digital resources over time and collect regular usage statistics and metrics for their data sets and digital resources. These activities will be performed in coordination with the ICC as part of an annual program-wide evaluation. Additionally, all CF DCCs will be eligible to participate in CFDE partnership projects aimed to integrate data sets and digital resources across multiple CF programs.

Synopsis of the planned major products:
Data Resource Portal: Portal that will serve as the platform that enables user-friendly query of CF data sets, tools, and other related digital resources and provides access to them. When they mature, the Knowledge Portal will be integrated into the Data Resource Portal to form the Resource Portal.
Knowledge Portal: Portal that will serve as the platform that enables user-friendly queries of CF generated knowledge and related digital resources. When they mature, the Knowledge Portal will be integrated into the Data Resource Portal to form the Resource Portal.
Resource Portal: Portal that will be formed by combining the Knowledge Portal into the Data Resource Portal when the two portals are mature and ready for integration.
CFDE Portal: Overall front end/landing page for the CFDE program to enable users to learn about CFDE resources and activities. CFDE Portal will encompass the Resource Portal (i.e., integrated Data Resource and Knowledge Portals) and any other relevant portals that the CFDE consortium produces.

This Research Opportunity Announcement (ROA) aims to establish the CFDE i) Data Resource Center (DRC) and ii) Knowledge Center (KC), which will provide technical and administrative coordination and leadership across DCCs of the CF programs engaged in CFDE to respectively enable broad use of data sets and knowledge generated by the CF programs.

DRC: The primary responsibility of the CFDE DRC will be to develop and maintain the CFDE Portal, which will function as the overall front-end for the CFDE program to enable users to learn about CFDE resources, training and scientific/technological activities and enable wider reuse of CF resources. Additionally, as part of the CFDE Portal, the DRC will also be responsible for establishing a Data Resource Portal that enables user-friendly queries of CF data sets, provides access to data sets that are identified in user queries, provides access to CF-generated tools and analysis platforms, and enables the use of the identified data sets and other CF digital resources in cloud platforms and workspaces. The DRC will also be responsible for developing the necessary material to train and help users for effective and wide usage of the overall CFDE Portal and the Data Resource Portal.

KC: The primary responsibility of the CFDE KC will be to establish the Knowledge Portal, a knowledge network platform that integrates the knowledge generated by different CF programs to amplify their impact, makes the knowledge accessible to a wide user community in a user-friendly manner, allows for various ways to query the available knowledge, enables the use of the identified knowledge information in cloud platforms and workspaces, and develops the necessary training material to train and help users for effective and wide usage of the Knowledge Portal.

An important distinction between the DRC and the KC is that the DRC will be focused on enabling the reuse of underlying datasets. On the other hand, the KC will focus on improving the scientific community's ability to leverage the knowledge and analyses generated by the participating CF programs.

When they mature, portals implemented by the CFDE DRC and KC are expected to merge into a single platform under the CFDE Portal which will encompass the CFDE front-end program website, integrated Data Resource and Knowledge Portals, and any other relevant portals that the CFDE consortium produces. Therefore, the DRC and KC will be required to work very closely. As increased use of cloud platforms and providing access to CF digital resources in the cloud is a high priority to CFDE, portals developed by both Centers will be required to integrate seamlessly with the planned CFDE designated Cloud Workspaces. Additionally, both Centers will coordinate their efforts with the Integration and Coordination Center (ICC), which will lead the efforts to coordinate and integrate the CFDE infrastructure and activities into a cohesive ecosystem. Similarly, CFDE approaches training and outreach holistically, thus close coordination with the CFDE CT and ICC on training material and content development and hands-on training activities will be required.

Applicants may choose to apply to establish either the Data Resource Center, the Knowledge Center, or both.

Objective Review: NIH will convene an appropriate review group to evaluate applications. See the Objective Review section of this opportunity for further details.

Eligibility: See the Eligibility section of this opportunity.

Application budget: The Common Fund may allocate up to $3,000,000 for the first-year total (direct + F&A) costs for these two centers and up to $3,500,000 per year for years 2-5. These awards are contingent upon NIH appropriations and the submission of a sufficient number of meritorious applications. Future year amounts will depend on annual appropriations. The level of funding for awards made under this solicitation and how funds may be split between the Data Resource and Knowledge Centers has not been predetermined. The funding split will depend on (1) the objectives for the centers proposed by the applicants and how well they fit within the goals of CFDE, (2) the quality of the applications received, (3) availability of funds, and (4) programmatic priorities. First-year funding for either the DRC or the KC individually is not expected to exceed $1,750,000 total costs, with no more than $3,000,000 total for both awards.

The application budget should reflect the proposed activities and personnel of the applied center. The OT mechanism allows for significant flexibility to make budget adjustments as needed to meet NIH's programmatic priorities. Award levels may increase or decrease over time based on funding availability, establishment or termination of sub-awards, recipient performance, and other programmatic priorities. It is anticipated that funds will be allocated on a yearly basis.

Cost share is not required but may be proposed. However, including a cost share will not impact an applicant's chances of selection.

Anticipated number of Awards: The Common Fund anticipates making one award to establish the CDFE Data Resource Center and one award to establish the CFDE Knowledge Center. If one application is selected to establish both centers, then a single award will be issued.

Award Project Duration: Initial project duration is anticipated to be up to five (5) years, subject to program needs and availability of funds. Research activities and the associated milestones may be shortened or extended as needed within that period. The OT award will be issued for one year initially and, with mutual agreement, modified and extended annually for future years. Workplans for research activities and the associated milestones will be negotiated with the NIH staff annually at a minimum.

Authority: Other Transactions awards will be made pursuant to current authorizing legislation, including Section 402(n) of the Public Health Service Act, 42 U.S.C. 282(n), as amended.

Release Date of this Research Opportunity Announcement: March 28, 2023

Frequently Asked Questions: https://commonfund.nih.gov/dataecosystem/faqs

Informational Webinar: Webinar information and its date will be posted on the Frequently Asked Questions website.

Letters of Intent (LOI) Due Date: April 28, 2023 by 5:00 PM local time of applicant organization. *LOIs are not required to be eligible to submit a full proposal. However, submitting an LOI is strongly recommended*.

Proposal Due Date: May 30, 2023 by 5:00 PM local time of applicant organization. Late applications to this ROA will not be accepted.

Earliest Start Date: August 1, 2023

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Outline of this Opportunity

1. Requirements – CFDE Data Resource Center

Main responsibilities of the CFDE Data Resource Center (DRC) will be to build the CFDE Portal and the Data Resource Portal. The development work to establish the DRC shall be pursued under the management and oversight of the Common Fund Other Transactions Program Official (OTPO), with scientific and strategic guidance from the CFDE Steering Committee (SC) composed of NIH staff and CFDE PIs. The DRC team must effectively and productively collaborate with the CFDE investigators and the ecosystem's other components.

During the pilot phase, the current CFDE-CC managed and coordinated activities across the CFDE. The CFDE-CC developed the CFDE Portal, a search platform that enables users to query and identify relevant data sets across multiple Common Fund programs. CF programs produce widely divergent types of data, some of which are access controlled and/or reside in controlled access repositories. To enable the collation of the metadata about the diverse CF data sets, CFDE-CC developed the C2M2, the cross-cut metadata model. The C2M2 was used to standardize the metadata elements across the engaged DCCs. The CFDE-CC worked with participating DCCs to enhance the FAIRness of data sets, capture best practices for CF programs to leverage, and harmonize metadata to optimize cross-data set search. The DRC may take advantage of these resources as appropriate.

Expected responsibilities for building the DRC and its portals include:

- **Create and maintain an outward-facing portal for CFDE, a.k.a., the CFDE Portal**
  - The CFDE Portal will be the central platform and landing page enabling users to discover information pertaining to the CFDE and its ongoing activities, data and tool products of CF programs, training and outreach materials, and opportunities. Describe how the design of the CFDE Portal emphasizes the best user experience/user interface (UX/UI) practices and targets a diverse spectrum of users ranging from clinicians to novice researchers to well-established bioinformaticians and data scientists.
  - Describe how the CFDE Portal will be evaluated by collecting system metrics and feedback from external users and how such information will be used to improve the CFDE Portal. Describe and discuss the plans for the maintenance of and continuous improvements (e.g., adoption of new technologies) to the CFDE Portal.
  - The CFDE Portal will incorporate the Data Resource Portal and the Knowledge Portal when those portals mature and are ready for integration and incorporation. As appropriate, the CFDE Portal will also incorporate and/or provide links and access to all other relevant tools, analysis modules and pipelines, and portals that the CFDE consortium produces. Describe the plans for the inclusion and integration of these resources in the CFDE Portal and how their readiness for inclusion will be assessed.
  - Whether proposing to build a new CFDE Portal or enhancing the existing portal, provide the rationale and justification for the choice.
  - The recipient will be responsible for Information Security of the created CFDE Portal. Specifically, recipient-hosted information systems should maintain security controls in a way that is FISMA-equivalent. Describe the plans for how this will be achieved.

- **Create and maintain the Data Resource Portal for CF generated data sets and tools, and search platform for inquiry and use of those data sets and tools**
  - The Data Resource Portal, which is to be integrated into and made available through the CFDE Portal, will compile the information about CF generated data sets and tools and make that information available to the users. The Data Resource Portal will not be required to store data from CF programs. The DRC will be required to establish the necessary infrastructure to receive,

ingest and collate information about data sets and tools (i.e., metadata and necessary auxiliary information) from the participating Data Coordinating Centers (DCCs) into the Data Resource Portal. The DRC will work with the engaged DCCs and help them install the proposed infrastructure as needed. Ideally, the DRC will employ a federated pull approach to extract the information from the DCCs that is as automated as possible without significant human involvement instead of a push model, which may involve manual work and can be error prone. If a push or hybrid model is proposed, applicants must provide a strong justification and rationale for the choice. Applicants need to describe and justify the approach (e.g., microservices such as APIs, schemas, data models, common data elements/data libraries) they will employ to set up the necessary infrastructure.

- CF programs produce widely divergent types of data, some of which are access controlled and/or reside in controlled access repositories. Applicants must describe their proposed approach to the collation of information about CF data sets that will be used in the query/search system. The description should include how the design might emphasize metadata and/or data level information, whether the proposed approach will be model, schema or common data element based, and, if applicable, justify why the proposed approach is more suitable than the C2M2 type metadata model-based approach. Applicants must describe and justify how the chosen approach will be able to address the needs of highly divergent data types (e.g., multiomics, image, assay, genomic, flow cytometry, survey, EHR, etc.) that are obtained for single cells, tissues, or organs, as well as patient reported outcomes and social determinants of health data.
- Created Data Resource Portal will enable the users to query for the CF data sets and tools and provide users the information about data sets identified in their query, including information about how to access the data sets. The employed search approach underlying the query system must be state-of-art and adaptable as search technologies advance and new novel search methods become available. Applicants must discuss how the installed query platform follows industry-recognized, best UX/UI practices, the employed search algorithms and methods have the necessary accuracy and sensitivity in addressing the user needs, and the deployed query platform is flexible enough to adapt and improve based on user feedback.
- Applicants must describe enabled search features with realistic examples that are reflective of biomedical researcher needs. Search elements shall include but are not limited to data type, assay type, sample type, species, anatomical site, disease, and gene.
- Describe how the Data Resource Portal will be evaluated by collecting system metrics and feedback from external users and how such information will be used to improve the Data Resource Portal. Describe and discuss the plans for the maintenance of and continuous improvements (e.g., adoption of new technologies) to the portal.
- The Data Resource Portal must allow the users to obtain information about the data sets identified and selected in their query and provide links to those data sets where the users can access and import them to workspaces. The Portal development team is expected to install Data Repository Service (DRS)-like microservices to link to the data set locations and employ NIH Researcher Auth Service (RAS) for controlled access data sets.
- Data and metadata generated by the CF programs are a mixture of open access and controlled access sets. Applicants must describe how the security and access issues for the controlled access data sets will be addressed, including linking to controlled-access data sets in repositories and ingesting and accessing such data sets in CFDE and other workspaces.
- The recipient will be responsible for Information Security of the created Data Resource Portal. Specifically, recipient-hosted information systems should maintain security controls in a way that is FISMA-equivalent. Describe the plans for how this will be achieved.

- **Form and advance a well-integrated ecosystem by providing leadership and guidance to standardize how metadata, data, and tools are handled and processed by the participating DCCs**

- A major responsibility of the DRC team will be coordinating the CFDE-wide activities related to metadata, data, and tools standardization, and providing leadership to such efforts. Applicants should describe their approach to standardization and team formation to address CFDE consortium-wide needs, including standardization of data sets, data set formats, metadata, ontology selection, models/schemas/data libraries, and approach to leadership project management, and team science.

- **Establish and maintain the necessary infrastructure that allows users to access the CF data sets and tools through the Data Resource Portal and allow the import of the select data sets to the CFDE cloud workspaces or other approved compute platforms**
  - The Data Resource Portal will be the site where users may discover and search for the available CF data sets and tools. Upon identifying data sets and/or tools of interest, users should be able to access and import those digital resources to a workspace/analysis platform in as direct and seamless manner as possible. CF generated data sets and tools reside in a variety of public repositories or in on-prem resources. Providing access requires containing the location and access information about the identified digital resources at the portal. Applicants should describe their approach to providing users access to the data sets and tools that they want to use, e.g., how the handshake with the user-preferred workspace/analysis platform will be supported, how the information about files and their locations (e.g., DRS) and user authorization and authentication (e.g., NIH RAS) will be managed.

- **Develop the necessary user manual and Frequently Asked Questions (FAQ) documentation, and offer training and help for the use of the portal by users with widely varying expertise and interests**
  - Wide usage of the CFDE Portal and the Data Resource Portal will require providing good documentation, manuals, tutorials, help desk, and outreach efforts. Applicants should describe how the developed platform will provide an environment where new and existing users can have a positive, productive experience using these portals, and can do so without encountering steep learning curves.
  - Working with the CFDE ICC and CT, the DRC team will be required to participate in community building efforts, prepare training materials, offer training on the use of the CFDE Portal and the Data Resource Portal, coordinate with the DCCs about their related training efforts, and partner with relevant NIH and external groups in outreach and training to increase the impact of CF programs. Applicants should describe how this will be achieved.

- **Develop implementation plans to seamlessly connect the knowledge integration platform that will be generated by the CFDE Knowledge Portal development team to the CFDE Portal**
  - Information contained in the data sets and knowledge products stemming from studies using those data sets are inherently linked. Even though CFDE may establish separate Data Resource and Knowledge Portals initially, the vision is to integrate and serve them through the CFDE Portal when they mature. Applicants should describe their plans and a high-level timeline to connect with the Knowledge Portal and how they will collaborate to eventually achieve the merger, and how the merged platform will serve the user community through CFDE Portal. Or, preferably, applicants should describe plans for how these two portals can be developed concurrently in an integrated manner from the start.

- **Organize and oversee relevant working groups and committees, and manage their meetings**
  - CFDE consortium wide efforts are often pursued under technical working groups or committees, which produce recommendations for consideration. These activities will mainly be managed by the planned ICC in collaboration with the DRC and KC. Applicants should describe their approach to forming and managing working groups/committees and experience in managing diverse groups of participants in handling such activities.

- **Serve as liaison with other relevant efforts, committees, and organizations within and outside the NIH (e.g., NIH Cross-Platform Interoperability (NCPI), NIH Research Auth Service (RAS), GA4GH, HL7, FHIR, OMOP, etc.).**
  - A major responsibility of the DRC team will be to coordinate and provide leadership for the standardization activities. This includes serving as CFDE's liaison in other relevant efforts, committees, and organizations within and outside the NIH. Applicants should describe their experience with such community-wide standardization efforts and their approach to serve as liaison for CFDE.

- **Provide recommendations to CFDE regarding the deployment of cloud workspaces**
  - The DRC implementation team is expected to work with the CFDE Cloud Workspace Implementation Center to allow integration of cloud workspaces into the portal structure and provide expertise in best practices as appropriate on key issues such as assessment of needs, optimization criteria, system security, resiliency requirements, and avoiding vendor lock-in through a hybrid approach.

2. Requirements – CFDE Knowledge Center

Main responsibilities of the CFDE Knowledge Center (KC) will be to establish a knowledge network ecosystem and to build the CFDE Knowledge Portal. The development work to establish the KC shall be pursued under the management and oversight of the Common Fund Other Transactions Program Official (OTPO), with scientific and strategic guidance from the CFDE Steering Committee (SC) composed of NIH staff and CFDE PIs. The KC team must effectively and productively collaborate with the CFDE investigators and the ecosystem's other components.

Expected responsibilities for building the KC and its Knowledge Portal include:

- **Create and maintain the Knowledge Portal, a knowledge integration platform that compiles and makes the knowledge generated by the CF programs available to the biomedical research community**
  - Create the Knowledge Portal that will enable users to learn about a knowledge network of the CF programs, the ongoing data and knowledge generation activities, data and tool products of CF programs to access and utilize knowledge, training and outreach materials, and opportunities. The design of the Knowledge Portal must emphasize the best UX/UI practices and target a very diverse spectrum of users ranging from clinicians to novice researchers and to well-established bioinformaticians and data scientists.
  - Establish the necessary infrastructure to receive, ingest, and collate the information from the participating Data Coordinating Centers (DCCs) about the knowledge generated in their programs. Such knowledge may be documented electronically as computer files and may be available in knowledge bases or knowledge graphs. Ideally, the KC will employ a federated pull approach to extract the knowledge information from the DCCs that is as automated as possible without significant human involvement instead of a push model, which may involve manual work and can be error prone. If a push or hybrid model is proposed, applicants must provide a strong justification and rationale for the choice. The KC will work with the engaged DCCs and help them install the proposed infrastructure as needed. Applicants need to describe and justify the approach (e.g., microservices such as APIs, schemas, data models, common data elements/data libraries) they will employ to set up the necessary infrastructure.
  - The Knowledge Portal will enable the users to query for CF generated knowledge. Applicants must describe how knowledge will be structured and stacked in the portal to make it searchable

in an efficient way. The employed search approach underlying the query system must be state-of-the-art and adaptable as search technologies advance and new and novel search methods become available. Applicants must discuss how: the installed query platform follows industry recognized best UX/UI practices, the employed search algorithms and methods have the necessary high accuracy and sensitivity in addressing the user needs, and the deployed query platform is sufficiently flexible to adapt and improve based on user feedback. Applicants must describe enabled search features with realistic examples that are reflective of biomedical researcher needs.

- Describe how the Knowledge Portal will be evaluated by collecting system metrics and feedback from external users and how such information will be used to improve the Knowledge Portal. Describe and discuss the plans for the maintenance of and continuous improvements (e.g., adoption of new technologies) to the portal.
- The Knowledge Portal must be designed to allow users to obtain the knowledge information identified and selected in their query and access and import it to cloud workspaces. In collaboration with the CFDE Portal development team (aka., CFDE DRC), the Knowledge Portal development team is expected to install DRS-like microservices to link to the knowledge resources and employ NIH RAS authentication and authorization services for controlled access knowledge. Applicants should describe their approach to how this will be achieved.
- The recipient will be responsible for Information Security of the created Knowledge Portal. Specifically, recipient-hosted information systems should maintain security controls in a way that is FISMA-equivalent. Describe the plans for how this will be achieved

- **Establish and maintain the necessary operating protocols for knowledge exchange, ingestion and use within CFDE and for linking to external, e.g., non-Common Fund, knowledge resources**
  - Knowledge can exist in multiple forms and formats and the best ways to combine knowledge cohesively and comprehensively is still an active area of research. A major responsibility of the KC team will be coordinating the CFDE-wide activities related to knowledge exchange, ingestion and use, as well as integrating CF-generated knowledge with knowledge that is externally available, e.g., non-Common Fund knowledge resources. Applicants should describe their approach to establish the necessary methods, approaches, and operating protocols for creating an integration platform to construct a knowledge network and its maintenance.
  - Knowledge platforms developed as part of CFDE can benefit by incorporating the knowledge made available by other complementary programs and resources. Applicants should describe how linkages to such resources will be established and details of the planning for how such knowledge incorporation and integration will be used to enhance and amplify the value of CF-generated knowledge.
  - CFDE has been supporting the development of knowledge graphs, knowledgebases, and knowledge networks through partnership projects among participating DCCs. These ongoing knowledge graph/base/network activities utilize Neo4j to contain and link the data assertions provided by DCCs. It uses the NIH Unified Medical Language System (UMLS) and several other supporting ontologies to help link concepts between assertions from the DCCs and describe their semantic relationships. These activities that integrate data and knowledge from the DCCs will enable complex inter-DCC queries, exploration, and discovery. Applicants should discuss whether the proposed approach will incorporate elements from these ongoing activities and describe how that will be accomplished. If a completely new approach and structure is proposed, applicants should justify the advantages of the proposed approach.

- **Form and advance a well-functioning knowledge ecosystem by providing leadership and guidance to standardize how knowledge generation pipelines and knowledge products are handled and processed by the participating DCCs**

- A major responsibility of the KC will be to provide leadership and help to coordinate the CFDE-wide knowledge network activities. This includes working with the DCCs of the CF programs to establish consensus on how knowledge is generated, documented, shared, and integrated. Additionally, standardization of the tools to process knowledge and make the products available for wider use among DCCs could be highly beneficial. Applicants should describe their approach to providing leadership to address such standardization needs of the CFDE consortium and discuss their approaches to effective team science, project management, and leadership.

- **Establish and maintain the necessary infrastructure that allows users to access CF generated knowledge through the developed platform and allow the import of the select knowledge assertions to the CFDE Workspaces or other approved compute platforms**
  - The Knowledge Portal will be the site where users may discover and search for the available knowledge generated and documented by the CF programs. Upon identifying knowledge information of interest, users should be able to access and import the discovered information and associated data sets to a workspace/analysis platform in as direct and seamless manner as possible. Applicants should describe their approach to working with the DRC (cf., Section 1) and Cloud Workspace Implementation teams to provide users access to the knowledge information they want to use.

- **Develop the necessary user manual and FAQ documentation, and offer training and help for the use of the knowledge platform by users with widely varying expertise and interests**
  - Wide usage of the Knowledge Portal will require providing good documentation, manuals, tutorials, help desk, and outreach efforts. Applicants should describe how they will provide a nurturing platform environment where new and existing users can have good experience using the Knowledge Portal, can learn about CF knowledge resources, and do so without encountering steep learning curves.
  - Working with ICC and CT, the KC team will be required to participate in community building efforts, prepare training materials related to knowledge handling, processing, and use, offer training on the use of CF knowledge resources, coordinate with the DCCs about their related training efforts, and partner with relevant NIH and external groups in outreach and training to increase the impact of CF programs.

- **Working with the CFDE Data Resource Center, develop implementation plans to seamlessly connect the knowledge integration platform to the CFDE portal**
  - Information contained in the data sets and knowledge products stemming from studies using those data sets are inherently linked. Even though CFDE may establish separate Data Resource and Knowledge Portals initially, the vision is to merge and serve them through the CFDE Portal when they mature (cf., Section 1). Applicants should describe their high-level plans and timeline to coordinate with the CFDE Portal development team in combining forces to eventually achieve the merger. Or, preferably, applicants should describe plans for developing the Knowledge Portal concurrently with the Data Resource Portal and the CFDE Portal in an integrated manner from the start.

- **Organize and oversee relevant working groups and committees, and manage their meetings**
  - CFDE consortium wide efforts are often pursued under technical working groups or committees, which produce recommendations for consideration. These activities will mainly be managed by the planned ICC in collaboration with the DRC and KC. Applicants should describe their approach to forming and managing working groups/committees and experience in managing diverse groups of participants in handling such activities.

- **Provide recommendations to CFDE regarding the deployment of cloud workspaces**
  - The KC implementation team is expected to work with the CFDE Cloud Workspace Implementation Center to allow integration of cloud workspaces into the portal structure and provide expertise in best practices as appropriate on key issues such as assessment of needs, optimization criteria, system security, resiliency requirements, and avoiding vendor lock-in through a hybrid approach.

3. Requirements – Integration of the Data Resource and Knowledge Portals into a unified Resource Portal

The Data Resource and Knowledge Portals' primary functions are, respectively, to enable user-friendly queries of CF data sets and knowledge products of the CF programs, and to provide access to data sets and knowledge information identified by respective queries. Applicants may form a team to apply to develop *both the Data Resource and Knowledge Portals* simultaneously or, preferably, as an integrated single *Resource Portal* platform from the start. However, as these two portals' structural and functional needs differ, it would be acceptable to establish them separately initially and then merge the Data Resource Portal and the Knowledge Portal into a single Resource Portal platform under the CFDE Portal as they mature. Therefore, the DRC and KC teams must work very closely.

If applicants form a team to apply to develop *both the Data Resource and Knowledge Portals,* the application should provide the details of the additional integration related responsibilities. However, applicants may apply to develop either the Data Resource Portal or the Knowledge Portal. In that case, the application should describe the plans for integration with the other portal and its timeline and discuss the expectations from the other portal for successful integration and potential mitigation strategies, especially those involving merging separate work products and work streams, communications, feedback, and scheduling deliverables. Required details for the milestones associated with integrating the Data Resource and Knowledge Portals include:

- **Plans for the Resource Portal that can accommodate both data set and knowledge-related information, allow for their query, and provide means to port the identified data sets and knowledge information to workspaces for use and further analysis**
  - Describe how disparate data sets and knowledge information will be (if applying for both Centers) or can be (if applying for a single Center) handled in the combined Resource Portal and discuss what types of representations will be utilized to combine them for increased impact.
  - Describe whether separate or unified search mechanisms and methods will be (if applying for both Centers) or can be (if applying for a single Center) used and discuss their appropriateness. Describe the plans for making the search results for data sets and knowledge available to the users, the strengths of the proposed approaches, and appropriateness for the best UX/UI experience.
  - Describe the novelty of the proposed approach for seamless integration of the data sets and knowledge components. Describe the expected added benefits of the integrated Resource Portal.
  - Describe the timeline of the integration process, decision points, and how go/no go decisions will be made.
  - Describe how the Resource Portal will be evaluated by collecting system metrics and feedback from external users and how such information will be used for its improvements. Describe and discuss the plans for the maintenance of and continuous improvements (e.g., adoption of new technologies) to the Resource Portal.

4. Eligible Organizations

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

Non-domestic components of domestic organizations **are not** eligible.

Foreign components, as defined in the *NIH Grants Policy Statement*, **are** allowed.

Any public or private non-domestic entity is ineligible to apply for this program as a primary applicant. Additionally, any non-domestic components of U.S. Organizations are ineligible to apply for this program as a primary applicant. Public or private non-domestic entities and non-domestic components of U.S. Organizations are eligible to be listed as sub-contractors/recipients, so long as, they are not excluded from applying for Federal programs throughout the U.S. Government (unless otherwise noted) and from receiving certain types of Federal financial and nonfinancial assistance and benefits.

Applicant organizations may submit more than one application, provided that each application is scientifically distinct. Individuals not affiliated with an organization, or who want to submit an application independently of their current organization, **may not** apply.

The following entities are eligible to apply under this ROA:

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)
- Faith-based or Community-based Organizations
- Regional Organizations

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

Governments
- State Governments
- County Governments
- City or Township Governments
- Special District Governments
- American Indian/Native American Tribal Governments (Federally Recognized)

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

Other
- Independent School Districts
- Native American Tribal Organizations (other than Federally recognized tribal governments)

5. Eligibility Requirements

A successful CFDE DRC and/or KC application will include teams of individuals with expertise in the following:
- Hands-on working experience in biomedical data and knowledge resources and their use
- Understanding of the needs of biomedical research and the wider user community in finding, accessing, and using biomedical data and knowledge
- Development and management of biomedical data resources and tools
- Portal development and management using best research software development practices, and experience in developing platforms with good UX/UI
- Management and security of biomedical research data (e.g., genomics, other omics, phenotypic and clinical data, imaging)
- Multi-cloud computing
- Interoperability solutions (e.g., APIs or other microservices, data standards and ontologies, portable workflow languages)
- Computer and biomedical data security (e.g., single sign-on, multi-factor authentication and authorization, audit logging, data de-identification, privacy preserving computation)
- Development and delivery of data science training, particularly cloud-based training
- Administration and project management of complex biomedical research projects involving federated teams

NOTE 1: Since the CFDE DRC and KC teams will be directly interacting with the Integration and Coordination Center (ICC) for CFDE, a PI/MPI will **not be** eligible to serve as the PI/MPI for both i) the DRC and/or KC and ii) the ICC awards. If an application to this ROA is selected for award, the PI/MPIs for that application will be **ineligible** to serve as PI/MPI of the ICC award, which is being planned for competition. PIs/MPIs who have questions concerning their eligibility **must** contact the CFDE NIH team to clarify their eligibility before applying.

NOTE 2: Applications proposing live vertebrate animals research, human subjects research, and/or clinical trials are not allowed. Specific data and/or knowledge integration projects may involve the use of human data, and must comply with all applicable laws and policies, including IRB review.

6. Multiple Principal Investigators and Partnerships among Applicants' Institutions

More than one individual may be named as Principal Investigator (PI) in the application. One individual must be identified as the contact Principal Investigator. The contact PI and all other individual PIs must each commit at least 10% level of effort to the proposed project. The contact Principal Investigator must

be employed by or affiliated with the applicant organization. ***If a multiple Principal Investigator (MPI) proposal is submitted, an MPI Leadership plan is required.***

Partnerships among institutions with investigators having complementary skills and expertise to meet the requirements of this ROA are not required but are allowed.

7. Project Manager/Director (PM/PD) Requirement

NIH expects the proposed project to include an individual that will serve as the PM/PD for the project, with the appropriate scientific expertise and project management responsibilities, who would support the PI(s) with project management and organizational oversight. Such individual should commit at least 50% level of effort to the project.

8. Financial and Risk Assessment

Applicants may be subject to financial analysis and risk assessment conducted by NIH staff.

9. Cost Sharing

Cost Sharing is not required but may be proposed. Those proposing to develop commercial applications or who are using other state or government resources may consider identifying a cost share percentage. Applicants may voluntarily choose to propose a financial plan that includes non-federal resources. The budget submission must clearly identify and justify the use of these resources. Any voluntary cost share must be supported in the application by including a letter of support from the providing organization(s)/individual(s). Inclusion of cost sharing will have no influence in application selection.

10. Developing Applications

10.1 Application Submission Instructions

Complete applications must be submitted under **OTA-23-004** via NIH eRA Commons ASSIST no later than the "***Proposal Due Date***" shown at the top of this notice, by 5 PM local time of applicant organization. Late applications submitted to this ROA will not be accepted.

For further information, please consult the FAQ page: https://commonfund.nih.gov/dataecosystem/faqs

Questions about the scientific scope of this announcement should be addressed to: CFDE@od.nih.gov

Letters of Intent (LOIs), due by the "***Letters of Intent Due Date***" shown at the top of this notice, are strongly recommended but not required.

NIH may also share, with PI's and recipient's business official's approval, applications between or among other applicants to ensure optimal configuration of funding, partnerships, and activities. For more details on the review process, see the **Objective Review** section below.

10.2 Letter of Intent

Interested applicants may submit a Letter of Intent (LOI) of no more than 4 pages with sections outlining the following:

- A Project Information Summary page (2 pages) as described below for the full application, which includes the name and email addresses for the Contact PI and the Recipient Business Official/Signing Official.
- A brief description of how the PI(s), their institutional affiliations, and teams meet the eligibility requirements stated above (1 page).
- An overview of the planned activities and approach (1 page maximum).

LOIs will be reviewed by NIH staff only to assess eligibility and to identify conflicts of interest for potential reviewers. ***NIH will not be providing feedback about the scientific and technical content for improvements***. Letters of intent must be submitted by email as a PDF attachment to CFDE@od.nih.gov. LOIs submitted by other means may not be considered.

10.3 Full Application

Applications will be accepted only from entities listed in the Eligible Organizations section of this Announcement, who meet the criteria listed in the Eligibility Requirements. Applications submitted from organizations not included in the Eligibility section will not be reviewed. Applications must be prepared and submitted using NIH's eRA ASSIST. Complete applications must be submitted by the Authorized Business Official. The organization must be registered in eRA Commons with one person designated as the contact principal investigator (PI) and one person designated as the Signing Official (SO). Registration process can take a long time, so applicants should begin the registration process as soon as possible. Failure to complete registrations in advance of the due date is not a valid reason for a late submission. The SO's signature certifies that the applicant has the ability to provide appropriate administrative and scientific oversight of the project and agrees to be fully accountable for the appropriate use of any funds awarded and for the performance of the OT award-supported project or activities resulting from the application.

Full applications must include the following components (page limit in parenthesis):

- **Abstract:** Provide a summary of the planned activities and approaches and key achievable goals (1 page)

- **Specific Aims:** Provide a narrative describing the rationale and significance of the planned project (1 page).

- **Project Information Summary** (2 pages): Provide the information about (note: do not upload this into the "Cover Letter Attachment" field in the ASSIST form but provide it as part of the Attachments section in the form):
  - Project Title
  - Number and title of this Research Opportunity Announcement
  - Principal Investigator(s) first and last name, title, institution, mailing address, email address, and phone number. If multiple Principal Investigators are named, the Contact Principal Investigator must be clearly identified.
  - Name and address of the submitting organization and department, if any, with the organizational

Unique Entity Identifier (UEI) number and employment identification number (EIN) provided.
  - Recipient Business Official/Signing Official first and last name, title, institution, mailing address, email address and phone number
  - Proposed budgets per year for 5 years (direct, indirect and total costs)
  - Proposed project period dates
  - Full names (last name, first name) of all key personnel, institutional affiliation, title, and percent effort
  - Confirmation that the work does not involve human subjects or vertebrate animals
  - Agreement that any or all parts of the application can be shared among other applicants.

- **Project Plan:** A full description of the planned activities and approaches (up to 8 pages total if applying to establish one of the Centers; up to 12 pages total if applying to establish both Centers) including:
  - A list of goals and the potential impact of the work to be done if it were successfully implemented
  - Advantages and strengths of the proposed approaches
  - Examples illustrating the experience and past successes of the project team and team members in similar infrastructure building projects
  - Discussion of potential risks and alternative plans for resolving them
  - Plans for partnering with the other CFDE components, e.g., working with other CFDE Centers, support of working groups, plans for supporting training, outreach and other community building activities
  - Plans for partnerships with complementary non-CFDE programs (e.g., other NIH programs, non-NIH programs)

- **Leadership Plan** (up to 3 pages total):
  - Organizational and reporting structure, and personnel responsibilities
  - Relevant past performance for the team working in and leading large projects and across teams (labs, companies, consortia) and any prior experience of the team working together
  - Describe how the proposed team meets the eligibility requirements stated above
  - Multiple Principal Investigator (MPI) Leadership Plan, if applicable.

- **Milestones and Deliverables** (up to 10 pages): The expected initial project duration is 5 years. Provide a list of detailed milestones and deliverables for the first year and high-level milestones and deliverables for years 2 -5. See Section 10.5 below for additional information on how this document should be prepared. A Gantt chart to illustrate the dependencies between the project milestones and project schedule should be provided and identified risks and their mitigation plans should be discussed.

- **Key Personnel and Biosketches** (biosketches are limited to maximum 3 pages per individual): Provide a list of PI(s), PM/PD, Key Personnel, other significant contributors and their proposed level of effort, as well as the biosketch of each named key individual. The information in the biosketch should include the name and position title, education/training (including institution, degree, date (or expected date), and field; list of positions and employment in chronological order (including dates); list of relevant publications, proposed level of effort and a personal statement that briefly describes the individual's role in the project and why they are well-suited for this role. Providing successful examples from past work on similar infrastructure building projects as appropriate to illustrate the relevant experience is desired. The format used for an NIH grant application is acceptable: https://grants.nih.gov/grants/forms/biosketch.htm.

- **Equipment and Facilities** (up to 2 pages): Provide the information about the equipment and other physical resources available to the project team to adequately complete the project milestones.

- **Institutional Letter of Support** (up to 2 pages): A letter of support from the applicant's organization indicating institutional commitment for the project (e.g., relaying support for contributions, including, but not limited to, support for training activities or consortium meetings, licenses, and other resources) and preparations to enter into a negotiated Other Transaction Agreement.

- **Budget and Budget Justification** (no page limitation): All applications should provide detailed budget information for planned activities and partnerships, as further described below (cf. Sections 10.4 and 10.5). Procurement of hardware, data, cloud computing, and the development of software capabilities to support the proposed activities are allowable costs. ***If an applicant is applying to both centers, the budgets for the centers should be clearly delineated and budget for each center should be provided, described, and justified separately.***

- **Bibliography** (no page limitation).

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

- **Data Management and Sharing Plan:** All applications, regardless of the amount of direct costs requested for any one year, must address a Data Management and Sharing Plan.

- **Plan for Enhancing Diverse Perspectives (PEDP)** (1 page): All applicants must include a summary of strategies to advance the scientific and technical merit of the proposed project through expanded inclusivity. Broadly, diverse perspectives can refer to the people who do the research and the places where the research is done, as well as who participates in the research as part of the study population. The PEDP should provide a holistic and integrated view of how enhancing diverse perspectives is viewed and supported throughout the application and can incorporate elements with relevance to any review criteria as appropriate. The PEDP will be considered a part of the scientific and technical merit of the proposed project and assessed as part of the scientific evaluation in making funding decisions consistent with applicable law.

  The PEDP will vary depending on the scientific aims, expertise required, the environment and performance site(s), as well as how the project aims are structured. Where possible, applicant(s) should align their description with the required elements within the research strategy section. The PEDP should include a timeline and milestones for relevant components. Examples of items that advance inclusivity in research and may be part of the PEDP can include, but are not limited to:
  - Discussion of engagement with different types of institutions and organizations (e.g., research-intensive, undergraduate-focused, minority-serving, community-based).
  - Description of any planned partnerships that may enhance geographic and regional diversity.
  - Plan to develop transdisciplinary collaboration(s) that require unique expertise and/or solicit diverse perspectives to address research question(s).
  - Outreach and planned engagement activities to enhance recruitment of individuals from diverse groups as participants including those from under-represented backgrounds.
  - Plan to ensure equitable dissemination of data, tools, and products to all end users.

  The PEDP must include the following:
  - Description of defined activities and actionable strategies for the inclusion of diverse

perspectives in the project
- Description of how the PEDP will bring unique advantages or capabilities to the project
- Milestones or other metrics for the evaluation of PEDP activity progress and success
- Proposed monitoring activities to identify and measure PEDP progress benchmarks.
- Anticipated timeline of proposed PEDP activities.

While applicants may discuss prior activities, the PEDP should emphasize efforts and contributions that directly relate to the proposed project. Additional information and FAQs about the PEDP are available on the program website at https://commonfund.nih.gov/dataecosystem/faqs .

Additional letters of support will not be considered during review process. Please do not include letters of support in the application beyond the required institutional letter of support.

Application Format: Applications must be prepared using 11-point font with 1" margins and be single-spaced. Use of graphics and images is allowed, although proposals deemed to be using images to bypass the font and margin requirements may be administratively withdrawn. The use of hyperlinks is strictly prohibited.

10.4 Budget details

The Common Fund may allocate up to $3,000,000 for the first-year total (direct + F&A) costs for these two centers. The level of funding for awards made under this solicitation and how funds may be split between the Data Resource and Knowledge Centers has not been predetermined. The funding split will depend on (1) the objectives for the centers proposed by the applicants and how well they fit with the goals of CFDE, (2) the quality of the applications received, (3) availability of funds and (4) programmatic priorities. First-year funding for either the DRC or the KC individually is not expected to exceed $1,750,000 total costs, with no more than $3,000,000 total for both awards

The NIH may elect to negotiate any or all elements of the proposed budget.

Institutions with an established Facilities and Administrative (F&A) rate should use their federally approved rate to calculate indirect costs for non-compute expenses.

Indirect costs for cloud computing expenses in any application funded under this OT mechanism will be capped at a rate of ten (10) percent.

F&A costs on foreign -component will be reimbursed at a rate of eight (8) percent of modified total direct costs, exclusive of tuition and related fees, direct expenditures for equipment, and subawards in excess of $25,000.

In ASSIST Core tab, applicants should enter the total dollar number in the field of **Total Requested Funds.** For budget details, applicants shall download the form from https://commonfund.nih.gov/OTforms and then complete SF424 budget forms on their own computers instead of in internet browsers. The prime applicant is responsible for including all third parties' budget and budget justification. In order to successfully upload budget forms as an attachment into ASSIST, the applicant should flatten the fillable PDF. There are a number of methods to flatten a PDF, the easiest of which is to print it as a PDF. To do this, go to File>Print, select the printer option from the menu that has says PDF, such as "Adobe PDF". Depending on the software available to applicant, the specific option may vary but should contain "PDF". Click the Print button and name the file. This will "print to a PDF"

and the file will be flattened.

The detailed budget request should provide the overall expected cost for each of the following categories: personnel, equipment, travel, funds for third parties (i.e., subrecipients), if applicable, other direct costs, and total cost (with indirect costs included). *The key Center team members must travel to attend CFDE-wide meetings (twice annually) and actively participate in consortium-wide working group and committee activities.* Costs associated with these activities must be appropriately reflected in the proposed budget.

Budget justification must be provided for all budget items.

If an applicant is applying to both centers, the budgets for the centers should be delineated and budget for each center should be provided, described, and justified separately.

Budgets must adhere to latest NIH salary limitation notice (See Salary Cap Summary/Guidance on Salary Limitation for Grants and Cooperative Agreements). https://grants.nih.gov/grants/guide/notice-files/NOT-OD-23-056.html

Subrecipients are required to provide details of cost breakdown. Prime recipient should follow their internal policies and procedures to calculate subrecipient's budget.

10.5 Milestones and Deliverables

The expected initial project duration is 5 years. Given the dynamic nature of CFDE, **applicants must provide detailed description of the goals, milestones and deliverables for the first year.** Provided details should include the goal of the milestone, its deliverables, completion criteria, due dates, how success is defined for a given milestone (e.g., Go/No-Go criteria), and payment/funding schedule. An *example template* is provided below for reference. **Applicants must also provide the goals, milestones and deliverables for years 2-5.** Details for the latter may not be as extensive, however, enough details should be provided such that the overall goals and aims of the project over the five-year period can be properly assessed in the review. For years 2-5, budget by milestone is optional and not required, but a total yearly budget estimate is required.

Applicants should plan such that key team members attend the mandatory in person CFDE PI meetings, twice a year. Similarly, the Center members are expected to participate in and often lead the technical working groups and committees, which needs to be considered in planning the project and personnel involvement.

Example table of milestones and deliverables:
Note 1: Applicants must ensure that the total budget request (cf. Sections 10.4 and 10.3) is consistent with the sum of item budget estimates in Milestones and Deliverables table for the project.
Note 2: Provided costs for the task should include all the costs for personnel, equipment, facilities, other resources, travel, and other associated costs.
Note 3: Total cost (direct and indirect) for the tasks should be provided.

Milestone	Tasks/ Subtasks	Due Date (Months after award)	Milestone Definition	Estimated total (direct and indirect) cost for the task
1	1.1	3	Milestone Name/Description • Bulleted list of tasks completed • Bulleted list of deliverables (including data sharing) • Completion criteria for the task • Potential risk factors and decision points	$10,000
1	1.2	3	Milestone Name/Description a. Bulleted list of tasks completed b. Bulleted list of deliverables (including data sharing) c. Completion criteria for the task d. Potential risk factors and decision points	$10,000
2	2.1	6	Milestone Name/Description 1. Bulleted list of tasks completed 2. Bulleted list of deliverables (including data sharing) 3. Completion criteria for the task 4. Potential risk factors and decision points	$10,000

10.6 Systems Registration

Applicants **invited** to submit a full application must submit via the NIH eRA Commons ASSIST system by 5:00 PM local time on the due date (see Key Dates below). Use OTA-23-004 in the Funding Opportunity Announcement field. Here are instructions for submitting via the NIH eRA ASSIST system. Technical assistance is available from the eRA Service Desk.

To submit a full application via ASSIST, the applicant organization must be registered in eRA Commons (See Submission Instructions). If you are invited to submit a full application, you must be registered in eRA Commons, which may take six (6) weeks or more to complete, applicants should therefore begin the registration process as soon as possible.

On the eRA Commons home page, select the "Register Organization" link for more details.

To complete registration, if you have not done so already, you may need to register for the following:

•System for Award Management (SAM) – Applicants must complete and maintain an active registration, which requires renewal at least annually. The renewal process may require as much time as the initial registration. SAM registration includes the assignment of a Commercial and Government Entity (CAGE) Code for domestic organizations which have not already been assigned a CAGE Code.

•Unique Entity Identifier (UEI)- A UEI is issued as part of the SAM.gov registration process. SAM registrations prior to fall 2021 were updated to include a UEI. The same UEI must be used for all registrations, as well as on the other transactions application.

•eRA Commons - Once the unique organization identifier (UEI after April 2022) is established, organizations can register with eRA Commons in tandem with completing their full SAM and Grants.gov registrations; all registrations must be in place by time of submission of the full application. 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.

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 guidance.

11. Objective Review

The intent of the objective review for the CFDE Data Resource and Knowledge Centers is to determine whether the proposed activities meet the goals and vision of CFDE for these centers.

Proposals to Other Transactions Research Opportunity announcements such as this one, are not reviewed by the standard NIH peer review process, but using custom processes referred to as Objective Review. Responsive, full applications submitted in response to the solicitation, will be reviewed by subject matter experts via an objective review process. Objective review will involve the submission of written critiques by subject matter experts against the Review Criteria described below, and interactive individual discussions between those experts and NIH program staff. The subject matter experts will include NIH staff, other federal staff, and may include individuals external to federal government. The review will facilitate further dialogue between select applicants, subject matter experts and NIH program staff so that applications are improved by the review process. Components of the full applications may be accepted into the final plan in whole, in part, or may be omitted. The outcome of each review could result into a modified work plan for each proposal based on reviewers' comments and recommendations. The modified workplan, as shaped by the review process, will serve as a blueprint for the final negotiated terms and milestones for the resulting awards.

NIH will NOT provide feedback on proposals, except as a part of follow-up on an as-needed basis.

NIH will not accept an appeal of the objective review or funding decision outcomes.

Review of Full Applications

Full proposals will undergo objective review by subject matter experts including NIH federal employees, federal employees of other agencies, and outside experts, as needed.

The Overall Impact will be assessed by the four Scored Review Criteria and Additional Review Criteria outlined below:

Scored Review Criteria

Applications will receive a cumulative score that may range between 0 (worst score) - 50 (best score). The following individual review criteria and their scores will contribute to the final cumulative score.

- Reasonableness and merit of the proposed plans and approaches (max 25 points)
  - To what extent are the planned activities likely to advance the goals of the CFDE program and successfully address the primary tasks listed in Sections 1-3 above, as applicable to the proposed center(s)

- Adequacy of the milestones and deliverables, and their timeline for fulfilling the planned activities and primary tasks of the project
- Ability to identify and mitigate technical and management risks
- Adequacy of the PEDP
- Plan for and/or documentation of ability to meet the necessary FISMA-equivalent information security compliance.

- Appropriateness of the key personnel (max 15 points)
  - Is the expertise, demonstrated capabilities, and past performance of the PI(s), PM/PDs, and key personnel appropriate for the proposed activities and successful execution of the proposed complex program? Is the necessary expertise illustrated, documented, and shown adequately with relevant examples from past work?
  - Are the leadership plan and the multiple PI (if applicable) plans appropriate? Is the organizational and reporting structure appropriate? What expertise, if any, is missing from the team?
  - Is there adequate Project Management and administrative support to ensure effective execution and monitoring of activities necessary to complete the project milestones?

- Appropriateness of the equipment and facilities, and other resources (max 5 points)
  - Are the proposed facilities, computing infrastructure, backup plans, physical security of any data, communication networks, relevant other equipment, and project management tools adequate to support the successful execution of the proposed program?
  - Are the plans for replacing, maintaining, and repairing equipment appropriate?

- Appropriateness of the proposed budget (max 5 points)
  - Is the proposed budget reasonable and commensurate with the proposed work?
  - Are there any areas where less funding is needed or where more funding would improve the overall impact?

As needed, the program may follow up with top-scoring applicants by allowing them an opportunity to respond to the weaknesses identified by the objective review, and any additional concerns identified by NIH program staff. Interviews may be conducted if appropriate. A funding decision will be made based on the results of the review and any the subsequent responses from the applicants. **NIH will NOT provide feedback on proposals, except as a part of follow-up on an as-needed basis**.

Post-review Funding Plan

NIH intends to fund one award each for the CFDE Data Resource Center and Knowledge Center but may fund a single award if an application proposing to build both centers is selected. However, the actual number of awards will depend in on the availability of funds and on how the objectives proposed by the applicants fit the goals of CFDE.

The level of funding for awards made under this solicitation and how funds may be split between both centers has not been predetermined and will depend on (1) the objectives for the centers proposed by the applicants and how well they fit with the goals of CFDE, (2) the quality of the applications received, (3) availability of funds and (4) programmatic priorities. The OT mechanism allows for significant flexibility to make budget adjustments as needed to meet NIH's programmatic priorities. Award levels may increase or decrease over time based on funding availability, establishment or termination of sub-contracts, recipient performance, and other program priorities.

Following the review of applications, NIH may assemble teams from all or parts of applications to

establish the CFDE Data Resource Center (DRC) and Knowledge Center (KC), or an application proposing to build both centers may be selected for funding. Individual components from distinct applications may be selectively funded to achieve the goals set forth herein. Additionally, if, over the duration of the project, some of the components either gain relevance or lose relevance to programmatic goals, the funding for such components may be increased, decreased, or discontinued.

At any relevant point in the process, including the objective review, NIH reserves the right to:

1) Invite all, some, one, or none of the Principal Investigators (PIs) submitting applications in response to this solicitation to present their application in a Web-based videoconference or a teleconference
2) Share applications between and among any proposer(s) as necessary for configuring teams, economizing work, and prioritizing activities
3) Select for negotiation all, some, one, or none of the applications received in response to this solicitation
4) Accept applications in their entirety or to select only portions of the proposal for award.

Appeals of the objective review will not be accepted for applications submitted in response to this ROA.

12. Application Timeline

Key Events	**Receipt Dates**	**Action needed by Applicants**
Research Opportunity Announcement (ROA) posted	March 28, 2023	Submit inquiries to CFDE@od.nih.gov
Informational Webinar	April/May 2023	Webinar information and its date will be posted on the Frequently Asked Questions website
Submission Deadline for Letters of Intent (LOI)	April 28, 2023	Submit to CFDE@od.nih.gov
Submission Deadline for Full Applications from invited applicants	May 30, 2023	Submit to ASSIST; **late applications wil NOT be accepted**
Award Negotiations expected to begin	June 12, 2023	Respond to written inquiries; attend videoconferences or teleconferences as requested
Earliest Start Date	August 1, 2023	

13. Special Award Terms and Information

NIH Discretion

The OT award mechanism allows significant ongoing involvement from NIH Program and Project Managers and OT Agreements Officer and Agreements Staff and provides the NIH the flexibility to alter the course of the project in real-time to meet the overarching goals. This may mean an awarded activity could be expanded, modified, partnered, not supported, or discontinued based on program needs, emerging methods or approaches, performance, or availability of funds.

Performance during the award period will be reviewed on an ongoing basis and course corrections will be made, as necessary. As a result, the NIH reserves the right to:

1. Fund projects in increments and/or with options for continued work depending on agreed upon milestones
2. Fund projects of two or more entities (potentially across different applications) as part of a reorganized collaboration, teaming arrangement, or other means acceptable to the government
3. Request additional documentation (certifications, etc.), and
4. Remove participants from award consideration should the parties fail to reach a finalized agreement by addressing the concerns identified in the objective review, and any additional concerns identified by NIH program staff, or the proposer fails to provide requested additional information in a timely manner.

Applications selected for award negotiation may result in the issuance of an OT award based on the nature of the work proposed, the required degree of interaction between parties, and other factors. The NIH reserves the right and sole discretion to engage in negotiation with the selectees submitting a full application under this solicitation.

Award Governance

The NIH will actively engage with awardee(s) to establish a vision and capabilities for the CFDE program and to oversee the effort of the awardees to achieve the vision.

NIH Roles and Responsibilities:

- Other Transactions Agreements Officer (OTAO): NIH representative responsible for legally committing the government to an OT award and to the agreement through which terms and conditions are established, and for the administrative and financial aspects of the award. The OTAO is the focal point for receiving and acting on requests for NIH prior approval and is the only NIH official authorized to change the funding, duration, or other terms and conditions of award.
- Other Transactions Agreements Specialist (OTAS): A designee of the OTAO for administrative and financial aspects of the award.
- Other Transactions Program Official (OTPO): Individual within NIH who provides day-to-day programmatic oversight of individual awards, working closely with the OTAO. The OTPO ensures the successful implementation of the CFDE program by integrating input from the OSC leadership, CFDE Program Management Team, CFDE Steering Committee, internal Technical Working Group of Project Scientists, and other stakeholders to create, adjust, or remove milestones. The OTPO evaluates and reviews strategic planning activities and recommends approval and acceptance of deliverables to the OTAO.

OT Agreement Governance

Other Transactions (OT) are a special type of legal instruments other than contracts, grants or cooperative agreements. Generally, these awarding instruments are not subject to the FAR, nor grant regulations unless otherwise noted for certain provisions in the terms and conditions of award. They are, however, subject to the OT authorities that govern the initiative and/or programs as well as applicable legislative mandates. The NIH and its components, including OSC, have been authorized by Congress to use them. They provide considerable flexibility to the government to establish policies for the awards, so the policies and terms for individual OT awards may vary between awards. Each award is therefore issued with a specific Agreement, which is negotiated with the recipient and details terms and conditions for that specific award. Program and administrative policies and the terms and conditions of individual awards are intended to supplement, rather than substitute for, governing statutory and regulatory requirements. Awards or a specified subset of awards also may be subject to additional requirements, such as those included in executive orders and appropriations acts (including the other transaction legislation cited in the Agreement), as well as all terms and conditions cited in the Agreement and its attachments, conditions on activities and expenditure of funds in other statutory or regulatory requirements, including any revisions in effect as of the beginning date of the next funding segment. The terms and conditions of the resulting OT awards are intended to be compliant with governing statutes.

For the awards funded under this ROA, the NIH will engage in negotiations (before, during, and at the end of award) and all agreed upon terms and conditions will be incorporated into the Agreement. Either a bilateral agreement or a Notice of Award (NoA) will be used as the official Agreement. The signature of the Signing Official will certify that the organization complies, or intends to comply, with all applicable terms and conditions, policies, and certifications and assurances referenced (and, in some cases, included) in the application instructions.

Reporting and Project Meetings

The terms and conditions of award will address this criterion as appropriate based upon the final negotiated terms and agreed upon budget.

The recipient and key project team members will be required to:

- Participate in an initial virtual kick off meeting with NIH staff and CFDE stakeholders.
- Participate in site visits or reverse site visits as deemed necessary by the OTPO.
- Participate in bi-weekly virtual progress meetings with NIH staff to ensure program continues to achieve objectives and to discuss progress and strategies. The meeting frequency may be adjusted at the discretion of the NIH program staff to maximize the probability of successfully meeting milestones.
- Submit written quarterly (or more frequent if there is a change of scope) budget and milestone reports.
- Attend CFDE-wide consortium meetings in-person (twice annually)
- Actively participate in consortium-wide working group and committee activities.
- i-Edison: Agreement terms and conditions will contain a requirement for patent reports and notifications to be submitted electronically through the i-Edison Federal patent reporting system at https://www.nist.gov/iedison.

Costs associated with these activities must be appropriately reflected in the proposed budget.

Indirect Costs

Indirect costs that are suitable under the regular NIH policies are allowed.

Institutions with an established Facilities and Administrative (F&A) rate should use up to their Federally approved indirect rate to calculate indirect costs for non-compute expenses.

Indirect costs for compute expenses in any application funded under this OT mechanism will be capped at a rate of ten (10) percent.

F&A costs on foreign components will be reimbursed at a rate of eight (8) percent of modified total direct costs, exclusive of tuition and related fees, direct expenditures for equipment, and subawards in excess of $25,000.

Additional information about budgetary details can be found in Section 10.4.

Enjoined Collaborations

While the intent is to select a single applicant each for the CFDE Data Resource Center and Knowledge Center to carry out the work outlined in this ROA, elements from two or more proposals may, if effectively combined, offer the best solution. In that case, an attempt will be made to negotiate with multiple applicants to assess the feasibility of a joint effort.

Third Parties

With mutual consent of the recipient and the NIH, the CFDE may be expected to issue third party awards to entities identified and approved by the NIH.

Management Systems and Procedures

Recipient organizations are expected to have systems, policies, and procedures in place by which they manage funds and activities. Recipients may use their existing systems to manage OT award funds and activities as long as they are consistently applied regardless of the source of funds and across their business functions. To ensure that an organization is committed to compliance, recipient organizations are expected to have in use clearly delineated roles and responsibilities for their organization's staff, both programmatic and administrative; written policies and procedures; training; management controls and other internal controls; performance assessment; administrative simplifications; and information sharing

Financial Management System Standards

Recipients must have in place accounting and internal control systems that provide for appropriate monitoring of other transaction accounts to ensure that obligations and expenditures are congruent with programmatic needs and are reasonable, allocable, and allowable. A list of unallowable costs will be included in the terms and conditions of the award. In addition, the systems must be able to identify unobligated balances, accelerated expenditures, inappropriate cost transfers, and other inappropriate obligation and expenditure of funds, and recipients must notify NIH when problems are identified. A recipient's failure to establish adequate control systems constitutes a material violation of the terms of the award.

Property Management System Standards

Recipients may use their own property management policies and procedures for property purchased, constructed, or fabricated as a direct cost using NIH OT award funds. The terms and conditions of award will address this criterion as appropriate based upon the final negotiated and agreed upon budget. Procurement System Standards and Requirements Recipients may acquire a variety of goods or services in connection with an OT award-supported project, ranging from those that are routinely purchased goods or services to those that involve substantive programmatic work. Recipients must acquire goods and services under OT awards in compliance with the organizations established policies and procedures. The terms and Conditions of award will address this criterion as appropriate based on the final negotiated and agreed upon budget.

Organizational Conflicts of Interest (OCIs)

Applicants are required to identify and disclose all facts relevant to potential OCIs involving subrecipients, consultants, etc. Under this section, the proposer is responsible for providing this disclosure with each Detailed Plan. The disclosure must include the PI/Collaborators', and as applicable, proposed member's OCI mitigation plan. The OCI mitigation plan must include a description of the actions the proposer has taken, or intends to take, to prevent the existence of conflicting roles that might bias the proposer's judgment and to prevent the proposer from having an unfair competitive advantage.

The government will evaluate OCI mitigation plans to avoid, neutralize, or mitigate potential OCI issues before award issuance and to determine whether it is in the government's interest to grant a waiver. The government will only evaluate OCI mitigation plans for proposals that are determined selectable. The government may require applicants to provide additional information to assist the government in evaluating the proposer's OCI mitigation plan. If the government determines that a proposer failed to fully disclose an OCI or failed to reasonably provide additional information requested by the government to assist in evaluating the proposer's OCI mitigation plan, the government may reject the Detailed Plan and withdraw it from consideration for award.

Monitoring

Recipients are responsible for managing the day-to-day operations of OT award-supported activities using their established controls and policies. However, to fulfill their role in regard to the stewardship of federal funds, the program team will monitor their OT awards to identify potential problems and areas where technical assistance might be necessary. This active monitoring is accomplished through review of reports and correspondence, audit reports, site visits and other information, which may be requested of the recipient. The names and contact information of the individuals responsible for monitoring the programmatic and business management aspects of awards will be provided to the recipient at the time of award.

Monitoring of a project or activity will continue for as long as NIH retains a financial interest in the project or activity as a result of property accountability, audit, and other requirements that may continue for a period of time after the OT award is administratively closed out and NIH is no longer providing active OT award support.

Record Retention and Access

For OT awards, the 3-year record retention period will be calculated from the date of the Federal Financial Report (FFR) for the entire competitive segment is submitted. Therefore, recipients must retain the records pertinent to the entire competitive segment for 3 years from the date the FFR is submitted to NIH. If any litigation, claim, financial management review, or audit is started before the expiration of the 3-year period, the records must be retained until all litigation, claims, or audit findings involving the records have been resolved and final action taken. These record retention policies apply to both paper and electronic storage of applicable information, including electronic storage of faxes, copies of paper documents, images, and other electronic media.

Audit

NIH OT recipients for the Program are subject to the audit requirements of OMB 2 CFR 200, Subpart F-Audit Requirements, as implemented by DHHS 45 CFR Subpart F. In general, 45 CFR 75, Subpart F-Audit Requirements requires a state government, local government, or non-profit organization (including institutions of higher education). Please consult the provisions within Subpart F to determine requirements for the program specific audit requirements.

For-profit organizations have two options regarding the type of audit that will satisfy the audit requirements. The recipient either may have (1) a financial-related audit (as defined in, and in accordance with, the Government Auditing Standards (commonly known as the “Yellow Book”), GPO stock 020-000-00-265-4, of a particular award in accordance with Government Auditing Standards, in those cases where the recipient receives awards under only one DHHS program, or (2) an audit that meets the requirements of 45 CFR 75, Subpart F-Audit Requirements.

Noncompliance or Enforcement Actions: Suspension, Termination, and Withholding of Support. If a recipient has failed to materially comply with the terms and conditions of award, NIH may take one or more enforcement actions, which include disallowing costs, withholding of further awards, or wholly or partly suspending the OT award, pending corrective action. NIH may also terminate the OT award.

NIH may suspend (rather than immediately terminate) an OT award and allow the recipient an opportunity to take appropriate corrective action before NIH makes a termination decision; however, NIH may decide to terminate the award if the recipient does not take appropriate corrective action during the period of suspension. NIH may immediately terminate an OT award when necessary, such as to protect the public health and welfare from the effects of a serious deficiency.

An NIH OT award also may be terminated, partially or totally, by the recipient. If the recipient decides to terminate a portion of an OT award, NIH may determine that the remaining portion of the award will not accomplish the purposes for which the award was originally made. In any such case, NIH will advise the recipient of the possibility of termination of the entire OT award and allow the recipient to

withdraw its termination request. If the recipient does not withdraw its request for partial termination, NIH may initiate procedures to terminate the entire award for cause.

If the NIH decides to terminate an OT award, the termination of the award will be considered a unilateral change and the recipient will not have the right to appeal. Although a decision is made to terminate an award, the recipient must continue to comply with the Record Retention and Access requirements.

Recovery of Funds

NIH may identify and administratively recover funds paid to a recipient at any time during the life cycle of an OT award. Debts may result from cost disallowances, unobligated balances, unpaid share of any required matching or cost-sharing, funds in the recipient's account that exceed the final amount determined to be allowable, or other circumstances.

Debt Collection

The debt collection process is governed by the Federal Claims Collection Act, as amended (Public Law [P.L.] 89-508, 80 Stat. 308, July 19, 1966); the Federal Debt Collection Act of 1982 (P.L. 97-365, 96 Stat. 1749, October 25, 1982); the Debt Collection Improvement Act (P. L.104-134, 110 Stat. 1321, April 26, 1996); and, the Federal Claims Collection Standards (31 CFR Parts 900-904), which are implemented for DHHS in 45 CFR 30. NIH is required to collect debts due to the Federal Government and, except where prohibited by law, to charge interest on all delinquent debts owed to NIH by recipients.

Closeout

The requirement for timely closeout is a recipient responsibility. Closeout includes ensuring timely and accurate submission of all required reports and adjustments for amounts due to the recipient or NIH. Terms and conditions of award will outline the specific timeline requirements for submission of the Final Federal Financial Report, the Final Progress Report, Final Invention Statement and Certification, and any other documentation or deliverables negotiated for award.

Public Policy Requirements and Objectives

NIH intends to uphold high ethical, health, and safety standards in both the conduct of the research it funds and the expenditure of public funds by its recipients. The signature of the Signing Official on the application certifies that the organization complies, or intends to comply, with all applicable policies, certifications, and assurances.

The policies, certifications and assurances listed may or may not be applicable to the project, program, or type of applicant organization. This list is not intended to be comprehensive and other laws may be determined to apply generally to all NIH OT awards, or specifically to a particular award depending on the terms of the OT.

a. Anti-Sexual Harassment

b. Debarment and Suspension

c. Dissemination of Deliberately False or Misleading Information

d. Federal Information Security Management Act (FISMA)

e. Financial Conflict of Interest (FCOI)

f. Fly America Act

g. Foreign Involvement

h. Gun Control

i. Human Embryo Research and Cloning Ban

j. Human Fetal Tissue Research

k. Human Stem Cell Research

l. Intellectual Property

m. Lobbying Prohibition

n. National Environmental Policy Act

o. NIH Data Sharing Requirement

p. NIH Salary Cap

q. Research Involving Recombinant or Synthetic Nucleic Acid Molecules

r. Research Misconduct

s. Restriction on Abortion Funding

t. Research Subjects Protections and Requirements

u. Pro-Children Act of 1994

v. Promotion or Legalization of Controlled Substances

w. Restriction of Pornography on Computer Networks

x. Restriction on Distribution of Sterile Needles

y. Select Agents

z. USA Patriot Act

TERMS AND CONDITIONS (Appendix I)

The Terms and Conditions attached in Appendix I serve as a baseline for Other Transactions (OT) agreements awarded by the CFDE Program. The NIH may modify these terms and conditions throughout the selection process. Requests by offeror(s) to modify the terms and conditions language will be considered by the NIH on a case-by-case basis and negotiated as deemed appropriate. Failure to reach an agreement within a timeframe identified by the NIH may result in the NIH not making an award.

APPENDIX I: TERMS AND CONDITIONS

OTHER TRANSACTIONS AGREEMENT

BETWEEN

Recipient

AND

NATIONAL INSTITUTES OF HEALTH (NIH)
OFFICE OF THE DIRECTOR (OD)
OFFICE OF STRATEGIC COORDINATION (OSC)
THE COMMON FUND
9000 ROCKVILLE PIKE
BETHESDA, MD 20892

CONCERNING

Common Fund Data Ecosystem

WITH

CFDE (Insert) Center
Common Fund Data Ecosystem

Other Transaction Agreement No.: xxxxxxxxxxxxxxx
Authority: 42 U.S.C. 282(n)(1)(C)

Table of Contents

ATTACHMENTS

Attachment 1	**Statement of Milestones**
Attachment 2	**Statement of Budgetary Projections**
Attachment 3	**Resource Sharing Plan**
Attachment 4	**Plan for Enhancing Diverse Perspectives (PEDP)**
Attachment 5	**Reporting Requirements**

NOTE: Attachments not included in this package.

ARTICLE I. SCOPE OF THE AGREEMENT

A. Background

Consistent with the proposal submitted by the Recipient on **DATE** and subsequent and final email update on **DATE,** the NIH and the Recipient set forth this Agreement and incorporated Attachment 1: Statement of Milestones (SOM) to define the scope of a partnership for CFDE (**NAME**) Center.

The NIH Common Fund (CF) supports bold scientific programs that catalyze discovery across all biomedical and behavioral research. CF programs create a space where investigators and multiple NIH Institutes and Centers (ICs) collaborate on innovative research addressing high-priority challenges for the NIH as a whole and make a broader impact in the scientific community.

The Common Fund Data Ecosystem (CFDE) is an infrastructure investment made by the CF to address the growing challenges facing scientific programs that leverage data-intensive strategies. To support these programs and downstream data users, CFDE is helping to ensure that all CF data sets are Findable, Accessible, Interoperable, and Reusable (FAIR), providing training for users to operate on the data in a cloud environment, and ensuring that CF data continue to be available after individual programs are completed. CFDE will amplify the impact of many CF programs by enabling researchers to interrogate disparate data sets, thereby making new kinds of scientific discoveries that are otherwise unattainable. CFDE is also being designed in parallel with NIH IC data platforms to enable crosstalk between CF and IC data sets and address NIH-wide data management objectives described in the NIH Strategic Plan for Data Science.

Structure of the CFDE
Building on the successful first phase, CFDE will be expanding its scope in increasing the reuse of CF generated data, knowledge, and tools, and significantly ramp up the skills development and training efforts. CFDE will establish data resource and knowledge portal(s) and cloud workspaces that will enable users to query across and use multiple CF resources, and by outreaching and training biomedical researchers to bring them to CF resources and to work in the cloud. To accommodate these changes in the scope and better address the needs, CFDE-CC will be structured as five tightly integrated centers: Data Resource Center (DRC), Knowledge Center (KC), Cloud Workspace Implementation Center (CWIC), Center for Training (CT), and Integration and Coordination Center (ICC).
A general description for the above centers is provided, although specific details, timelines, requirements, and objectives are provided in each relevant FOA/ROA:

Data Resource Center (DRC): This center will be responsible for creating and maintaining the CFDE portal that enables users to query and use data sets from across CF programs. The portal will include a landing page for CFDE that integrates information and products from the other CFDE centers.

Knowledge Center (KC): This center will be responsible for establishing a Knowledge Portal, a knowledge management platform that: aggregates and integrates the knowledge generated by different CF programs to amplify their impact, makes the knowledge accessible to a wide user community in a user-friendly manner, and enables various ways to query and access the available knowledge.

Cloud Workspace Implementation Center (CWIC): This center will be responsible for creating a cloud workspace that enables users to import their data and co-analyze them with other CF data sets and/or utilize CFDE-constructed analysis pipelines, workflows, and other analytical or visualization resources. The cloud workspace

will meet the needs of both novice and expert users.

Center for Training (CT): This center will be responsible for performing a landscape analysis to identify the training opportunities and needs of the CFDE community. It will also help develop and administer targeted training to address gaps in the training landscape.

Integration and Coordination Center (ICC): This center will focus on ensuring internal cohesion within CFDE and implementing a structured evaluation process to ensure a continuous improvement cycle. It will have three major responsibilities: (1) Integration and coordination across the CFDE Centers and CFDE-related activities among participating CF programs; (2) Sustainability services; and (3) Leading an annual program evaluation.

Throughout the life of this partnership the NIH and the Recipient will create and modify objectives, milestones and deliverables aimed at achieving the goals set forth herein. These objectives and milestones may be executed sequentially or concurrently as appropriate.

The Recipient must embrace the speed and flexibilities of the Other Transaction mechanism by taking a more active and direct role than may be usual in helping the government foster the success of the program as such, the Recipient cannot passively monitor progress but rather must become a skilled facilitator dedicated to foster overall success.

B. Definitions

In this Agreement, the following definitions apply:

Agreement: This Agreement and any Attachments or other documents that are expressly incorporated in and made a part of the Agreement, including but not limited to Attachments 1-5.

Award: The provision of funds by NIH, based on an approved application and budget or progress report, to an organizational entity to carry out a project or activity.

Compute: Compute refers to activities, applications or workloads including storage, networking, and computation (including, but not limited to CPU/GPU/neural processing).

Data: Recorded information, regardless of form or method of recording, which includes but is not limited to, technical data, software, mask works, trade secrets, text, sound, images, metadata, video files, drawings, designs, forms, diagrams, data files, statistical records, and other research data.

Deliverables: Any tangible or intangible work product (including third party materials) provided by Recipient to NIH because of the performance of work under the Statement of Milestones (SOM) and identified as a deliverable in the SOM or the Reporting Requirements Attachments.

Enjoined Collaboration: An enjoined collaboration is joint effort of multiple individuals or work groups brought together by an outside party to accomplish a task or project.

Foreign Firm or Institution: A firm or institution organized or existing under the laws of a country other than the United States, its territories, or possessions. The term includes, for purposes of this Agreement, any agency or instrumentality of a foreign government; and firms, institutions or business organizations which are owned or substantially controlled by foreign governments, firms, institutions, or individuals.

Government: The United States of America, as represented by the Office of the Director (OD) / National Institutes of Health (NIH).

Intellectual Property: All copyrights and copyrightable subject matter, including any and all worldwide applications, registrations, renewals, and extensions thereof and all rights of reproduction and publication, rights to create derivative works and all of the rights incident to copyright ownership; all trade secrets, defined as any and all confidential information, technology, ideas, know-how, and proprietary processes and formulae; all inventions, designs, models, mask works, patents, and pending patent applications; all trademarks, tradenames, service marks, logos, and other commercial symbols, whether registered or unregistered, and pending trademark applications.

Indirect (Facilities & Administrative (F & A)) Costs: It means those costs incurred for a common or joint purpose benefitting more than one cost objective, and not readily assignable to the cost objectives specifically benefitted, without effort disproportionate to the results achieved. To facilitate equitable distribution of indirect expenses to the cost objectives served, it may be necessary to establish a number of pools of indirect (F&A) costs. Indirect (F&A) cost pools must be distributed to benefitted cost objectives on bases that will produce an equitable result in consideration of relative benefits derived.

Invention: Any invention or discovery which is or may be patentable or otherwise protectable under Title 35 of the United States Code.

Key Personnel: The Program Director/Principal Investigator (PD/PI) and other individuals who contribute to the scientific development or execution of a project in a substantive, measurable way, whether or not they receive salaries or compensation under this agreement. "Zero percent" effort or "as needed" are not acceptable levels of involvement for those designated as Key Personnel.

Know-How: All information including, but not limited to discoveries, formulas, materials, inventions, processes, ideas, approaches, concepts, techniques, methods, software, programs, documentation, procedures, firmware, hardware, technical data, specifications, devices, apparatus, and machines.

Made: Relates to any invention and means the conception or first actual reduction to practice of such invention.

Milestones: Milestones are objective measures of progress toward program goals.

Other Transactions Agreements (OT): OT awards are not grants, cooperative agreements, or contracts. They are used by the NIH, including the Office of Strategic Coordination, which have been authorized by Congress to use them. They provide considerable flexibility to the government to establish policies for the awards, so policies and terms for individual OT awards may vary between awards. Each award is therefore issued with a specific Agreement, which is negotiated with the Recipient and details specific terms and conditions for that award. Program and administrative policies and the terms and conditions of individual awards are intended to supplement, rather than substitute for, governing statutory and regulatory requirements. Awards or a specified subset of awards also may be subject to additional requirements, such as those included in executive orders and appropriations acts [including the other transaction legislation cited in the Notice of Award (NoA)], as well as all terms and conditions cited in the NoA and its attachments, conditions on activities and expenditure of funds in other statutory or regulatory requirements, including any revisions in effect as of the beginning date of the next funding segment. The terms and conditions of the resulting OT awards are intended to be compliant with governing statutes.

Other Transactions Agreements Officer (OTAO): Individual responsible for legally committing the government

to an OT award and to the Agreement through which terms and conditions are established, and for the administrative and financial aspects of the award.

Other Transactions Agreements Specialist (OTAS): A designee of the OTAO for administrative and financial aspects of the award.

Other Transactions Program Official (OTPO): The NIH official responsible for programmatic oversight and direction of the work performed under the Statement of Milestones (SOM).

Party: Includes the NIH, the Recipient, or both.

Practical Application: To manufacture, in the case of a composition of product; to practice, in the case of a process or method, or to operate, in the case of a machine or system; and, in each case, under such conditions as to establish that the invention is capable of being utilized and that its benefits are, to the extent permitted by law or Federal regulations, available to the public on reasonable terms.

Program Director/ Principal Investigator (PD/PI): Individual designated by the Recipient to have the appropriate level of authority and responsibility to direct the project or program supported by the other transactions agreement award.

Project: Research and development being conducted by the Recipient, as set forth in Article I, Paragraph E.

Recipient: The entity responsible for performing the administrative and programmatic activities described in this Agreement.

Recipient Business Official (RBO): Individual responsible for the legal commitment by the Recipient and for the administrative and financial reporting compliance with terms and conditions of the Agreement. In signing the Other Transaction (OT) Agreement, this individual certifies that the Recipient will comply with all applicable assurances and certifications referenced in the Agreement. This individual's signature further certifies that the Recipient will be accountable both for the appropriate use of funds awarded and for the performance of the OT supported project or activities. This individual is responsible for ensuring that the Recipient complies with applicable Federal laws and regulations, including required certifications and assurances, its application and terms and conditions of this OT award. All official correspondence must be submitted by the RBO.

Sub-recipient: An entity, usually but not limited to non-Federal entities, that receives a subaward from a pass-through entity (OT Recipient) to carry out part of a Federal award; but does not include an individual that is a beneficiary of such award. A subrecipient may also be a recipient of other Federal awards directly from a Federal awarding agency.

Subject Invention: Any invention conceived or first actually reduced to practice in the performance of work under this Agreement.

Technology: Discoveries, innovations, Know-How, and inventions, whether patentable or not, including computer software, recognized under U.S. law as intellectual creations to which rights of ownership accrue, including, but not limited to, patents, trade secrets, mask works, and copyrights developed under this Agreement.

Third Party: A third party is an entity that is involved in some way in an interaction that is primarily between two other entities.

Unlimited Rights: The rights to use, disclose, reproduce, prepare derivative works, distribute copies to the public, and perform publicly and display publicly, in any manner and for any purpose, and to have or permit others to do so.

C. Award Notice

This award is supported by the NIH Office of Strategic Coordination (OSC) – The Common Fund / Office of the NIH Director pursuant to Research opportunity Announcement OTA-23-004, "XXX (OT2)". Future award segment costs and duration are dependent on scientific advancements, programmatic needs, and availability of funds.

D. Authorization

This award is an "other transactions" agreement made under the Other Transaction Authority (OTA) as authorized by section 402(n) of the Public Health Service Act as amended [42 USC 282(n)(1)(C)]. This agreement is not governed by the Federal Acquisition Regulation or administrative regulations governing grants.

E. CFDE Program Goals and Objectives

The goal of this Agreement is to meaningfully contribute to the NIH CFDE program goals and objectives:

1. Objective 1; Enable users to query across & use multiple CF data sets;
2. Objective 2; Provide training and outreach to bring people to CF data, and train them to work in the cloud; and,
3. Objective 3; Coordinate and integrate infrastructure and activities into a cohesive ecosystem

Completion of these objectives will allow CFDE to foster scientific discovery through (re)use of data generated by the Common Fund (CF) programs.

The NIH will have continuous involvement with the Recipient. The NIH will obtain access to program results and certain rights in patents and data pursuant to the Terms and Conditions herein. NIH and the Recipient are bound to each other by a duty of good faith in achieving the Program objectives.

F. Scope

The recipient shall perform a coordinated (**project description, e.g., research and development**) project (hereafter referred to as "Project") for CFDE Program. The work shall be carried out in accordance with the "Statement of Milestones: (SOM) incorporated into this Agreement as Attachment 1.

Subject to the availability of funds, the Recipient shall be paid as described in the Article V: Obligation and Payment and Attachment 2 Statement of Budgetary Projections of this award.

ARTICLE II. TERM

A. Term of this Agreement

The Program commenced on **DATE** with the release of the Notice of Award (NOA), while the terms and conditions of the OT Agreement are finalized or until milestones have been successfully completed as mutually agreed to by the Parties, whichever is sooner, or the Agreement has been terminated pursuant to Article II, subject to the availability of funds. If all funds are expended prior to the project end date, the Parties have no obligation to continue performance and may elect to end this Agreement at that point.

B. Termination Provisions

1. The NIH may terminate this Agreement by written notice to the Recipient, provided that such written notice is preceded by consultation between the Parties. The Recipient may terminate this Agreement by giving the NIH Other Transactions Agreements Officer (OTAO) sixty (60) calendar days written notification of its intent to do so, provided that such written notice is preceded by consultation between the Parties.
2. The NIH and the Recipient shall negotiate in good faith a reasonable and timely adjustment of all outstanding issues including amounts due between the Parties as a result of termination, which may include non-cancelable commitments.
3. The Recipient will develop a termination transition plan to be approved by NIH, which includes the following terms:
    a. Information security, including confidentiality, integrity, and availability of Data and systems;
    b. Data transfer process for Data;
    c. Relevant records and information to effect termination and public Data transfer to a publicly accessible repository; and
    d. Any other terms deemed necessary by both Parties.
4. In the event that this Agreement is terminated, the NIH shall have paid-up rights in Data intended for public release as described in Article VIII, Data Rights.
5. Failure of the Parties to agree to an equitable adjustment shall be resolved pursuant to Article VI, Disputes.

C. Enforcement, Termination

If Recipient has failed to materially comply with the terms and conditions of award, NIH may take one or more enforcement actions, which include disallowing costs, withholding of further awards, or wholly or partly suspending the OT award, pending corrective action. NIH also reserves the right to unilaterally terminate the OT award by providing a written notice to the Recipient.

NIH may suspend, partially or totally, rather than immediately terminate, the OT award and allow the Recipient an opportunity to take appropriate corrective action before NIH makes a termination decision; however, NIH may decide to terminate, partially or totally, the award if the Recipient does not take appropriate corrective action during the period of suspension, which shall be no less than thirty (30) days. NIH may immediately terminate an OT award when necessary, such as to protect the public health and welfare from the effects of a serious deficiency.

This award also may be terminated, partially or totally, by the Recipient. If the Recipient decides to terminate a

portion of an OT award, NIH may determine that the remaining portion of the award will not accomplish the purposes for which the award was originally made. In any such case, NIH will advise the Recipient of the possibility of termination of the entire OT award and allow the recipient to withdraw its termination request. If the Recipient does not withdraw its request for partial termination, NIH may initiate procedures to terminate the entire award for cause. The Recipient may terminate this Agreement by giving the NIH sixty (60) calendar days written notification of its intent to do so, provided that such written notice is preceded by consultation between the Parties.

With the written unilateral termination and per Article II.C, the Recipient does not have a right to appeal**.** Although a decision is made to terminate an award, the Recipient must continue to comply with the Record Retention and Access requirements.

D. Flow Down

Unless modified by the Other Transactions Agreements Officer (OTAO) in writing, the terms of Agreement flow down to sub-recipients. Recipient is responsible for ensuring the Sub-OT Recipient is compliant with the flow down terms.

E. Extending the Term

The Parties may extend by mutual written agreement the term of this Agreement if research opportunities within the scope set forth in Article I reasonably warrant. Any extension shall be formalized through revision of the Agreement by the OTAO, in consultation with the NIH OTPO, and the Recipient Business Official (RBO) and shall be subject to the availability of funds.

F. No Cost Extension

For other transaction awards, any project period extension beyond the initial project period requires NIH prior approval. The request should include a description of the project activities that require support during the extension and a statement about the unspent funds available to support the extension.

All Federal agencies are required by 31 U.S.C. 1552(a) to close fixed year appropriation accounts and cancel any remaining balances by September 30th of the fifth fiscal year after the year of availability. In order for the NIH to meet its obligation to close these accounts and cancel any remaining balances by September 30th, Recipient must report disbursement on the quarterly cash transaction report using the Federal Financial Report (FFR) no later than June 30th of the fifth fiscal year after the year of availability. At the end of the five years, the funds are cancelled and returned to the Treasury. This provision may limit NIH's ability to further extend the final budget period.

G. Changing the Award Terms

Post-award changes to the terms and conditions are negotiated between the OTAO, in consultation with the NIH OTPO, and the RBO. The OT award mechanism allows significant ongoing involvement from NIH OTPO and provides the NIH the flexibility to alter the course of the project in real-time to meet the overarching goals. This may mean an awarded activity could be expanded, modified, partnered, not supported, or discontinued based on program needs, emerging methods or approaches, performance, or availability of funds. Performance during the award period will be reviewed on an ongoing basis and course corrections will be made as necessary.

H. Unilateral Changes

The OT award mechanism allows significant ongoing involvement from NIH OTPO and provides the NIH the flexibility to alter the course of the project in real-time to meet the overarching goals. This may mean an awarded activity could be expanded, modified, partnered, not supported, or discontinued based on program needs, emerging methods or approaches, performance, or availability of funds. Performance during the award period will be reviewed on an ongoing basis and course corrections will be made as necessary. As a result, the NIH reserves the right to:

- Fund projects in increments and/or with options for continued work at the end of one or more stages;
- Fund projects of two or more entities (potentially across different applications) as part of a reorganized collaboration, teaming arrangement, or other means acceptable to the government;
- Request additional documentation (certifications, etc.);
- Remove participants from award consideration should the parties fail to reach a finalized, fully- executed agreement prior to a date determined by the NIH, or the recipient fails to provide requested additional information in a timely manner; and
- Make post award changes authorized by the OTAO that do not impact the Statement of the Milestones.

I. Prior Approval

Any prior approval request must be submitted by the RBO to the OTAO (or designated OTAS) and OTPO. Examples of prior approval include but are not limited to:

1. Change of PD/PI
The Recipient must notify the OTAO in writing of a change in key personnel listed in the Terms and Conditions of the Agreement. Any change in Key Personnel requires the written approval of the OTAO in consultation with the NIH OTPO, and upon approval a notice or revision to the Agreement will be provided to the Recipient.

Key Personnel:
Dr. First Name Last Name 1
Dr. First Name Last Name 2
Dr. First Name Last Name 3

2. Foreign Component
Any significant changes, including but not limited to, addition of a foreign site requires written prior approval of the OTAO.

3. Milestone Activities
The Recipient will adhere to the Statement of Milestones (SOM) in Attachment 1. Updates, additions, and adjustments to milestones are coordinated with the CFDE OTPO and OTAO on an as needed basis.

4. Site Changes
Changes to site(s) performing the activities under this Agreement or effort required to achieve

stated milestones need prior approval from the OTAO, in consultation with the NIH OTPO.

J. eRA Commons Registration for the Principal Investigator (PI)

The individual(s) designated as the PI(s) on the proposal must be registered in eRA Commons. The PI must hold a Project Director (PD) eRA Commons role and be affiliated with the applicant organization. The initial registration must be done by a Recipient Business Official (RBO), who has the Signing Official (SO) role in eRA Commons or other authorized accounts administrators at the organization.

Designating the PI/PD role in the eRA Commons provides the individual with the administrative authority needed to see pertinent information regarding an application (e.g., electronic submission status, review assignment, etc.). The PI/PD role within the eRA Commons is necessary to complete the other transaction application process, and if an award is made, to complete required post-award actions (such as the submission of a progress report).

K. The System for Award Management (SAM)

All recipients must register in the System for Award Management (SAM) and maintain an active registration with current information at all times during which it has an award with NIH. SAM is the primary registrant database for the federal government and is the repository into which an entity must provide information required for the conduct of business.

L. Research Integrity Procedures and Plans

The Recipient, in compliance with Public Health Service (PHS) Title 42 CFR 93, PHS Policies on Research Misconduct, Subpart C, "Responsibilities of Institutions" must develop and file an Assurance of Compliance with the U.S. Department of Health and Human Services (HHS) Office of Research Integrity (ORI). The assurance must specify the written policies and procedures for addressing allegations of research misconduct in PHS-supported research. The specific filing requirements can be found at https://ori.hhs.gov.

M. The Notice of Award (NoA)

NIH notifies the Recipient via E-mail when an award has been issued. In order to receive the E-mail notification of the Notice of Award (NoA), Recipient must register a valid E-mail address in the NoA E-mail field in the eRA Commons Institutional Profile once the initial eRA Commons registration process is complete. Organizations are encouraged to use a unique E-mail address that is not specific to an individual to avoid communication problems when personnel change. It is the responsibility of the Recipient to maintain a current and accurate E-mail address for NoAs. NIH will not distribute NoAs other than through this system-generated E-mail notification process. Recipients that do not maintain a current NoA notification E-mail address will be responsible for accessing NoAs via the eRA Commons.

N. Reporting

For detailed reporting requirements, see Attachment 5.

ARTICLE III. MANAGEMENT OF THE PROJECT

The Recipient shall be responsible for the overall technical and program management of the project and technical planning and execution shall remain with the Recipient. The NIH OTPO shall provide recommendations to Recipient regarding development and technical/scientific collaboration and be responsible for the review and verification of the milestone completion.

A. Modifications

1. As a result of interactions with the Recipient or at any time during the term of the Agreement, progress or results may indicate that a change in the SOM would be beneficial to program objectives. Recommendations to modify the SOM may be initiated by either Party. The initiating Party will document in writing and submit its recommendations for modifying the SOM to the other Party, including justifications to support the change. The NIH OTAO, in consultation with the NIH OTPO and the RBO, shall approve any Agreement revision (modification).
2. The NIH is not obligated to pay for additional or revised future work to be performed until the SOM is formally revised by the NIH OTAO and made part of this Agreement.
3. The NIH OTPO shall be responsible for the review and verification of any recommendations to revise or otherwise modify the SOM, prospective work, or other proposed changes to the terms and conditions of this Agreement.
4. The NIH OTAO/OTAS and OTPO will be responsible for documenting, communicating, and securing any necessary NIH approvals related to modifications to this Agreement.
5. Unilateral revisions by the NIH may include but are not limited to for administrative changes (i.e., changes in the payment office or appropriation data, changes to the Government personnel identified in the Agreement, etc.).
6. A bilateral revision is any proposed significant changes to this Agreement that would impact the timeline of the project periods, changes in the approved facilities/administrative and/or indirect cost rate, equipment purchases greater than $5,000 per unit not previously included in the approved budget, and other changes affecting the cost, etc.
7. All requests for NIH approval of revisions must be made in writing by the RBO no less than thirty (30) days prior to the proposed date of change. The NIH will review the request and provide a formal response.

B. Monitoring

The Recipient is responsible for managing the day-to-day operations of Agreement activities using their established controls and policies. The NIH OTPO will monitor and identify potential problems and areas where technical assistance might be necessary. NIH OTPO monitoring is accomplished through review of reports provided pursuant to the SOM (Attachment 1) and Reporting Requirements (Attachment 5).

C. Management Systems and Procedures

The Recipient is expected to have clearly delineated roles and responsibilities for its organization's staff. The Recipient may use its existing systems to manage Agreement funds and activities, provided that policies and procedures are consistently applied across its business functions.

ARTICLE IV: AGREEMENT ADMINISTRATION

The NIH will actively engage with Recipients to establish a vision and capabilities for the CFDE program and to oversee the effort of individual Recipients to achieve the vision. Each Party may change its representatives named in this Article by written notification to the other Party. The NIH will effect the change as stated in this Agreement.

Unless otherwise provided in this Agreement, approvals permitted or required to be made by NIH may be made only by the NIH OTAO. Administrative and programmatic matters under this Agreement shall be referred to the following representatives of the Parties:

A. NIH Points of Contact

Other Transactions Agreements Officer (OTAO)
Name
Phone

Other Transactions Agreements Specialist (OTAS)
Name
Phone

Other Transactions Program Official (OTPO)
Name, Ph.D.
Phone
Email: CFDE@od.nih.gov

B. Recipient Points of Contact

Recipient Business Official (RBO)/Signing Official:
Name
Phone Number
Email Address

Principal Investigator (PI)/Program Director (PD):
Name
Phone Number
Email Address

ARTICLE V: OBLIGATION AND PAYMENT

A. Obligation

The NoA provides funds for the budget period as appropriate for the negotiated and agreed upon work.

Subsequent funding periods represent projections of future funding levels contingent on the availability of funds, achievement of agreed-upon activities, and continued alignment with programmatic goals. The NIH's liability to make payments to the Recipient is limited to only those funds obligated under the Agreement, modification to the Agreement, and/or issuance of the NOA and is subject to availability of funds. NIH may obligate funds to the Agreement incrementally. If modification becomes necessary in performance of this Agreement, the NIH OTAO, in consultation with the OTPO, and the RBO shall execute a revised SOM.

B. Payment

The Payment Management System (PMS) is a centralized payment and cash management system, operated by the Department of Health and human Services (DHHS) Program Support Center (PSC). Agreement payments by the PMS may be made by one of several advance payment methods, including SMARTLINK II/SCH, cash request, or by cash request on a requirement basis. Payments under this program generally are made on a reimbursement basis. These requirements are intended to minimize the time elapsing between the transfer of funds from the Federal Government and disbursement to the Recipient.

Advances made by Recipients to third parties under the Agreement must conform to substantially the same standards of timing and amount that govern advances to the Recipient.
Operational guidance for the Recipient is provided through training from the DHHS PSC. Inquiries regarding drawdown request, cash management rules, and the disbursement of funds through the Federal Financial Report (FFR) SF 425 should be directed to the DHHS PSC (https://pms.psc.gov/grant-recipients/ffr-updates.html).

C. Interest Earned on Advances

The Parties do not anticipate that Recipient will receive advance payments. Recipients receiving advance payments are expected to maintain those advanced funds in an interest- bearing account and promptly return any funds not spent within three (3) business days. Interest earned on federal advance payments deposited in interest-bearing accounts must be remitted annually to the Department of Health and Human Services, Payment Management System, Rockville, MD 20852. Interest amounts up to $500 per year may be retained by the Recipient for administrative expenses.

D. Limitation of Funds

In no case shall the NIH's financial liability exceed the amount obligated under this Agreement.

E. Appropriation Mandates

This award must comply with NIH fiscal appropriation mandates.

F. Close out of Fixed Year Appropriations Amounts

Fixed year appropriation accounts have a five (5)-year availability span. Recipients must draw down all appropriated fiscal year award funds no later than June 30th of the fifth year after the year of availability of funds. At the end of five years, the funds are cancelled and returned to the Treasury. This provision may limit the NIH's ability to further extend the final budget period.

G. Financial Records and Audits Requirements

The Recipient shall maintain adequate records to account for all funding under this Agreement and internal control systems to ensure that obligations and expenditures are reasonable, allocable, and allowable under this Agreement. In addition, the systems must be able to identify unobligated balances, accelerated expenditures, inappropriate cost transfers, and other inappropriate obligation and expenditure of funds, and the Recipient must notify the Government within 5 business days when problems in financial management are identified. The Recipient's failure to establish adequate control systems, notify the Government when financial management problems arise, or to resolve problems in a reasonable timeframe when identified may, upon investigation by the Government or a cognizant auditor, constitute a material breach of this Agreement and may result in the Government's exercise of available enforcement remedies.

The Recipient is deemed to be subject to the audit requirements of OMB, 2 CFR 200, Subpart F-Audit Requirements, as implemented by DHHS 45 CFR Subpart F.

For-profit organizations have two options regarding the type of audit that will satisfy the audit requirements. The recipient either may have (1) a financial-related audit (as defined in, and in accordance with, the Government Auditing Standards (commonly known as the "Yellow Book"), GPO stock 020-000-00-265-4, of a particular award in accordance with Government Auditing Standards, in those cases where the recipient receives awards under only one DHHS program, or (2) an audit that meets the requirements of 45 CFR 75, Subpart F-Audit Requirements.

Upon completion or termination of this Agreement, whichever occurs earlier, the Recipients RBO shall furnish to the OTAO a copy of the Final Federal Financial Report. The Recipient's relevant financial records are subject to examination or audit on behalf of NIH by the Government for a period not to exceed three (3) years from the date of submission of the final financial report, described in Attachment 5. The OTAO or designee shall have direct access to sufficient records and information of the Recipient, to ensure full accountability for all funding under this Agreement. Such audit, examination, or access (if or when necessary) shall be performed during business hours on business days upon prior written notice and shall be subject to the security requirements of the audited party. If any litigation, claim, financial management review, or audit is started before the expiration of the 3-year period, the records must be retained until all litigation, claims, or audit findings involving the records have been resolved and final action taken. These record retention policies apply to both paper and electronic storage of applicable information, including electronic storage of faxes, copies of paper document, images, and other electronic media.

Comptroller General Access: To the extent that the total Government payment under this Agreement exceeds $5,000,000, the Comptroller General, at its discretion, shall have access to and the right to examine records of any entity that participates in the performance of this Agreement for a period of three (3) years after final payment is made. This requirement shall not apply with respect to any entity that has already entered into any other agreement (contract, grant, cooperative agreement, or "other transaction") that grants audit access by a Government entity in the year prior to the date of this Agreement. This paragraph only applies to any record that is created or maintained in the ordinary course of business or pursuant to a provision of law. The terms of this paragraph shall be included in all Sub-Agreements of this Agreement.

H. Financial Management System Standards

The Recipient must have in place accounting and internal control systems that provide for appropriate monitoring of award accounts to ensure that obligations and expenditures are reasonable, allocable, and

allowable. In addition, the systems must be able to identify unobligated balances, accelerated expenditures, inappropriate cost transfers, and other inappropriate obligation and expenditure of funds, and Recipient must notify the NIH OTAO when problems are identified. The Recipient's failure to establish adequate control systems constitutes a material breach of this Agreement and may result in exercise of available enforcement remedies. Recipient must notify the Government within 5 business days when problems in financial management are identified.

I. Unobligated Balances and Actual Expenditures

Using the principle of "first-in, first-out," unobligated funds carried over are expected to be used before newly awarded funds.

J. Procurement System Standards and Requirements

Recipients may acquire a variety of goods or services in connection with an OT award-supported project, ranging from those that are routinely purchased goods or services to those that involve substantive programmatic work. Recipients must acquire goods and services under OT awards in compliance with the organization's established policies and procedures and for the negotiated purposes outlined in the SOM.

K. Cost Principles

In general, this Agreement is subject to reimbursement of actual, allowable costs incurred and are expected to align with generally accepted and established federal cost principles for the entity receiving funding (academic, non-profit, for-profit, etc.).

L. Human Subjects Research (if applicable)

No funds may be drawn down from the payment system and no obligations may be made against Federal funds for research involving human subjects by any site engaged in such research for any period not covered by both an Office for human Research Protections (OHRP) approved Federal Wide Assurance and approval from the Institutional Review Board (IRB), as required, consistent with 45 CFR Part 46 and any NIH required policies. This Agreement requires the institution to ensure that all personnel and partners who engage in human subjects research have completed education on the protection of human subjects as described in https://grants.nih.gov/policy/humansubjets/training-and-resources.htm#Education%20Requirement. Any individual involved in the design or conduct of the study must satisfy this requirement prior to participating in human subjects research. Failure to comply will result in the immediate suspension and/or termination of this Agreement.

M. Salary Cap

None of the funds in this award shall be used to pay the salary of an individual at a rate more than the current salary cap. See current salary cap levels at the following URL: http://grants.nih.gov/grants/policy/salcap_summary.htm.

N. Other Support

Pursuant to this Agreement, Recipient shall submit information in accordance with NIH policy on "other support," which includes all resources made available to all individuals who will make a scientific contribution to the project. These reportable resources include support of and/or related to all of their research endeavors, regardless of whether or not they have monetary value and regardless of whether they are based at the organization the researcher identifies for the current Agreement. This includes resource and/or financial support from all foreign and domestic entities, including but not limited to, financial support for laboratory personnel, positions and scientific appointments both domestic and foreign held by senior/key personnel that are relevant to an application including affiliations with foreign entities or governments, domestic research collaborations that directly benefit the researcher's research endeavors, and provision of high-value materials that are not freely available. NIH policy can be found at https://grants.nih.gov/grants/guide/notice-files/NOT-OD-19-114.html and https://grants.nih.gov/grants/guide/notice-files/NOT-OD-21-073.html.

Commitment overlap occurs when any project-supported personnel (including support staff and key personnel) have time commitments exceeding 100 percent, regardless of how the effort/salary is being supported or funded. Therefore, no individual may reflect over 100 percent in the total effort he/she spends on research and other organizational responsibilities. An investigator may be affiliated with several organizations; however, the combination of appointments cannot exceed 100 percent. (Reporting zero percent of effort is not acceptable.) The award organization is responsible for ensuring no individual supported by this award exceeds 100 percent committed effort.

O. Recovery of Funds

NIH may identify and administratively recover funds paid to a Recipient at any time during the life cycle of an OT award. Debts may result from cost disallowances, unobligated balances, unpaid share of any required matching or cost-sharing, funds in the account that exceed the final amount determined to be allowable, or other circumstances. NIH is required to collect debts due to the Federal Government and, except where prohibited by law, to charge interest on all delinquent debts owed to the Government by the Recipient.

P. Debt Collection

The debt collection process is governed by the Federal Claims Collection Act, as amended (Public Law [P.L.] 89-508, 80 Stat. 308, July 19, 1966); the Federal Debt Collection Act of 1982 (P.L. 97-365, 96 Stat. 1749, October 25, 1982); the Debt Collection Improvement Act (P. L. 104-134, 110 Stat. 1321, April 26, 1996); and the Federal Claims Collection Standards (31 CFR Parts 900-904), which are implemented for DHHS in 45 CFR 30. NIH is required to collect debts due to the Federal Government and, except where prohibited by law, to charge interest on all delinquent debts owed to NIH by Recipients.

ARTICLE VI: DISPUTES

A. General

The Parties shall communicate with one another in good faith and in a timely and cooperative manner when raising issues under this Article.

B. Dispute Resolution Procedures

Any disagreement, claim or dispute between NIH and the Recipient concerning questions of fact or law arising from or in connection with this Agreement, and whether or not, involving an alleged breach of this Agreement (in whole or in part), may be raised only under this Article. Whenever disputes, disagreements, or misunderstandings arise, the Parties shall first attempt to resolve the issue(s) involved by discussion and mutual agreement as soon as practicable.

C. Limitation of Damages

To the extent allowed by law, each Party will be responsible for its negligent acts or omissions and the negligent acts or omissions of its employees, officers, and directors in the performance and the administration of this Agreement. No indemnification for any loss, claim, damage, or liability is intended or provided by the Government under this Agreement. Claims for damages of any nature whatsoever pursued under this Agreement shall be limited to direct damages only up to the aggregate amount of the Government funding disbursed as of the time the dispute arises, and for the Government, are subject to the availability of funds at the time that such claim is to be paid. In no event shall either Party be liable for claims for consequential, punitive, special and incidental damages, claims for lost profits, or other indirect damages.

ARTICLE VII: INTELLECTUAL PROPERTY RIGHTS

A. General

Each Party owns and retains all right, title and interest in and to its intellectual property rights, including all derivative and enhancements thereof, and this Agreement does not grant, by implication, estoppel or otherwise, either Party any right, title, interest, or license in or to the other Party's intellectual property rights except as expressly provided herein.

B. Joint Development

The Parties do not intend to jointly conceive or reduce to practice any technology or Intellectual Property rights under this Agreement ("Joint IP"). Notwithstanding the above, in the event Joint IP is created by operation of law, the Parties will own the IP in accordance with the provisions of U.S. patent and copyright law unless alternative terms are mutually agreed to in a separate agreement pertaining thereto.

C. Freedom of Action

This Agreement is non-exclusive, and the relationship established by its terms is intended to be non-exclusive. Subject to its obligations of confidentiality and to each Party's Intellectual Property Rights, as described in the Agreement, in no event shall either party be:

- precluded from developing or providing for itself, or for others, materials that are competitive with the products and services of the other Party, irrespective of their similarity to any products or services offered by the other Party in connection with this Agreement; or
- precluded from entering into similar agreements with others or from developing, selling, or licensing products and services competitive with the products and services of the other Party, except as may be otherwise set forth in a separate agreement between the Parties.

D. Data Protection

Section 301(d) of the Public Health Service Act, 42 U.S.C. 241(d), protects from disclosure identifiable, sensitive information collected or used during the course of biomedical, behavioral, clinical, or other research. Such protection is granted through the issuance of a "Certificate of Confidentiality." Recipient must comply with Section 301(d) of the Public Health Service Act, 42 U.S.C. 241(d).

ARTICLE VIII: PATENT RIGHTS

A. *Allocation of Principal Rights*

Unless the recipient shall have notified NIH that the Recipient does not intend to retain title, the Recipient shall retain the entire right, title, and interest throughout the world to each Subject Invention consistent with the provisions of this Article.

With respect to any Subject Invention in which the Recipient retains title, the Government shall have a nonexclusive, nontransferable, irrevocable, royalty-free, paid-up license to practice or have practiced on behalf of the United States the Subject Invention throughout the world.

B. Invention Disclosure, Election of Title, and Filing of Patent Application

The Recipient shall disclose each Subject Invention to NIH within four (4) months after the inventor discloses it in writing to the Recipient personnel responsible for patent matters. The disclosure to NIH shall be in the form of a written report and shall identify the Agreement and circumstances under which the Invention was made and the identity of the inventor(s). It shall be sufficiently complete in technical detail to convey a clear understanding, to the extent known at the time of the disclosure, of the nature, purpose, operation, and the physical, chemical, biological, or electrical characteristics of the Invention. The disclosure shall also identify any publication, sale, or public use of the invention and whether a manuscript describing the Invention has been submitted and/or accepted for publication at the time of disclosure.

The Recipient will elect whether or not to retain title to any such Invention by notifying the NIH, in writing within two years of disclosure to NIH. However, in any case where publication, sale, or public use has initiated the one-year statutory period wherein valid patent protection can still be obtained in the United States, the period for such notice may be shortened by NIH to a date that is no more than sixty (60) calendar days prior to the end of the statutory period.

The recipient shall file its initial application on a Subject Invention to which it elects to retain title within one (1) year after election of title or, if earlier, prior to the end of the statutory period wherein valid patent protection can be obtained in the United States after a publication, or sale, or public use.

The Recipient may elect to file patent applications in additional countries, including the European Patent Office and the Patent Cooperation Treaty, within either ten (10) months of the corresponding initial patent application or six (6) months from the date permission is granted by the Commissioner for Patents to file foreign patent applications, where such filing has been prohibited by a Secrecy Order.

The Recipient shall notify NIH of any decisions not to continue the prosecution of a patent application, pay maintenance fees, or defend in a reexamination or opposition proceedings on a patent, in any country, not less than thirty (30) calendar days before the expiration of the response period required by the relevance patent office.

Requests for extension of the time for disclosure election, and filing under Article VII, may be granted at NIH's discretion after considering the circumstances of the Recipient and the overall effect of the extension.

The recipient shall submit to NIH annual listings of Subject Inventions, negative annual reports are not required. At the completion of the Agreement, the Recipient shall submit a comprehensive listing of all Subject Inventions identified during the course of the Agreement and the current status of each. A negative report is required at the completion of the Agreement, if there are no Subject Inventions. If there were no inventions, the form must indicate "None."

C. Conditions When the NIH May Obtain Title

Upon NIH's written request, the Recipient shall convey title to any Subject Invention to NIH under any of the following conditions:

If the Recipient fails to disclose or elects not to retain title to the Subject Invention within the times specified in this Article;

In those countries in which the Recipient fails to file patent applications within the times specified in this Article; however, if the Recipient has filed a patent application in a country after the times specified in this Article, but prior to its receipt of the written request by NIH, the Recipient shall continue to retain title in that country; or

In any country in which the Recipient decides not to continue the prosecution of any application for, to pay the maintenance fees on, or defend in reexamination or opposition proceedings on, a patent on a Subject Invention.

D. Minimum Rights to the Recipient and Protection of the Recipient's Right to File

The Recipient shall retain a nonexclusive, royalty-free, license throughout the world in each Subject invention to which the NIH obtains title, except if the Recipient fails to disclose the Subject Invention within the times specified in this Article. The Recipient's license extends to its domestic subsidiaries and affiliates, if any, and includes the right to grant licenses of the same scope to the extent that the Recipient was legally obligated to do so at the time the Agreement was awarded. Any extension of the Recipient's license to its subsidiaries and affiliates that are based outside the United States must comply with all export control laws and other federal laws that may apply. The license is transferrable only with the approval of NIH, except when transferred to the successor of that part of the business to which the Subject Invention pertains. NIH approval for license transfer shall not be unreasonably withheld.

The Recipient's domestic license may be revoked or modified by NIH to the extent necessary to achieve expeditious practical application of the Subject Invention pursuant to an application for an exclusive license submitted consistent with appropriate provisions at 37 C.F.R. Part 404.

This license shall not be revoked in that field of use or the geographical areas in which the Recipient has achieved practical application and continues to make the benefits of the Subject Invention reasonably accessible to the public. The license in any foreign country may be revoked or modified at the discretion of NIH to the

extent the Recipient, its licensees, or the subsidiaries or affiliates have failed to achieve practical application in that foreign country.

Before revocation or modification of the license, NIH shall furnish the Recipient a written notice of its intention to revoke or modify the license, and the Recipient shall be allowed thirty (30) calendar days (or such other time as may be authorized for good cause shown) after the notice to show cause why the license should not be revoked or modified.

E. Recipient Action to Protect the NIH's Interest

The Recipient agrees to execute or to have executed and promptly deliver to NIH all instruments necessary to (i) establish or confirm the rights the NIH has throughout the world in those Subject Inventions to which the Recipient elects to retain title, and (ii) convey title to NIH when requested under this Article and to enable the NIH to obtain patent protection throughout the world in that Subject Invention.

The Recipient agrees to require by written agreement with its employees, other than clerical and non- technical employees, to disclose promptly in writing to personnel identified as responsible for the administration of patent matters and in a format suggested by the Recipient each Subject Invention made under this Agreement in order that the Recipient can comply with the disclosure provisions of this Article. The Recipient shall instruct employees, through employee agreements or other suitable educational programs, on the importance of reporting inventions in sufficient time to permit the filing of patent applications prior to United States or foreign statutory bars.

The Recipient shall include, within the specification of any United States patent application and any patent issuing thereon covering a subject invention, the following statement: "This invention was made with government support under the Agreement No: 1OT2ODXXXXX-XX awarded by the National Institutes of Health. The government has certain rights in the invention."

F. Reporting on Utilization of Subject Inventions

The Recipient agrees to submit, during and after the term of the Agreement, an annual report on the utilization of a Subject Invention or on efforts at obtaining such utilization that are being made by the Recipient or its licensees or assignees. Such reports shall include information regarding the status of development, date of first commercial sale or use, and gross royalties received by the Recipient. The Recipient also agrees to provide additional reports as may be requested by NIH in connection with any march-in proceedings undertaken by NIH in accordance with this Article. NIH agrees it shall not disclose such information to persons outside the NIH without permission of the Recipient, unless required by law.

All required reporting shall be accomplished, to the extent possible, using the iEdison portal at iEdison.gov To the extent any such reporting cannot be carried out by use of iEdison, reports and communications shall be submitted to the OTAO.

G. Preference for American Industry

Notwithstanding any other provision of this clause, the Recipient agrees that it shall not grant to any person the exclusive right to use or sell any Subject Invention in the United States unless such person agrees that any product embodying the Subject Invention or produced through the use of the subject invention shall be manufactured substantially in the United States. However, in individual cases, the requirements for such an

agreement may be waived by NIH upon a showing by the Recipient that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States or that, under the circumstances, domestic manufacture is not commercially feasible.

H. March-in Rights

The Recipient agrees that, with respect to any Subject Invention in which it has retained title, NIH has the right to require the Recipient, an assignee, or exclusive licensee of a Subject Invention to grant a non-exclusive license to a responsible applicant or applicants, upon terms that are reasonable under the circumstances, and if the Recipient, assignee, or exclusive licensee refuses such a request, NIH has the right to grant such a license itself if NIH determines that:

- Such action is necessary because the Recipient or assignee has not taken effective steps, consistent with the intent of this Agreement, to achieve practical application of the Subject Invention;
- Such action is necessary to alleviate health or safety needs which are not reasonably satisfied by the Recipient, assignee, or their licensees;
- Such action is necessary to meet requirements for public use and such requirements are not reasonably satisfied by the Recipient, assignee, or licensees; or
- Such action is necessary because the agreement required by this Article has not been obtained or waived or because a licensee of the exclusive right to use or sell any Subject Invention in the United States is in breach of such agreement.

ARTICLE IX: SOFTWARE AND DATA RIGHTS

A. Principal Rights

The Parties agree that in consideration for NIH funding, the Recipient intends to reduce to practical application terms, components and processes developed under this Agreement. With respect to any Data (which includes Software) provided under this Agreement, the Recipient warrants that Recipient or Sub-Recipient are sole author or owner of, or have the right to use and license, any Data, developed under this Agreement and that any Data provided or developed under this Agreement does not infringe any rights, including Intellectual Property rights of any third party of which the Recipient is aware. With respect to any Data provided or developed under this Agreement, the Recipient will only own the Data developed under this award. The Recipient grants to the Government a nonexclusive, irrevocable, sublicensable, worldwide, royalty-free, license to use, disclose, reproduce, prepare derivative works, distribute copies to the public, and perform publicly and display publicly, the Data in any manner for any non-commercial purpose.

B. Derivative Works

The Recipient grants to NIH a royalty-free, nonexclusive, irrevocable right to use, disclose, reproduce, post, link to, prepare derivative works, distribute copies to the public, and perform publicly and display publicly, in any manner and for any purpose, and to have or permit others to do so on NIH's behalf anywhere in the world, any derivative works of the Data or Software provided or developed by Recipient under this Agreement. Derivative

works, in this context, includes data (including associated labels, annotations, assertions, inferences, relationships, and indices), queries, graphical and graph representations, data models, topologies, procedural manuals, forms, diagrams, work-flow charts, and statistical records.

C. March-In Rights

In the event the NIH chooses to exercise its March-in Rights under Article VIII, the Recipient agrees, upon written request from the NIH, to deliver at no additional cost to the NIH, all Data necessary to achieve practical application within sixty (60) calendar days from the date of the written request. The NIH shall retain Unlimited Rights to this delivered Data. To facilitate any potential deliveries, the Recipient agrees to retain and maintain in good condition until three years after completion or termination of this Agreement, all Data necessary to achieve practical application of any Subject Invention.

D. Resources Due at Termination

Subject to the Resource Sharing Plan, upon termination of the award, whichever comes first, the Recipient shall make all Data (including associated labels, annotations, and indices) and training materials provided or developed under this Agreement available to the NIH under a Creative Commons By (CCBY) or comparable license. Recipient is not precluded from making all Data (including associated labels, annotations, and indices) and training materials provided or developed under this Agreement available to the NIH under a Creative Commons By (CCBY) or comparable license. It is the Recipient's responsibility to ensure that any PII or PHI in any Data, Software, tools, resources, training materials, technical solutions, or methods provided or developed under this Agreement be deidentified prior to availability to the public. A suitable repository or repositories selected in concurrence with NIH (subject to limitations noted) maybe used to facilitate making Data, Software, tools, resources, training materials, technical solutions, and methods available to the public. Repositories selected should have a sustainability plan reviewed by NIH. Resources shall also be provided to NIH via a physical copy.

E. Rights in Data (Publication and Copyrighting)

Except as otherwise provided in the terms and conditions of the award, the Recipient is entitled to assert copyright in any publications or other copyrightable works developed under a CFDE OT award without NIH approval. Recipient agrees to notify NIH, in writing, of the assertion of copyright in any publication or other copyrightable work developed under this Award, NIH approval to assert copyright is not required.

Rights in publication and other copyrightable works also extend to students, fellows, or trainees under awards whose primary purpose is educational, with the authors free to assert copyright in works without NIH approval. As a means of sharing knowledge, NIH encourages recipients to arrange for publication of NIH-supported original research in primary scientific journals. Recipients also may assert copyright in scientific and technical articles based on data produced under the OT award where necessary to effect journal publication or inclusion in proceedings associated with professional activities. Journal or other copyright practices are acceptable unless the copyright policy prevents the Recipient from making copies for its own use. All Recipients must acknowledge Federal funding when issuing statements, press releases, requests for proposals, bid invitations, and other documents describing projects or programs funded in whole or in part with Federal money. Each publication, press release, or other document about research supported by an NIH OT award must include:

- An acknowledgment of NIH OT award support such as: "Research reported in this [publication, release] was

supported by the Office of the Director, National Institutes of Health under OT award number [OTA-23-004}. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health."

- If the recipient plans to issue a press release about research supported by a CFDE OT award, it should notify the NIH OTAO, OTPO and OTAS in advance to allow for coordination. Publications resulting from work performed under a CFDE OT award-supported project must be included as part of the interim, annual, or final progress report submitted to the NIH OTAO, OTPO and OTAS.

F. NIH Public Access Policy

The NIH Public Access Policy implements Division F, Section 217 of PL 111-8 (Omnibus Appropriations Act, 2009). The policy ensures that the public has access to the published results of NIH-funded research at the NIH National Library of Medicine PubMed Central (NLM PMC), a free digital archive of full-text biomedical and life sciences journal literature (http://www.pubmedcentral.nih.gov/). Under the policy NIH-funded investigators must submit (or have submitted for them) to PMC (https://publicaccess.nih.gov/) an electronic version of the final, peer-reviewed manuscript upon acceptance for publication, to be made publicly available no later than 12 months after the official date of publication. The author's final peer-reviewed manuscript is defined as the final version accepted for journal publication and includes all modifications from the publishing peer review process, and all graphics and supplemental material associated with the article. Institutions and investigators are responsible for ensuring that any publishing or copyright agreements concerning submitted articles reserve adequate right to fully comply with this policy.

G. Sharing Research Resources

NIH considers the sharing of research resources (also called research tools) an important means to enhance the value of NIH-sponsored research. Restricting the availability of unique resources can impede the advancement of further research. Therefore, when these resources are developed with NIH funds and the associated research findings have been accepted for publication, or after they have been provided to NIH, it is important that they be made readily available for research purposes to qualified individuals within the scientific community and the public. Program staff are responsible for overseeing resource sharing policies and for assessing the appropriateness and adequacy of any proposed resource sharing plans. To provide further clarification of the NIH policy on disseminating unique research resources, NIH published Principles and Guidelines for Recipient of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Resources (64 FR 72090, December 23, 1999; NIH Grants Policy Statement, Section 8.2.3[1] and Best Practices for the Licensing of Genomic Inventions (70 FR 18413, April 11, 2005). These policy documents will assist recipients in determining reasonable terms and conditions for disseminating and acquiring research tools.

NIH Data Sharing Policy: The Recipient agrees to comply with the NIH Policy for Data Management and Sharing[2] that went into effect on January 25, 2023 and the GDS Policy[3].The NIH Genomic Data Sharing Policy sets forth expectations that ensure the broad and responsible sharing of genomic research data. Sharing research data supports the NIH mission and facilitates the translation of research results into knowledge, products, and procedures that improve human health. For the purposes of this Policy, genomic data includes genome sequence, transcriptomic, epigenomic, immunological and gene expression data. For additional information,

[1] NIH GPS, Sec. 8.2.3, https://grants.nih.gov/grants/policy/nihgps/html5/section_8/8.2.3_sharing_research_resources.htm
[2] NIH Policy for Data Management and Sharing, https://grants.nih.gov/grants/guide/notice-files/NOT-OD-21-013.html
[3] GDS Policy, https://osp.od.nih.gov/wp-content/uploads/NIH_GDS_Policy_Overview.pdf

see: https://grants.nih.gov/grants/guide/notice-files/not-od-14-124.html. Questions about the GDS policy can be E- mailed to GDS@mail.nih.gov.

General Data Sharing: Data sharing is essential for expedited translation of research results into knowledge, products, and procedures to improve human health. NIH endorses the sharing of final research data to serve these and other important scientific goals and expects and supports the timely release and sharing of final research data from NIH-supported studies for use by other researchers. "Timely release and sharing" is defined as no later than the acceptance for publication of the main findings from the final data set. Final and approved Data Sharing Plan must describe a data release schedule and plan for how the data to be acquired will be continuously made available for use and re-use by a broad variety of researchers, beginning no later than the second year of funding. Considerations in this plan might include but are not limited to: choice of repository or cloud platform, budgeting for data hosting and transfer, de-identification methods as appropriate, and plans for controlling access to protected data. A non-exhaustive list of data repositories of interest may be found here: https://www.nlm.nih.gov/NIHbmic/nih_data_sharing_repositories.html

Human Subject Data Sharing: NIH recognizes that data sharing may be complicated or limited, in some cases, by organizational policies, and local, state, and federal laws and regulations, including the HIPAA Privacy Rule. The rights and privacy of individuals who participate in NIH-sponsored research must be protected at all times. Thus, data intended for broader use should be free of identifiers that would permit linkages to individual research participants and variables that could lead to deductive disclosure of the identity of individual subjects. When data-sharing is limited, applicants should explain such limitations in their data-sharing plans. Recipients must exercise great care to ensure that resources involving human cells or tissues do not identify original donors or subjects, directly or through identifiers such as codes linked to the donors or subjects. Organizations that believe they will be unable to meet these data sharing expectations should promptly contact the OTAO and OTPO to discuss the circumstances, obtain information that might enable them to share data, and reach an understanding in advance of an award.

Genomic Data Sharing (GDS) Policy: The NIH Genomic Data Sharing (GDS) Policy sets forth expectations that ensure the broad and responsible sharing of genomic research data. Sharing research data supports the NIH mission and facilitates the translation of research results into knowledge, products, and procedures that improve human health. For the purposes of this Policy, genomic data includes single nucleotide polymorphisms (SNP) arrays, and genome sequence, transcriptomic, epigenomic, and gene expression data. All applications, regardless of the amount requested, proposing research that will generate large-scale genomic data, are expected to include a genomic data sharing plan (see https://sharing.nih.gov/genomic-data-sharing-policy/developing-genomic-data-sharing-plans). For additional information, see: https://sharing.nih.gov/genomic-data-sharing-policy. Questions about the GDS policy can be E-mailed to GDS@mail.nih.gov.

ARTICLE X: TITLE TO AND DISPOSITION OF PROPERTY

A. Title to Property

No significant items of property are expected to be acquired under this Agreement. Title to each item of property acquired under this Agreement with an acquisition value of $5,000 or less shall vest in the Recipient upon acquisition with no further obligation of the Parties unless otherwise determined by the OTAO. Should

any item of property with an acquisition value greater than $5,000 be required, the Recipient shall obtain prior written approval of the OTAO. All items of property, including equipment, in the approved proposal budget shall be considered pre-approved for the purposes of this clause. Title to this property shall also vest in the Recipient upon acquisition. The Recipient shall be responsible for the maintenance, repair, protection, and preservation of all property at its own expense. The Recipient's deliverable shall not be classified as property. The Government does not accept responsibility for loss or damage to any property or work it has not accepted.

B. Disposition of Property

At the completion of the term of this Agreement, items of property acquired with NIH funds with a value greater than $5,000 shall be disposed of in the following manner:

- Retained by Recipient for the use in another ongoing NIH research; or
- Purchased by the Recipient at an agreed-upon price, the price to represent fair market value, with the proceeds of the sale being returned to NIH; or
- Transferred to an NIH research facility with title and ownership being transferred to the NIH; or
- Donated to a mutually agreed upon university or technical learning center for research purposes; or
- Any other NIH-approved disposition procedure.

C. Property Management System Standards

Recipient may use their own property management policies and procedures for property purchased, constructed, or fabricated as a direct cost using NIH OT award funds.

ARTICLE XI: INFORMATION SHARING

A. *Public Release or Dissemination of Information*

A Recipient planning to issue communications such as a press release concerning the outcome of supported research under this Agreement must notify the NIH Office of the Director, Office of Strategic Coordination (OSC) Communications Team at CFComms@od.nih.gov, in advance to allow for coordination.

B. Publications and Presentations

Publications derived from this research should acknowledge support by the NIH Office of Strategic Coordination Common Fund Data Ecosystem (CFDE) Program, with reference to OTA-23-004 and the award number **[OT Award #]** In addition, articles for publication or presentation will contain a statement on the title page worded substantially as follows:

This research was, in part, funded by the National Institutes of Health (NIH) under other transactions award **[OT Award #}.** The views and conclusions contained in this document are those of the authors and should not be interpreted as representing official policies, either expressed or implied, of the NIH.

Recipients are required to fully comply with the NIH Public Access Policy, which ensures that the public has access to the published results of NIH-funded research at the NIH National Library of Medicine PubMed Central (PMC) (www.pubmedcentral.nih.gov). The NIH Public Access Policy can be found at https://publicaccess.nih.gov/policy.htm

C. Prohibition from Confidential Information Release

The Recipient agrees to exclude any and all Confidential Information prior to public release of the material. The Parties agree that they shall take appropriate and reasonable measures to protect Confidential Information received under this Agreement. Confidential Information shall mean information, any form, disclosed by one Party (Disclosing Party) to the other Party (Receiving Party) and marked as confidential or proprietary at the time of disclosure. Receiving Party agrees not to disclose Confidential Information to anyone, other than its employees' performing services under this Agreement, or to use Confidential Information for any purpose other than to carry out its role pursuant to this Agreement, except as required by law or a court of competent jurisdiction.

This restriction on disclosure and use of Confidential Information survives the Recipient Party's withdrawal or termination from this Agreement for five (5) years, unless required by law to be protected for a longer period. The previously stated obligations of confidentiality do not apply to any information that:

- Becomes a matter of public knowledge by means other than a wrongful act, omission or fault of the Recipient Party, its employees, or agents;
- Is rightfully received from a third party without restriction;
- Is approved for release by the submitting Party; or
- Can be demonstrably shown to have been independently developed by the Receiving Party without use of the Confidential Information; or
- Is disclosed pursuant to a court order or as required by law.

ARTICLE XII: FOREIGN ACCESS TO TECHNOLOGY

A. General

Recipient will take no possession of any International Traffic in Arms Regulations (ITAR) controlled information or materials in performance of this Agreement. At no time, is any Recipient information technology product, as shipped from Recipient, subject to ITAR, and no information technology products are being provided in performance of this Agreement (i.e., no Recipient products are on the United States Munitions List).

B. Restrictions on Sale or Transfer of Technology to Foreign Firms or Institutions

1. In order to promote the national security interests of the United States and to effectuate the policies that underlie the export and ITAR regulations, the procedures stated in subparagraphs B.2, B.3, and B.4 below shall apply to any transfer of Technology under this Agreement. For purposes of this paragraph, a transfer includes a sale of the company, and sales or licensing of Technology. Transfers do not include:
    - Information made publicly available or open source under Article IX, Section D-G, or Article XI,

Section B, or
- Sales of products or components, or
- Licenses of software or documentation related to sales of products or components, or
- Transfer to foreign subsidiaries of the Recipient for purposes related to this Agreement, or
- Transfer which provides access to Technology to a Foreign Firm or Institution which is an approved source of supply or source for the performance of work under this Agreement provided that such transfer shall be limited to that necessary to allow the firm or institution to perform its approved role under this Agreement.

2. The Recipient shall provide timely notice to NIH of any proposed transfers from the Recipient of Technology developed under this Agreement to Foreign Firms or Institutions. If NIH determines that the transfer may have adverse consequences to the national security interests of the United States, the Recipient, its vendors, and NIH shall jointly endeavor to find alternatives to the proposed transfer which obviate or mitigate potential adverse consequences of the transfer, but which provide substantially equivalent benefits to the Recipient.

3. In any event, the Recipient shall provide written notice to the NIH OTAO and OTPO of any proposed transfer to a Foreign Firm or Institution at least sixty (60) calendar days prior to the proposed date of transfer. Such notice shall cite this Article and shall state specifically what is to be transferred and the general terms of the transfer. Within thirty (30) calendar days of receipt of the Recipient's written notification, the NIH OTAO shall advise the Recipient whether it consents to the proposed transfer. In cases where NIH does not concur or sixty (60) calendar days after receipt and NIH provides no decision, the Recipient may utilize the procedures under Article VI, Disputes. No transfer shall take place until Parties come to an agreement.

4. In the event a transfer of Technology to Foreign Firms or Institutions which is NOT approved by NIH takes place, the Recipient shall (a) refund to NIH funds paid for the development of the Technology and (b) the Government shall have a non-exclusive, nontransferable, irrevocable, royalty-free, paid-up license to practice or have practiced on behalf of the United States the Technology throughout the world for Government and any and all other purposes, particularly to effectuate the intent of this Agreement. Upon request of the Government, the Recipient shall provide written confirmation of such licenses.

C. Prohibition On Certain Telecommunications and Video Surveillance Services or Equipment

OT recipients and subrecipients are prohibited from expending OT funds to:
1. Procure or obtain;
2. Extend or renew an existing OT award; or
3. Enter into a contract (or extend or renew a contract) to procure or obtain equipment, services, or systems that use covered telecommunications equipment or services as a substantial or essential component of any system, or as critical technology as part of any system. As described in Public Law 115-232, section 889, covered telecommunications equipment is telecommunications equipment produced by Huawei Technologies Company or ZTE Corporation (or any subsidiary or affiliate of such entities).
    i. For the purpose of public safety, security of government facilities, physical security surveillance of critical infrastructure, and other national security purposes, video surveillance and telecommunications equipment produced by Hytera Communications Corporation, Hangzhou Hikvision Digital Technology Company, or Dahua Technology Company (or any subsidiary or affiliate of such entities).

ii. Telecommunications or video surveillance services provided by such entities or using such equipment.
iii. Telecommunications or video surveillance equipment or services produced or provided by an entity that the Secretary of Defense, in consultation with the Director of the National Intelligence or the Director of the Federal Bureau of Investigation, reasonably believes to be an entity owned or controlled by, or otherwise connected to, the government of a covered foreign country (i.e., the People's Republic of China).

ARTICLE XIII: INFORMATION SECURITY

The Parties agree that maintaining the integrity, confidentiality, availability, and security of NIH Data is of critical importance. For Data stored under this Agreement:

The owner of the Data will specify information security protocols and standards that are appropriate to the sensitivity level and risk associated with unauthorized disclosure, modification, or loss of the Data.

a. NIH anticipates that all Data will be equivalent to "low" or "moderate" risk levels, as defined by NIST Federal Information Processing Standards Publication 199 ("FIPS 199").
b. NIH anticipates that all Data will be stored within the Continental United States.
c. NIH does not anticipate storing Data that is subject to the Health Insurance Portability and Accountability Act (HIPAA) at this time. If Designated Recipient does use a cloud service provider (CSP) to store, process, or transmit Data subject to HIPAA, then execution of Designated Recipient's (as the case may be) applicable Enrollment shall include execution of the HIPAA Business Associate Agreement ("BAA"), the full text of which identifies the Online Services to which it applies and is available at http://aka.ms/BAA.
d. Unless otherwise informed in writing by the NIH, all Controlled-Access Data is protected by Section 301(d) of the Public Health Service Act, 42 U.S.C. 241(d).

The Recipient's administrative role is to ensure that data and information systems pertinent to this award are maintained in a manner equivalent to appropriate federal standards such as NIST SP 800-53, and that documented procedures and evidence of administrative processes can be made available to NIH upon request.

The Parties also acknowledge that information security protocols and standards are likely to evolve over time. Therefore, the systems and processes made accessible to the NIH by the Recipient under this Agreement may need to be revisited and/or adapted to ensure the continued integrity, confidentiality, and security of NIH Data.

The Recipient is responsible for the information security of data generated under this Agreement. All information systems, electronic or hard copy which contain Federal data need to be protected from unauthorized access.

ARTICLE XIV: LOWER TIER AGREEMENTS

A. *Definitions*

1. "Lower Tier Agreement" means a written agreement between the Recipient and an OT award Sub-

Recipient.

2. "Sub-Recipient" means any legal entity that, pursuant to a Lower Tier Agreement, uses Federal funds to carry out a public purpose consistent with NIH's statutory authorities, has its performance measured in relation to whether the objectives of the NIH program were met, or has responsibility for programmatic decision making. A Sub-Recipient is distinguished from a contractor providing goods and services within normal business operations for the Recipient's own use or that are ancillary to conducting/completing activities under this Agreement, provides similar goods or services to many different purchasers, and normally operates in a competitive environment. The Recipient is responsible for determining whether a legal entity is a Sub-Recipient on a case-by-case basis, consistent with any additional guidance supplied by the NIH to support these determinations.

B. Authorization

The Recipient is authorized to enter into Lower Tier Agreements with Sub-Recipients provided Recipient complies with the authorization process described in Paragraph C of this Article. Recipient is responsible for ensuring the Sub-OT Recipient is compliant with the flow down terms.

C. Authorization Process

1. Either party may recommend to the other the need for a Lower Tier Agreement. This recommendation should include a written justification describing the need for a Lower Tier Agreement and may also include, if feasible, the proposed scope of work, the identity of the suitably qualified Sub-Recipient(s), and the anticipated cost.
2. Lower Tier Agreements are subject to the review of the OTAO, in consultation with the OTPO, and may not be executed or modified by the Recipient until the Recipient has received the written approval of the OTAO.

D. *General*

The Recipient shall give the OTAO prompt written notice of any action or suit filed and prompt notice of any claim made against the Recipient by any Sub-Recipient that, in the opinion of the Recipient, may result in litigation related in any way to this Agreement.

ARTICLE XV: HUMAN SUBJECTS RESEARCH

The Recipient shall not engage in human subjects and clinical trials research under this Agreement.

ARTICLE XVI: ANIMAL WELFARE

The Recipient shall not engage in animal subjects research under this Agreement.

ARTICLE XVII: ADDITIONAL ADMINISTRATIVE REQUIREMENTS

A. Financial Conflict of Interest

The NIH is committed to preserving the public's trust that the research we support is conducted without bias and with the highest scientific and ethical standards. The Recipient shall submit their publicly accessible Financial Conflict of Interest policy to NIH via the eRA Commons Institution Profile (IPF) Module. For information about the NIH FCOI policy, refer to https://grants.nih.gov/grants/policy/coi/index.htm.

B. Organizational Conflicts of Interest (OCI)

Recipients are required to identify and disclose all facts relevant to potential OCIs involving sub-recipients, consultants, etc. Under this section, the Recipient is responsible for providing this disclosure as appropriate when it occurs. The disclosure must include the PI/Collaborators', and as applicable, proposed member's OCI mitigation plan. The OCI mitigation plan must include a description of the actions the proposer has taken, or intends to take, to prevent the existence of conflicting roles that might bias the proposer's judgment and to prevent the proposer from having an unfair competitive advantage.

The government will evaluate OCI mitigation plans to avoid, neutralize, or mitigate potential OCI issues before award issuance and to determine whether it is in the government's interest to grant a waiver. The government may require proposers to provide additional information to assist the government in evaluating the proposer's OCI mitigation plan. If the government determines that a proposer failed to fully disclose an OCI or failed to reasonably provide additional information requested by the government to assist in evaluating the proposer's OCI mitigation plan, the government may reject the Detailed Plan and withdraw it from consideration for award.

C. Organizational Responsibility Regarding Investigator Financial Conflicts-Of-Interest

The Recipient shall be deemed responsible for compliance with the requirements of 45 CFR Part 94, Responsible Prospective Contractors, which promotes objectivity in research by establishing standards to ensure that Principal Investigators and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded under this Agreements or proposed for such funding (which may include, for example, collaborators or consultants) will not be biased by any Investigator financial conflicts-of-interest. Further information is available at: 45 CFR Part 94—Responsible Prospective Contractors.[4]

C. Closeout

The requirement for timely closeout is a Recipient responsibility. Closeout includes ensuring timely and accurate submission of all required reports and adjustments for amounts due to the Recipient or NIH. Attachment 5: Reporting Requirement will outline the specific timeline requirements for submission of the Final Financial Report, the Final Progress Report, and Final Invention Statement and Certification.

[4]45 CFR Part 94, https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-94

ARTICLE XVIII: APPLICABLE STATUTES AND REGULATIONS

NIH intends to uphold high ethical, health, and safety standards in both the conduct of the research it funds and the expenditure of public funds by its Recipients. The signature of the RBO on the application certifies that the organization complies, or intends to comply, with all laws, regulations, and NIH policies applicable to the Recipient and the performance of work outlined in the SOM. These include, but are not limited to, the following:

A. Civil Rights Act

This Agreement is subject to the compliance requirements of Title VI of the Civil Rights Act of 1964 as amended (42 U.S.C. § 2000d) relating to nondiscrimination in Federally assisted programs. The Recipient has signed an Assurance of Compliance with the nondiscriminatory provisions of the Act (https://www.hhs.gov/civil-rights/index.html).

B. Federal Information Security Management Act (FISMA)

The Recipient's information systems, electronic or hard copy, which contain data funded under this award need to be protected from unauthorized access. The applicability of FISMA to NIH recipients applies only when recipients collect, store, process, transmit or use information on behalf of HHS or any of its component organizations. For details on FISMA, refer https://www.cisa.gov/federal-information-security-modernization-act.

C. Harassment and Discrimination Protections

The Recipient certifies the commitment to:

1. Ensuring that proper policies, procedures, and oversight are in place to prevent discriminatory harassment and other discriminatory practices;
2. Responding appropriately to allegations of discriminatory practices; and
3. Adopting and following institutional procedure for requesting NIH prior approval of a change in the status of the Program Director/Principal Investigator (PI/PD) or other senior/key personnel if administrative or disciplinary action is taken that impacts the ability of the PI/PD or other key personnel to continue his/her role on the NIH award (https://www.nih.gov/anti-sexual-harassment/nih-recipient-organizations-those-who-work-there).

D. No Individuals or Entities on OT Award Debarred or Suspended from Receiving Federal Funds

The Recipient certifies that no individuals or entities on this OT Award are debarred or suspended from receiving Federal funds (https://www.gsa.gov/policy-regulations/policy/acquisition-policy/office-of-acquisition-policy/gsa-acq-policy-integrity-workforce/suspension-debarment-and-agency-protests/frequently-asked-questions-suspension-debarment & https://grants.nih.gov/grants/policy/nihgps/html5/section_4/4.1.6_debarment_and_suspension.htm).

E. Additional Public Policy Requirements

More information about public policy requirements for Common Fund OT Agreements can be found here: https://commonfund.nih.gov/dotm/publicpolicy.

ARTICLE XIX: ORDER OF PRECEDENCE

In the event of any inconsistency between the terms of this Agreement and language set forth in the Attachments, the inconsistency shall be resolved by giving precedence in the following order: (1) The Agreement, and then (2) all Attachments to the Agreement.

ARTICLE XX: EXECUTION

This Agreement constitutes the entire agreement of the Parties and supersedes all prior and contemporaneous agreements, understandings, negotiations, and discussions among the Parties, whether oral or written, with respect to the subject matter hereof. This Agreement may be revised only by written consent of the Recipient and the NIH OTAO, in consultation with the OTPO. This Agreement, or modifications thereto, may be executed in counterparts each of which shall be deemed as original, but all of which taken together shall constitute one and the same instrument.