ENGAGING COMMON FUND DATA COORDINATING CENTERS TO ESTABLISH THE COMMON FUND DATA ECOSYSTEM

Engagement Opportunity Announcement

Overview Information

Participating Organization(s)	National Institutes of Health
Components of Participating Organizations	This Other Transaction Engagement Opportunity Announcement (OT EOA) is developed as an ongoing Common Fund effort through the NIH Office of the Director, Office of Strategic Coordination.
Engagement Opportunity Title	Engaging Common Fund Data Coordinating Centers to Establish the Common Fund Data Ecosystem (CFDE)
Activity Code	**OT2 Other Transaction (OT)** OT awards are not grants, cooperative agreements, or contracts. They are used by components within the NIH, including the Common Fund, 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.
Funding Announcement (FA) Number	OTA-20-005
Related Notice	
Catalogue of Federal Domestic Assistance (CFDA) Number(s)	93.310
Engagement Opportunity Purpose	The purpose of this announcement is to invite Engagement Plans from Data Coordinating Centers (DCCs) from Common Fund programs to engage with the Common Fund Data Ecosystem Coordinating Center (CFDE-CC) and with each other to establish the CFDE. The CFDE is a network of data sets and data managers who will work together in an effort to advance science by making Common Fund data sets more useful alone and in

	combination with other Common Fund data sets. The CFDE-CC supports efforts to make Common Fund data sets more findable, accessible, interoperable, and reusable (FAIR) for the scientific community through collaboration, end-user training, and data set sustainability.
Objective Review	NIH will convene an appropriate review group to evaluate Detailed Engagement Plans. See the Objective Review section of this opportunity for further details.
Eligibility	See the Eligibility section of this opportunity.
Funds Available and Anticipated Number of Awards	The current budget for this effort is planned for approximately $7.5 million over a 3-year period for up to 13 awards. However, NIH Common Fund procedures and OT mechanisms allow for significant flexibilities to make adjustments necessary to pursue catalytic and transformative initiatives. Award levels may increase or decrease over time based on programmatic needs, funding availability, and recipient performance.
Award Project Duration	Initial Project duration is anticipated to be three years, but individual projects may be extended to meet the requirements of individual data sets.
Detailed Engagement Plan Submission Instructions	Detailed Engagement Plans must be submitted via the NIH eRA ASSIST System by 5:00 p.m. local time on the due date (see Key Dates below). To submit a Detailed Engagement Plan via ASSIST, the proposer organization must be registered in eRA Commons (see instructions). Organizations already registered in eRA Commons do not need to register. Once the organization is registered, the individual(s) with the roles of Authorized Organizational Representative (AOR) and Principal Investigator must be affiliated with the organization and have eRA Commons credentials to complete the submission process. Complete Detailed Plans must be submitted via ASSIST by the Authorized Organizational Representative. Use OTA-20-005 in the field requesting Funding Opportunity Announcement. Here are instructions for submitting via the NIH eRA ASSIST system. Technical help is available at the eRA Service Desk.
Authority	Other Transaction 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.

Key Dates

Release Date of this Engagement Opportunity Announcement	1/29/20
Cross-pollination meeting (optional)	January 30-31, 2020 for the first round of engagements. There will be an additional cross-pollination workshop for the second round of engagements, date to be determined.
Engagement Plan Overview Due Date	The NIH intends to conduct two cycles of solicitation and review of Engagement Plans, both of which will require DCCs to submit an Engagement Plan Overview first followed by Detailed Engagement Plans. The first deadline for providing Engagement Plan Overviews is Tuesday, February 18, 2020. The second is Monday, May 18, 2020. The Engagement Plan Overview must be emailed to Lora Kutkat (CFDE@od.nih.gov) by 11:59 PM ET on or before the due date by the institution's AOR. The contact Principal Investigator and other relevant institutional officials must be cc'd.
Detailed Engagement Plan Due Date	Monday, March 16, 2020 for the first cycle OR Monday, June 15, 2020 for the second cycle. Detailed Engagement Plans must be submitted via ASSIST (see Detailed Engagement Plan Submission Instructions section).
Earliest Start Date	On or around May 1, 2020 OR August 3, 2020
Kickoff Meeting	An initial CFDE kickoff meeting will be held May 13-14, 2020 in Bethesda, MD for those DCCs who elect to engage during the first submission. A second CFDE meeting will be held September 9-10, 2020 and will incorporate DCCs that engage via the second submission.

Agency Contacts

NIH encourages inquiries concerning this announcement and welcomes the opportunity to answer questions from potential proposers.

Scientific/Research Contact(s):	Lora Kutkat - Division of Program Coordination, Planning, and Strategic Initiatives, NIH Office of the Director (OD); Common Fund Program Officer Telephone: 309-616-9059 Email: CFDE@od.nih.gov

Financial/Agreements Officer Contact(s):	Terri Jarosik: National Institute of Mental Health Telephone: 301-443-3858 Email: tjarosik@mail.nih.gov

Outline of this Opportunity

1. The Common Fund Data Ecosystem Overview

Background

Common Fund programs are intended to provide resources that accelerate discovery across many different biomedical research fields. Often these resources include large data sets and associated digital tools needed to mine and analyze the data. To maximize impact, these data sets and tools must be leveraged by researchers from different disciplines, with varying expertise in bioinformatics and large-scale data analysis. Additionally, these data sets must be usable together across interoperable platforms. However, current approaches to data storage, management, and analysis mean that data are often not Findable, Accessible, Interoperable, and Reusable (FAIR).

To address this challenge, the Common Fund is supporting the Common Fund Data Ecosystem (CFDE), an ongoing investment in cloud-based data management infrastructure that will support Common Fund data sets. The goals of the CFDE are:

- Enhance the ability to ask scientific questions across data sets using cloud-based infrastructure and tools
- Enable the uptake, reuse, and addition of Common Fund data and tools
- Support the storage, sharing, and sustainability of Common Fund data sets
- Provide training that maximizes scientists' ability to upload data and use Common Fund data and other resources, particularly in a cloud environment

To accomplish these goals, the CFDE includes several integrated efforts:

- **CFDE-Coordinating Center (CFDE-CC)** – The CFDE-CC manages and organizes CFDE activities, engages with participating Common Fund programs, connects with user communities, supports training, develops tools and standards, and provides technical expertise. The CFDE-CC will work with the Common Fund DCCs to:
    - Make Common Fund data sets more useful and usable within a program and between programs by improving FAIRness,
    - Capture and develop best practices for Common Fund programs to leverage,
    - Enhance the ability to ask scientific questions across data sets,
    - Establish training tools and/or courses to facilitate the use of the data, including training to facilitate use of the data in a cloud environment,
    - Increase reuse of data and tools across and between programs and after a program ends, and
    - Provide a pathway to sustainability after Common Fund programs end.

  The CFDE-CC is already funded to manage and organize CFDE activities, engage with participating Common Fund programs, connect with user communities, support training, develop tools and standards, and provide technical expertise. Since April 2019, the CFDE-CC has engaged with several Common Fund programs to understand the opportunities and challenges that they face with respect to making their data and other digital objects more useful and usable within and between Common Fund programs. The CFDE-CC has also been actively laying a foundation for interoperability that will facilitate the FAIRness of these Common Fund data sets through the CFDE. In addition, the CFDE will establish a portal for easy access to multiple data sets and will support the development of technical solutions that will enhance interoperability when multiple data sets need to be queried together. These activities will be conducted in close partnership with relevant Common Fund programs. Additional information about the CFDE-CC can be found at https://nih-cfde.org/.

- **Common Fund DCCs** – Through this Engagement Opportunity Opportunity, DCCs that are managing data from Common Fund programs will work with the CFDE-CC to understand their program's unique requirements for data storage and analysis in a cloud environment, adopt/adapt guidelines and best practices, share resources and tools with other DCCs, establish and enable use cases for cross-data analyses, and provide training. The DCCs will serve as a contact point between the CFDE and the data-generating components of each participating program. They will work with the data generating components as needed to ensure that the CFDE evolves to meet their needs. NIH intends to support all DCCs to participate in the CFDE who develop compelling Detailed Engagement Plans, as determined by expert review. See the Eligibility section below for a list of Common Fund DCCs invited to submit a Detailed Engagement Plan.

- **Leveraging the Science and Technology Research Infrastructure for Discovery, Experimentation, and Sustainability (STRIDES) Initiative** - A key component of the CFDE is enabling computing in a cloud environment. Working with the STRIDES Initiative from the NIH Office of Data Science Strategy (ODSS), the CFDE will develop guidelines to ensure data and tools are stored and organized optimally for proper data versioning and upkeep. Working with the STRIDES Initiative also will provide favorable pricing for cloud data storage and use of Common Fund data sets.

The combination of these three efforts through the CFDE is thus intended to provide ongoing data management infrastructure that will support existing, and future Common Fund data sets in a manner that enables novel scientific research that was not possible before.

2. Partnering with the CFDE-CC

The purpose of this solicitation is to fund Common Fund DCCs who will partner with the CFDE-CC and with each other to establish the CFDE in any or all of the 3 key areas described below. While each DCC may not elect to participate in all three areas, each is expected to actively collaborate with the CFDE-CC in the first area. Note that the areas and descriptions below are examples and not exhaustive. Importantly, each application will be considered as a partner with the CFDE-CC, specifically the recipient funded through OT3OD025259 (Principal Investigator Owen White). Through this partnership, the CFDE-CC will help proposers orient plans throughout the Engagement Opportunity process to fully address the needs of the CFDE.

Area 1. Enabling access to, and computation across, multiple data sets in a cloud environment.

- *Implementation of FAIRShake and FAIRness Remediation*

The CFDE-CC will work with Common Fund DCCs to assess the FAIRness of their data and other digital objects through the FAIRShake tool and provide support to increase FAIRness. A particular emphasis of the FAIR assessment involves interoperability – a measure of FAIRness that must be assessed in combination with other data sets. DCCs will work with the CFDE-CC to increase the FAIRness of their data and digital objects.

- *Data Portal – design, functions, features, UI/UX*

The CFDE-CC will work with the DCCs to refine requirements for and prototype a public facing portal to provide a centralized way to query Common Fund data sets maintained by the participating DCCs in a FAIR way. The portal will facilitate cross-data set queries using an expanding number of Common Fund data sets. Participating DCCs will collaborate on and test the design, features, function, UI/UX, and other requirements of the portal from the perspective of a DCC and the end-user community. DCC involvement is likely to vary between programs, but a common area of collaboration will involve working with the CFDE-CC to correct and complete metadata ingests into the underlying system, DERIVA.

- *Data Asset Specification and Manifest Development*

A review of the data types and studies hosted by each DCC shows an incredible diversity of data types. While many of the same types of data are hosted between sites, data may not be useful in combination

due to a variety of incompatibilities that currently prevent DCCs from making use of each other's data. The CFDE-CC is working to standardize the ability to bundle a list of CFDE data assets into a machine-readable file to facilitate finding data sets among DCCs and effectively transport these data sets to resources such as cloud-based analysis tools. In addition, the DCCs will work with the CFDE-CC to generate manifests for all of their data assets, enabling both comprehensive inventories for their files, the use of that information to find and access all of their data in a CFDE portal, and to analyze that data within the cloud environment. All DCCs will be expected to participate in assisting with generation of data asset manifests. Proposers may also elect to assist with the on-going development of asset and manifest specifications, offer existing technologies they have developed to the broader CFDE consortium, or propose new methods for consideration for adoption across the CFDE.

- *Use Case Development and Testing*

The CFDE-CC will assist the DCCs, to the extent necessary, in completing their proposed use cases with other DCCs. In addition, the CFDE-CC will collaborate with participating recipients to develop and accomplish more complicated scientific questions as data sets become more interoperable.

- *SSO/Authorization & Authentication Coordination with the NIH*

The CFDE-CC will partner with the NIH to pilot the NIH Researcher Authorization Service and the CFDE-CC's Globus infrastructure to understand the benefits and challenges such implementations would pose to Common Fund DCCs. Among other things, the prototyping efforts will inform the Common Fund of a secure way to authorize users that is in sync with dbGaP, improve the process for incorporating other program's data into a portal, and maintain alignment with efforts across the NIH.

- *Cross-Pollination Events*

Individual DCCs have significant expertise in complementary areas, and ongoing, regular engagement to discuss technological challenges, approaches, and solutions will further efforts to de-silo Common Fund data and people and continue data and digital object interoperability beyond initial joint exercises and use cases. The CFDE-CC will coordinate several cross-pollination events to facilitate interactions, information exchange, and use cases.

Area 2. Facilitating set-up and ramp-down of Common Fund DCCs.

- *Planning for Data Collection, Storage, and Sustainability*

The CFDE will work to provide comprehensive sustainability of Common Fund data that addresses two needs: helping newly formed DCCs to join the CFDE, and participating in the best FAIRness practices that will enable cross-data set querying after DCCs are decommissioned. The CFDE-CC is working to produce software and methods that will reduce costs and efforts of individual DCCs implementing similar systems. In addition, CFDE-CC will develop a robust data life cycle program to manage continued long-term stewardship of data. DCCs will be asked to contribute to a scalable and otherwise adaptable data life cycle model and consider what, if any, efficiencies can be found in adopting standardized FISMA or other documentation that may be required to operate a DCC.

- *Best Practice Documents*

One goal of the CFDE is to help new DCCs ramp up quickly and enable sustainability of Common Fund data sets when a program is scheduled to end. Participating DCCs will collaborate with the CFDE-CC on developing best practices for future, newly formed, and mature Common Fund DCCs on such topics as:

- FAIR guidelines
- New data set onboarding
- Toolkit to assist new Common Fund DCCs
- Tool and other digital object development for reuse
- Cloud computing without egress
- Data asset specification
- GUID generation
- Implementation of the NIH Researcher Authorization Service and/or other SSO/authentication and authorization strategies
- Data set and digital object sustainability after a program ends

Area 3. Enabling end-users to compute on data in the cloud.

- *Training for End-Users*

The Common Fund's intent to increase cloud computing will place many end-users in unfamiliar analytic and other computational spaces. The DCCs will be asked to work with the CFDE-CC, specifically its training coordination center, to understand and fulfill training needs of end-users to query and analyze one or more data sets in the cloud environment. Such needs include training bioinformaticians to analyze clinical data, training clinicians to use bioinformatics tools, and basic training in cloud computing. The CFDE-CC will work with individuals in the DCCs to organize workshops or other events, host outreach activities, develop general bioinformatics resources, and enact a communication strategy to facilitate the use of individual data sets and data sets made interoperable through the CFDE.

3. Partnering with other DCCs

Since a key goal of the CFDE is to enable expanded utility of Common Fund data sets through interoperation across data sets, DCCs will work with each other to identify scientific opportunities that would be enabled by cross-querying and then, through collaboration with the CFDE-CC, to identify and adopt appropriate standards to enable the queries. This may involve several approaches that include, but are not limited to, use case identification and refinement, assessments of FAIRness and remediation strategies, data harmonization with other Common Fund DCCs, data management, cloud computing (without egress), workflow, API support, digital object reuse between environments, single sign-on or authorization and authentication support, and troubleshooting. Activities may involve partnering with multiple Common Fund DCCs. Activities may involve partnering with resources external to Common Fund in addition to at least one Common Fund DCC.

4. Eligibility

This Engagement Opportunity targets current Common Fund DCCs in seeking plans for establishing the CFDE. Principal Investigators for each of the DCCs below are strongly encouraged to work with each other to identify opportunities for collaboration (see Developing Engagement Plans instructions below):

- 4D Nucleome
- Acute to Chronic Pain Signatures (A2CPS)
- Extracellular RNA Communication (ExRNA)
- Gabriella Miller Kids First
- Genotype Tissue Expression (GTEx)
- The Human Biomolecular Atlas Project (HuBMAP)
- Illuminating the Druggable Genome (IDG)
- Knock-Out Mouse Phenotyping Project (KOMP2)
- Library of Integrated Network-Based Cellular Signatures (LINCS)
- Metabolomics
- Molecular Transducers of Physical Activity Consortium (MoTrPAC)
- Stimulating Peripheral Activity to Relieve Conditions (SPARC)
- Undiagnosed Diseases Network (UDN)

Multiple Principal Investigators

More than one individual may be named as Principal Investigator on the Engagement Plans. One individual must be identified as the contact Principal Investigator. The contact Principal Investigator must be employed by or affiliated with the proposer organization.

Financial and Risk Assessment

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

5. Developing Engagement Plans

The Engagement Plans will be developed through a two-phase process. In the first phase, an Engagement Plan Overview (Overview) will be provided; in the second phase, Detailed Engagement Plans (Detailed Plans) will be provided. The purpose of the Overviews is to allow the NIH to: 1) establish a unique review process that will bring together DCC Principal Investigators who plan to work together, the CFDE-CC Principal Investigators, and external experts; and 2) orient or re-orient one or more

applications to satisfy the needs of the CFDE. Reviews of Detailed Plans from DCC Principal Investigators who plan to collaborate will therefore be conducted together. NIH may also share, with PI agreement, Overviews and/or Detailed Plans between or among teams to ensure optimal configuration of funding, partnerships, and activities. The Overviews (phase 1) will allow these review meetings to be arranged. The Detailed Plans (phase 2) will be considered during the review. For more details on the review process, see section 6 (Objective Review) below.

Phase 1: Engagement Overview

Engagement Overviews will be accepted only from DCCs listed in the Eligibility section of this Announcement. DCC Principal Investigators who wish to participate in the CFDE must submit an overview of their proposed engagement plans which outlines how they intend to partner with the CFDE-CC on the goals described above for the CFDE-CC and how they intend to collaborate with other DCC Principal Investigators. The Overview must be emailed to Lora Kutkat (CFDE@od.nih.gov) by 11:59 PM ET on or before the due date by the Authorized Organizational Representative of the submitting institution. The contact Principal Investigator and other appropriate institutional officials should be cc'd.

Overviews may not exceed 2 pages and must include the following:

- Number and title of this Engagement Opportunity Announcement
- Descriptive title of the proposed activity
- Designated project lead(s) with address, phone number, email address, and organizational affiliation
- List of all anticipated key personnel and organizational affiliations
- Brief description of the Common Fund program DCC
- Overview of interest in partnering with the CFDE-CC to address any of the key goals of the CFDE-CC as described in the "Partnering with the CFDE-CC" section above
- Overview of interest in partnering with other DCCs
    - The partnering DCC(s) must be named, and a brief statement about the relevant data types, tools, or methods that will form the basis for the partnership described. The ideas for partnering with other DCC(s) do not have to be developed in collaboration with the relevant DCC(s). However, **Principal Investigators are encouraged to reach out to the proposed partner before submitting Overview/Detailed Plans**.
    - Goals for the DCC-to-DCC partnership should be described, drawing from the "Partnering with other DCCs" section above.
- Agreement that any and all parts of the Overviews can be shared among other proposers

Phase 2: Detailed Engagement Plans

Detailed Plans will be accepted only from DCCs listed in the Eligibility section of this Announcement and that submit an Overview as described above. The NIH will not review and will return Detailed Plans submitted from organizations not included in the Eligibility section and without a submitted Engagement Overview. **Complete Detailed Plans must be submitted via ASSIST by the Authorized Organizational Representative (see Detailed Engagement Plan Submission Instructions section).** The Authorized Organizational Representative's signature certifies that the proposer 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 Detailed Plan.

Plans must be submitted by the due date, in text-recognizable PDF (Adobe) format, use Arial 10 point font with 1" margins, be single-spaced, may not exceed 12 pages, and the file size must be no greater than 20 MB.

Cover Page (up to 1 page)

1. Project Title
2. 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 is clearly identified.
3. Name and address of the submitting organization and department, if any, with the organizational DUNS number and employment identification number (EIN) provided.
4. Authorized Organizational Representative first and last name, title, institution, mailing address, email address and phone number
5. Approximate budget (direct and total)
6. Proposed Project Period Dates
7. Other key personnel names and organizations (multiple Principal Investigators, co-Investigators, collaborators, etc.)
8. Confirmation that the work involves no human subjects.
9. Agreement that any and all parts of the Detailed Engagement Plan can be shared among other proposers

Biosketches of Senior/Key Personnel and Other Significant Contributors (no more than five pages per individual)

At a minimum, 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); and a personal statement that briefly describes the individual's role in the project and why they are well-suited for this role. The format (https://grants.nih.gov/grants/forms/biosketch-blankformat.docx?) used for an NIH grant application is acceptable.

The remainder of the plan should be organized into the following sections to facilitate review:

Section 1: The potential impact of the work to be done if it were successfully implemented. At a minimum:

- Describe the driving scientific question(s) that will be addressed by engaging with the CFDE and why it has not yet been feasible.
- Describe the impact of the work to be done on the overarching goals of the CFDE to establish a series of interoperable data sets, computable in a cloud environment.
- Describe how the participating DCCs will work to successfully overcome the challenges described above and complete the technical work. Describe the nimbleness of the team to correct course, as needed.

- Describe the objectives to be met and milestones to gauge progress toward successfully completing the use cases between the DCCs, including metrics related to the driving scientific question.
- Include a project management plan, risks, and dependencies.

Section 2: Plans for engaging other participating DCCs, the CFDE-CC, end-user community (where relevant), and other stakeholders. At a minimum:

- Provide a plan that describes how the Proposer expects to collaborate with other DCC(s), the CFDE-CC, and other partners as relevant. The Detailed Plan should generally describe the work of all partners but should focus more specifically on the work to be done by the Proposer's group and any collaborators who are not eligible to submit plans through this announcement (see eligibility list above). The NIH does not expect duplicate material to be submitted by partnering DCCs who are eligible to submit plans via this announcement.
- Describe the involvement of any end-users, data generating components of the relevant Common Fund program, or other stakeholders.
- If a non-Common Fund DCC is proposed as a collaborator, describe how such participation will benefit the vision and how these collaborators will participate.
- Describe how Data Generating Centers from the relevant Common Fund programs will be engaged in this effort.

Section 3: Openness to exchanging software, data, digital objects, and other resources, as needed, to establish the CFDE. At a minimum:

- Describe the software, data, digital objects, and other resources that will be utilized by your team members in completing the technical work.
- Describe the extent to which these resources need to be further developed or supplemented to accomplish the work.
- Describe the extent to which proposed resources can be leveraged throughout the CFDE as increasing levels of interoperability are realized.

Section 4: Past performance and expertise of the team members and complementarity with other recipients. At a minimum:

- Identify key personnel, project leads, and other personnel
- Specify contribution levels and specific roles for each person
- Describe how key personnel will accomplish the objectives(s)
- Describe how the project will leverage the expertise of the CFDE-CC
- Include relevant past performance for the team and any prior experience working together
- Leadership plan for plans that involve multiple PIs

Section 5: The adequacy and appropriateness of the budget, resources, data and resource sharing.

- See Budget details below

Include any graphs, pictures, or data tables in the body of the text. Proposers are encouraged to provide links to videos (duration not to exceed 2 minutes total) and demos/simulations. For this OT2 Engagement Opportunity Announcement, proposers should refer to the guidelines described at NOT-OD-12-141, unless superseded. Files must be converted into MPEG4 (.mp4) format and submitted as a separate attachment via ASSIST no later than the due date. If the video file is larger than 25 MB, SEFT

file-sharing service may be used. Proposers submitting video files greater than 25 MB must first register for a SEFT account by calling the NIH Help Desk (+1-301-496-4357 or +1-866-319-4357 toll free or +1-301-496-8294 TTY). Once registered, notify Lora Kutkat that you have a SEFT account by emailing (CFDE@od.nih.gov). Proposers are then able to reply and attach videos greater than 25 MB to NIH-initiated SEFT emails. Additional information and system requirements are available through the EES-Enterprise Email Service website. Once the video has successfully been downloaded, you will be emailed to confirm that it has been received.

Additional information to include in the submission:

- A letter of support from the proposer's organization indicating institutional commitment for the project, e.g., relaying support for contributions (including, but not limited to space for training activities or consortium meetings, licenses, and other resources) and preparations to enter into negotiated other transactions agreements)
- No more than 3 letters of support from proposed collaborators (e.g., Common Fund DCCs, DCCs external to the Common Fund, external collaborators)
- A bibliography (not to exceed 1 page)

Budget details

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

Detailed Plans must provide a realistic budget and cost estimate for performing the work for the first year. The budget should address costs associated with the Proposer's group and any non-Common Fund collaborators, but **should not include costs for Common Fund partner DCCs or the CFDE-CC** (see eligibility list above). Budgets for individual awards are expected to vary, depending on the scope of the work proposed, including the number of collaborations involved. Future year budget estimates should also be provided, but these budgets will be reassessed as the projects proceed and may be increased or decreased depending on progress, the needs of the CFDE, and funds available.

Provide the overall expected cost for each of the following categories: personnel, equipment, travel, subawards, other direct costs, and total cost (with indirect costs included). Provide a budget justification. Subawards need to provide details of cost breakdown. **Any costs associated with cloud services must be broken out as specific, separate costs with a justification, but the costs should not be included within the total costs for the project**. These costs will be provided via in-kind provision of cloud services as described for Common Fund participation in the STRIDES initiative. NIH staff will work with award recipients and their institutions to establish STRIDES accounts as needed.

Provide a list of milestones including: description, completion criteria, due date, and payment/funding schedule. While agreements may be fixed price or expenditure-based, subject to negotiation, the use of fixed price milestones with discrete deliverables and a payment/funding schedule is preferred.

Proposers need to budget for attending a mandatory, 2-day kickoff meeting of the CFDE, to be held in Bethesda, MD on May 13-14 (first round of awards) or September 9-10 (second round of awards). Additionally, proposers need to budget for travel to at least 2 different consortium sites for information exchange, 2 training workshops, and 1 cross-pollination workshop in the 1st year.

Institutions with an established Facilities and Administrative (F&A) rate should use the approved rate to calculate indirect costs. F&A costs on foreign awards will be reimbursed at a rate of eight (8) percent of total direct cost, less only equipment.

Institutions

Participating organizations must complete and maintain the following registrations to be eligible to receive an award. There should NOT be any cost associated with ANY of these registrations. All registrations must be completed prior to award issuance. Registration can take 6 weeks or more, so **proposers should begin the registration process as soon as possible**.

- Dun and Bradstreet Universal Numbering System (DUNS) – All registrations require that proposers be issued a DUNS number. After obtaining a DUNS number, proposers can begin both SAM and eRA Commons registrations. The same DUNS number must be used for all registrations, as well as on the grant application.
- System for Award Management (SAM) (formerly CCR) – Proposers must complete and maintain an active registration, which requires renewal at least annually. The renewal process may require as much time as the initial registration. SAM registration includes the assignment of a Commercial and Government Entity (CAGE) Code for domestic organizations which have not already been assigned a CAGE Code.
    - NATO Commercial and Government Entity (NCAGE) Code – Foreign organizations must obtain an NCAGE code (in lieu of a CAGE code) in order to register in SAM.
- eRA Commons - Proposers must have an active DUNS number and SAM registration in order to complete the eRA Commons registration. Organizations can register with the eRA Commons as they are working through their SAM registration. eRA Commons requires organizations to identify at least one Authorized Organizational Representative and at least one Program Director/Principal Investigator account in order to receive an award. Unaffiliated individuals will be registered as "independent scholars" and will also act as the Authorized Organizational Representative, with the same authority in eRA Commons that the Authorized Organizational Representative(s) has in Grants.gov.

Principal Investigators

All Principal Investigators(s) should already have an eRA Commons account. If not, Principal Investigators should work with their organizational officials to either create a new account or to affiliate their existing account with the proposer organization in eRA Commons. If the Principal Investigator is also the organizational Authorized Organizational Representative, they must have two distinct eRA Commons accounts, one for each role. Obtaining an eRA Commons account can take up to 2 weeks.

6. Objective Review

The intent of the objective review for the Detailed Plans is not to prioritize among the applications, since the hope for the CFDE is to engage all of the Common Fund DCCs. The purpose of the Objective Review is to determine, for each Detailed Plan, whether the objectives will contribute to, and enhance, a robust data ecosystem. The review is also intended to facilitate dialog between DCC collaborators, the CFDE-CC, and external experts so that the Detailed Plans for each DCC are improved by the review process. The outcome of each review is therefore intended to be a modified work plan for each DCC and for the

CFDE-CC as it works with each DCC. Components of the DCC's Detailed Plans may be accepted into the final plan in whole, in part, or may be omitted. 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.

Review of Engagement Plan Overviews

The NIH will conduct an internal review of Overviews to determine how the proposed projects will be grouped for review of the Detailed Plans. Each eligible DCC may submit only one Overview, but that may describe collaborations with multiple Common Fund or non-Common Fund DCCs (collaborations must include at least one other Common Fund DCC). The NIH will use these Overviews to: 1) initiate discussions with the designated project lead(s), the NIH, and the CFDE-CC; 2) provide feedback, if deemed appropriate, to inform the Detailed Plans; and 3) assemble reviewers necessary to evaluate the Detailed Plans.

Review of Detailed Plans

The review of the Detailed Plans will be conducted as in-person interviews (or videoconference if travel is impossible or impractical). Travel of the Principal Investigator(s) will be supported by the NIH; logistical details will be provided upon receipt of Overviews. The review will involve 1) the submitting DCC Principal Investigator(s), 2) the proposed partnering DCC Principal Investigator(s) if possible, 3) the CFDE CC Principal Investigator and Training Director, 4) relevant NIH staff, and 5) External consultants. Each discussion for the first round of submissions will be held over a half day on either April 2 or April 3, 2020 for the first round of plans. Review dates for the second round of submissions will be announced at a later date.

The objective review of the Detailed Plans will consider:

- The potential impact of each planned activity if it were successfully implemented [25 points]
- Plans for engaging other participating DCCs, the CFDE-CC, end-user community (where relevant), and other stakeholders [35 points]
- Openness to exchanging software, data, digital objects, and other resources, as needed, to establish the CFDE. [15 points]
- Past performance and expertise of the team members and complementarity with other recipients [15 points]
- The adequacy and appropriateness of the leadership plan (required for applications with multiple Principal Investigators), budget, resources, data and resource sharing, and collaboration plans [10 points]

Note that past performance and expertise could refer to the proposers' demonstrated track record of particular behaviors (data community participation, collaborative efforts, openness to exchanging software and data, etc.), or to traditional measures of scientific productivity such as publication counts, invited presentations, or past funding success.

Principal Investigators who submit Detailed Plans will be invited to present their plans to a panel of reviewers via Web-based or in-person participation. Discussions will be grouped according to collaborations proposed, so that plans from collaborating Principal Investigators will be reviewed and discussed together. The purpose of the presentation is to talk through the plans, answer questions, and to work with the NIH to refine the application, if needed, to better suit the goals or capabilities of the

CFDE. NIH will support travel for those invited to the Detailed Plan review discussions. Additional information about the presentation and travel logistics will be provided upon review of the Overview.

Funding decisions will be based on the outcome of the review discussion. Up to 13 awards will be issued. The level of funding for awards made under this solicitation has not been predetermined but will depend on (1) the objectives proposed by the participant and how well they fit with the goals of the CFDE, (2) quality of the Detailed Plans received, and (3) availability of funds. Agreements for all awards will be negotiated with eligible entities whose applications are determined to be the most advantageous and provide the best value to the NIH.

Following the review of Detailed Plans, NIH may assemble teams from all or parts of applications to establish the CFDE. Individual components from distinct plans 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.

NIH reserves the right to:

- Invite all, some, one, or none of the Principal Investigators submitting Detailed Plans in response to this solicitation to present their application in person;
- Share Overviews and/or Detailed Plans between and among any proposer(s) as necessary for configuring teams, economizing work, and prioritizing activities.
- Select for negotiation all, some, one, or none of the Detailed Plans received in response to this solicitation;
- Accept Detailed Plans in their entirety or to select only portions of plans for award.

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

7. Application Timeline

Key Events	**1st Receipt Date**	**2nd Receipt Date**	**Action needed by Proposers**
Engagement Opportunity posted	January 29, 2020	Same as previous	
Cross-pollination meeting	January 30-31, 2020	TBD	Register and attend
Engagement Overview (Phase 1) due	Tuesday, February 18, 2020	Monday, May 18, 2020	Submit
Review of Engagement Overview complete	Monday, February 24, 2020	Friday, May 22, 2020	
Detailed Engagement Plans (Phase 2) due	Monday, March 16, 2020	Monday, June 15, 2020	Submit

Review	Thursday – Friday, April 2-3, 2020	TBD	Travel to Bethesda, presentation of plans, discussion of plans with proposed collaborators, NIH, and consultants
Award Negotiations begin	Monday, April 6, 2020	TBD	
Awards announced	On or before May 1, 2020	On or before August 3, 2020	
Kickoff meeting (mandatory)	May 13-14, 2020	September 9-10, 2020	Register and attend

8. Special Award Terms and Information

NIH Discretion

The OT award mechanism allows significant ongoing involvement from NIH Program and Project Managers 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 phases;
- 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.); and
- 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 proposer fails to provide requested additional information in a timely manner.

Detailed Plans selected for award negotiation are anticipated to 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 applying under this solicitation during all phases of the application lifecycle.

Award Governance

The NIH will actively engage with recipients to establish a vision and capabilities for the CFDE and to oversee the effort of individual recipients to achieve the vision.

NIH Roles and Responsibilities:

1. Agreements Officer: NIH 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. The AO 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.
2. Agreement Specialist: A designee of the Agreements Officer for administrative and financial aspects of the award.
3. Common Fund Program Officer: Individual within NIH who provides day-to-day programmatic oversight of individual awards, working closely with the Agreements Officer and with the Office that manages the Common Fund.

OT Agreement Governance

OT awards are not grants, cooperative agreements, or contracts. They are used by the NIH, including the Common Fund, 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.

For the awards funded under this Engagement Opportunity Announcement, 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.

Intellectual Property

The CFDE will emphasize creating and using available open source technology and architecture to the extent practicable. Intellectual property rights asserted by proposers must be aligned with the open source regime used to distribute software made under the award. Exceptions to open source technology will be considered only in compelling cases. Specific terms with respect to intellectual property will be negotiated at the time of award; however, any negotiation will consider other laws (as relevant) that affect the government's issue and handling of intellectual property, such as the Bayh-Dole Act (35.U.S.C. 200-212); the Trade Secrets Act (18U.S.C. 1905) the Freedom of Information Act (5 U.S.C. 552); 10 U.S.C. 130; 28 U.S.C. 1498; 35 U.S.C. 205 and 207-209; and the Lanham Act, partially codified at 15 U.S.C.1114 and 1122.

Budget

The OT award 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.

Payment

The OT award will use the Payment Management System (PMS) operated by the DHHS Program Support Center. Payments by PMS may be made by one of several payment methods, including SMARTLINK II/ACH, cash request, or by cash request on a reimbursement basis as specified in the terms of the Agreement. Generally, payments align with achievement of milestones and a payment schedule will be negotiated prior to issuance of the award to minimize the amount of time elapsing between the transfer of funds from the Federal Government and disbursement by the recipient.

Reporting

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

1. Financial and Progress Reports:

- Recipients will be asked to provide regular progress reports to the Common Fund Program Officer and Agreements Officer. The frequency and types of technical and financial reports (e.g., Federal Financial Reports) required will be specified in the Agreement document, and will include, as a minimum, financial status reports that will establish the burn rate for the project and a bi-annual status report.
- A final report that summarizes the project and tasks will be required at the end of the Agreement period. The reports shall be prepared and submitted in accordance with the terms and conditions requirements.

2. 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://public.era.nih.gov/iedison.

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 consistent applied regardless of the source of funds. 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. Recipients may use their existing systems to manage NIH OT award funds and activities as long as policies and procedures are consistently applied across their business functions.

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 upon the final negotiated and agreed upon budget.

Organizational Conflicts of Interest (OCIs)

Proposers 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 Detailed Plans that are determined selectable. 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 an 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 CFDE 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 funding recipients 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) that expends $750,000 or more per year under federal awards must have a single or program-specific audit conducted for that year in accordance with the provisions in Subpart F.

For-profit organizations expending less than $750,000 a year are not required to have an annual audit for that year but must make their award-related records available to NIH or other designated officials for review or audit.

A for-profit organization is required to have a non-federal audit if, during its fiscal year, it expended a total of $750,000 or more in DHHS awards. 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 CFDE 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 Financial Report, the Final Progress Report, and Final Invention Statement and Certification

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 Authorized Organizational Representative 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 OTA. Details of these public policy requirements may be found on the HuBMAP website at: https://commonfund.nih.gov/hubmap/othertransactions

- Animal Welfare Requirements (*PHS Policy on Humane Care and Use of Laboratory Animals*)
- ClinicalTrials.gov Requirements
- Comptroller General Access
- Debarment and Suspension
- Dissemination of False or Deliberately Misleading Information
- Federal Information Security Management Act
- Financial Conflict of Interest
- Fly America Act
- Gun Control
- Human Embryo Research and Cloning Ban
- Human Fetal Tissue Research
- Human Subjects Protections
- Human Stem Cell Research (NIH Guidelines)
- Lobbying Prohibition
- Metric System
- National Environmental Policy Act
- Pro-Children Act of 1994
- Prohibition on Promotion or Legalization of Controlled Substances
- Research Involving Recombinant or Synthetic Nucleic Acid Molecule
- Research on Transplantation of Human Fetal Tissue
- Restriction of Abortion Funding
- Restriction on Distribution of Sterile Needles
- Restriction of Pornography on Computer Networks
- Salary Cap/Salary Limitation
- Research Misconduct
- Select Agents
- Trafficking in Persons
- USA Patriot Act

9. Frequently Asked Questions

Is the January cross-pollination meeting mandatory? No, it is optional, but eligible proposers and their invitees are highly encouraged to attend.

Is the date and location of the January cross-pollination meeting firm? Yes.

May an eligible Common Fund DCC propose to partner with a DCC that is not a past or current Common Fund Program? Yes. While the scope of the CFDE is principally restricted to Common Fund data sets, this initiative is also intended to support the broader goals of enabling NIH-wide interoperability. Common Fund DCCs may propose to partner with a non-Common Fund program to accomplish a joint exercise so long as 1) the partnership is reasonable and appropriate for the project, and 2) the application involves a DCC from at least one other Common Fund program (see Eligibility section).

If a single Common Fund program has more than one DCC, would a collaboration amongst members of those DCCs be sufficient? No, collaborations need to cross eligible Common Fund programs.

Are multiple principal investigators permitted? Yes, but the principal investigators must be affiliated with a participating Common Fund DCC. In other words, an individual affiliated with a non-Common Fund DCC cannot serve as a principal investigator.