OVERVIEW INFORMATION

Participating Organization(s)	National Institutes of Health (NIH)
Components of Participating Organizations	This Other Transaction Research Opportunity Announcement (OT ROA) is developed as a Common Fund Initiative through the NIH Office of the Director, Office of Strategic Coordination. The Research Opportunity Announcement will be administered by the National Heart, Lung, and Blood Institute (NHLBI) on behalf of the NIH.
Funding Opportunity Title	NIH Data Commons Pilot Phase
Activity Code	OT3 Multi-Component Research Project – Other Transaction (OT)
Funding Announcement (FA) Number	RM-17-026
Related Notice	NOT-RM-17-031
Catalog of Federal Domestic Assistance (CFDA) Number(s)	93.310
Number of Applications	Multiple applications per applicant are allowed; however, each application must be scientifically distinct.
Funding Opportunity Purpose	Awards made under this OT ROA will support the NIH Data Commons Pilot Phase Consortium (DCPPC). In addition to awards made under this ROA, the DCPPC will include contractors engaged by the NIH, data providers funded via NIH grants as described below, and NIH staff. The purpose of this announcement is to invite applications from applicants who have an interest in performing high impact, cutting-edge scientific and computing activities necessary to establish an NIH Data Commons. NIH expects to make several OT awards under this funding opportunity. In the first stage, awardees will design innovative solutions that meet the needs of one or more of the computational, data and scientific key capabilities of

	the Data Commons. It is expected that awardees will participate collectively as a consortium and work cooperatively toward achieving NIH's comprehensive vision for an interoperable, FAIR (Findable, Accessible, Interoperable and Reusable) compliant, multi-cloud NIH Data Commons founded on open source and open standards. The Commons will be designed to comply with the principles of making digital objects FAIR. In the second stage, the solutions developed by the DCPPC will be implemented.
Objective Review	Evaluation of Letters of Intent (LOIs) and applications will be conducted by an appropriate review group convened by NIH. See Objective Review section of this announcement for further details.
Eligibility	See Eligibility section of this announcement.
Funds Available and Anticipated Number of Awards	The OT component of the DCPPC budget is currently planned for $21 million over a 4-year period. However, NIH Common Fund procedures and OT mechanisms allow for significant flexibilities to make adjustments that may be needed to pursue catalytic and transformative initiatives. Award levels may increase or decrease over time based on programmatic needs, funding availability, and awardee performance.
Award Project Period	Project duration is anticipated to be four years.

KEY DATES

Post Date	June 16, 2017
Letter of Intent (LOI) Due Date	June 30, 2017 (5:00 PM United States Eastern Time) Please note that submission of a **Letter of Intent (LOI) is required. LOIs will be used to select individuals or groups who will be invited to submit an application by July 12, 2017. Only those who are invited may apply.**

	Applications submitted without an invitation from the NIH will be returned and not reviewed.
Application Due Date	July 31, 2017 (5:00 PM United States Eastern Time)
Earliest Start Date	September 29, 2017
Funding Opportunity Expiration Date	August 1, 2017
Mandatory Kick-Off Meeting	October 23-25, Bethesda, MD, United States

AGENCY CONTACTS

We encourage inquiries concerning this Research Opportunity Announcement and welcome the opportunity to answer questions from potential applicants.

Scientific/Research Contact(s)	Vivien Bonazzi, Ph.D. Office of the Director, NIH Email: commonspilot@od.nih.gov
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OUTLINE OF THIS OT ROA

1. NIH Data Commons Pilot Phase Overview
2. Key Capabilities of the Data Commons Pilot Phase
3. Two Stage Process and Data Commons Pilot Phase Consortium
4. Special Award Information and terms
5. Eligibility
6. Application Content
7. Application Timeline
8. Objective Review Process
9. Additional Information

1. NIH DATA COMMONS PILOT PHASE OVERVIEW

Background

The NIH Big Data to Knowledge (BD2K, https://commonfund.nih.gov/bd2k/index) program is a trans-NIH data science program that was launched in 2013 to facilitate broad use of biomedical big data, develop and disseminate analysis methods and software, enhance training relevant for large scale data analysis, and establish centers of excellence for biomedical big data – all within the context of proper protection of human subjects. BD2K is entering a second program phase that will test the feasibility of, and develop best practices for, making NIH-funded datasets, semantics and computational tools available through communal, collaborative platforms on public clouds.

Datasets can provide unique resources for research inquiries and data analyses. Examples of such valuable resources include model organism databases (MODs); biorepositories; imaging, clinical, and other data from NIH-supported cohort studies; registries; and clinical trials. Trans-NIH initiatives such as the Genotype-Tissue Expression (GTEx) program and the Trans-Omics for Precision Medicine (TOPMed) program are generating genomics and other datasets at an unprecedented scale that require cutting-edge approaches for data management, access, and analysis. The NIH plans to implement a Data Commons initially as a Pilot Phase in which three high-value datasets will serve as test cases for the principles, policies, processes, and architectures that need to be developed. NIH expects the Pilot Phase will occur over 3-4 years. The test case datasets include the GTEx and TOPMed datasets mentioned above, as well as several Model Organism Databases (MODs) that are working as a consortium to create an integrated resource known as the Alliance of Genome Resources. Test case dataset selection derives from the high value of these data to many users in the biomedical research community as well as from the diversity of the data they contain. However, it is envisioned the Data Commons will expand to include other data resources once this pilot phase has achieved its primary objectives.

Cloud platforms can facilitate access and use across data sources that are often isolated (siloed) from each other. Use of cloud platforms will help push biomedical research beyond the conventional data-driven download/local analysis paradigm that is inefficient, burdensome, and can result in less reproducible research. Cloud platforms will form the basis of a Data Commons – allowing a way to access, deposit, analyze, collaborate, and share digital objects[1] generated

[1] Digital objects can be data, software tools, workflows, methods, documents, etc.

from biomedical research, with the goal of accelerating new biomedical discoveries that will enable more accurate disease risk prediction, tailored diagnostics, and prevention and treatment strategies.

At the same time, increased data access and availability through a cloud environment may elevate concerns over information privacy and security, and may raise questions over the ethical, legal, and social implications (ELSI) inherent in such availability. The range of issues involved in storing, accumulating, and accessing digital data in a cloud environment are likely to be complex. These issues are of paramount importance to the NIH and will be specifically emphasized in the Data Commons Pilot Phase.

The Data Commons Pilot Phase Consortium (DCPPC) will include PIs from the repositories housing the identified test case datasets, OT awardees identified through this solicitation, independent contractors, and NIH staff. The NIH will engage independent contractors to help develop, assess, and evaluate business models and practices, as well as human subjects, privacy, security, and ELSI matters as the pilot phase proceeds. In subsequent years, the broader data science community will be engaged to help test the utility of the Data Commons as it is developed, and input will be sought from entities with a working knowledge of applicable research ethics and information privacy laws and regulations. Applicants for this OT ROA must be willing to actively engage with the consortium and the broader community and to adapt as needed.

Purpose and Goals

The goal of the NIH Data Commons is to accelerate new biomedical discoveries by providing a cloud-based platform where investigators can store, share, access and compute on digital objects (data, software, etc.) generated from biomedical research and perform novel scientific research including hypothesis generation, discovery, and validation. The Data Commons Pilot Phase Consortium (DCPPC) will initially focus on digital objects generated by NIH-supported biomedical research from the TOPMed, GTEx, and MODs datasets.

Support of such an effective and secure digital environment for the Data Commons will initially require:

1. A portal with authentication and authorization-controlled access to digital objects.
2. A search and analysis workspace that supports a broad range of authenticated users.

3. A platform that supports implementation of the FAIR[2] principles, including granular assignment of contributions to individuals and teams, as well as understanding the value of those contributions in research and discovery.
4. An environment that is interoperable with cloud platforms and resources from multiple organizations to ensure that digital objects can be available to the broadest possible group of users and the wider research community.

For critical design aspects of the Data Commons, NIH expects that:

- Accessibility of the Data Commons will extend beyond experts in data science and bioinformatics, to general researchers in basic science, clinical research, and others to take advantage of large scale "big data."
- Cloud platforms will be built using Open Science[3] precepts. Open science speeds the pace of scientific discovery and significantly improves reproducibility of research. These tenets also provide researchers with a resource that can continually evolve through collaboration, data sharing, and methods development.[4]
- Digital objects within the Data Commons will be constructed employing FAIR[5] principles and consistent with research participant consents, notification of privacy practices, laws, regulations, and policies, as applicable. Protection of research participants' information must be ensured, at a minimum, through controlled access and authentication security protocols and related policies.
- Data access policies and procedures will govern accessibility of the Data Commons. The initial user community will be composed of experts in data science and bioinformatics, but future users are expected to include researchers in basic science, clinical research, and others with appropriate justification and approval to access these large scale "big data".

The NIH community has a broad spectrum of potential end-users of such a cloud platform, from sophisticated command-line experts to less-expert users who would require a simple, accessible user interface. The goal of the Data Commons is to provide a cloud platform in which end-users of varying disciplines and levels of expertise will want to bring their data, their pipelines, and their research questions **to** the big data of the larger community, without

[2] Findable, Accessible, Interoperable, and Reusable. Wilkinson, M.D. et al. The FAIR Guiding Principles for scientific data management and stewardship (2016) Sci. Data, 3:160018 doi: 10.1038/sdata.2016.18.

[3] Open Science refers to "the practice of making everything in the discovery process fully and openly available, creating transparency and driving further discovery by allowing others to build on existing work." See especially: Ross, J.S. and Krumholz, H.M. Ushering in a new era of open science through data sharing: The wall must come down (2013) JAMA Volume 309, Issue 13, Pages 1355-1356.

[4] McKiernan, E.C. et al. How open science helps researchers succeed (2016) eLife Volume 5, Issue JULY, 7 July 2016, Article number e16800.

[5] Findable, Accessible, Interoperable, and Reusable. Wilkinson, M.D. et al. The FAIR Guiding Principles for scientific data management and stewardship (2016) Sci. Data, 3:160018 doi: 10.1038/sdata.2016.18.

needing to understand all the technology that makes this big data effort work and how the harmonization is technically operating "under the hood."

The Data Commons should ultimately provide an environment that supports interconnection among genotypic, phenotypic, clinical, imaging, biospecimen, and model organism data, as well as all relevant visualization and analytic tools under a policy and procedural framework that appropriately addresses human subjects, ELSI, privacy, and security matters. It will also be designed to serve varying levels of research end users, and its implementation will require robust data sharing and access protocols, large scale data curation/harmonization, and a high throughput computing infrastructure.

2. KEY CAPABILITIES OF THE DATA COMMONS PILOT PHASE

The Data Commons will provide new, and integration of existing, computing infrastructures and tools, FAIR data best practices and scientific use cases that demonstrate the potential of open science and scientific discovery. The combination of computing, data best practices, and biomedical science is what will make the Data Commons cloud platform effective in enabling biomedical research and discovery.

Applicants are encouraged to develop innovative approaches to one or more key computational, data, analytical, and scientific capabilities of the Data Commons. Proposals must meet certain minimum standards that serve as guiding principles for a successful NIH Data Commons. The minimum standards for the Data Commons are:

1. Interoperable and Portable: The NIH Data Commons must allow portability of discovery and analytical tools and user interfaces between at least two cloud service providers. It is anticipated that the NIH Data Commons will interoperate with other data repositories or other research data Commons platforms across the globe. However, for purposes of this pilot, all data must be stored in environments within states or territories of the United States of America.
2. Open Source Technology: Capabilities and software built as part of the NIH Data Commons must be delivered under an open source model. Organizations may propose to use proprietary platforms, so long as the requirements for data transparency and interoperability are maintained. Tools must be openly available to biomedical researchers through existing community resources, such as Dockstore (https://dockstore.org), that provide a place to share tools encapsulated in Docker, and

described using the emerging standards of CWL (Common Workflow Language) and WDL (Workflow Description Language).

3. Research Ethics, Privacy, Security, and Controlled Access: To the extent that information considered for inclusion in the Data Commons – either as separate datasets or in combination with other data – triggers human subjects, privacy, or other laws or regulations, the DCPPC must establish appropriate data sharing policies and data access procedures, and take other steps to protect the information of research participants. In addition, because the cloud platform will store and permit controlled access to genomic data, projects that support the DCPPC must be consistent with the *NIH Genomic Data Sharing Policy* (NOT-OD-14-124) and the *NIH Notice for Use of Cloud Computing Services for Storage and Analysis of Controlled-Access Data Subject to the NIH Genomic Data Sharing Policy* (NOT-OD-15-086), as applicable.

   Applicants to this Announcement should note that the NIH has separate contract mechanisms to engage Trusted Partners. Awardees under this agreement are not expected to operate a controlled access process as a Trusted Partner.

4. Open Standards: The NIH Data Commons must be founded upon existing and emerging open standards. It is anticipated that during the implementation of the NIH Data Commons the consortium will contribute proposals for new or revised standards.

5. FAIR Compliant: The data stored in the Data Commons must be Findable, Accessible, Interoperable, and Reusable for the widest possible end-user audience. Evolving community-based FAIR guidelines should be adopted, and the Data Commons is expected to help define these guidelines.

6. Data Transparency: All data in the Data Commons must be available to all authenticated and authorized researchers regardless of the components of the platform used to access the data. Data access policies must address authorization to data use including controlled access and consents.

Key Capabilities

NIH has identified eight Key Capabilities, described below, for the DCPPC. Applicants are encouraged to develop innovative approaches to one or more key computational, data, analytical, and scientific capabilities of the Data Commons as described below. A proposal need not address all key capabilities to be competitive.

The NIH anticipates proposals will include the methods and techniques to be used to address one or more of the key capabilities below, including specific architectures, designs, and approaches, and how these will enable the science the Data Commons is designed to support. Additional capabilities can be suggested, but must be fully described and justified. Projects using additional capabilities not described in this solicitation may be included with any key

capabilities listed below. At a minimum, the approach must address the accession, integration, and distribution of the three identified test case data sets, and provide for analytical capabilities for those data sets. Additional datasets that increase the utility of Data Commons Pilot Phase test case datasets (TOPMed, GTEx, and MODs) may be included in an applicant's response; however, additional datasets need to be fully justified and NIH must approve use of funds to work with other data sets.

1. Development and Implementation Plan for Community Supported FAIR Guidelines and Metrics

The research community has begun to embrace FAIR principles for data, standards, and tooling; however, there are no clear guidelines for what it means to be FAIR or how to measure FAIR-ness. For the NIH Data Commons to be FAIR compliant, there need to be community endorsed guidelines and metrics on applying FAIR principles to digital research assets, roles, and relationships. The development of FAIR guidelines and metrics will require structured reporting methods, a quantification of FAIR-ness, FAIR use cases, and interfaces to capture and report FAIR-ness statistics. Proposed guidelines and metrics will need to be assessed for their usability and utility. The guidelines and metrics must be developed through engagement with the research community and have the community's demonstrated endorsement. The applicant should propose approaches to developing community endorsed FAIR guidelines and metrics that enable biomedical scientists to annotate and release the products of science digitally, and in a FAIR manner, so the products can be part of a FAIR compliant Data Commons.

2. Global Unique Identifiers (GUID) for FAIR Biomedical Digital Objects

The Data Commons will need to uniquely identify any and all FAIR digital objects to enable long-term resolution of cited persistent data and potentially provide the capability to link disparate datasets. New methods that support this activity are encouraged but must reuse, adopt, or extend community based standards already in place. There must be demonstrated community engagement with and endorsement of the proposed methods.

3. Open Standard APIs

The DCPPC should develop a strategy for maximizing interoperability and reuse of web-based biomedical APIs, through the development of standards for API metadata, registries and workflows. Working with existing communities that are defining API standards, such as the Global Alliance for Genomics and Health (https://genomicsandhealth.org) and adopting and extending community-defined API standards will be critical to the success of the Data Commons.

4. Cloud Agnostic Architecture and Frameworks

The ability to exchange data, semantics, universal identifier conventions, and tooling between cloud infrastructures is crucial to FAIR-compliance and to providing a long-term, adaptable, and

future-proof Data Commons platform. Commercial cloud storage and cloud computational infrastructure is likely to be the long-term underlying infrastructure for the Data Commons. The Data Commons Framework will need to provide a cloud agnostic abstraction layer that enables researchers to access, contribute to, and learn from data, tooling, and semantics available in the Data Commons. This must be possible without requiring direct knowledge of the underlying infrastructure of the Commons, to the extent possible, based on the technical and implementation differences between the cloud providers. A successful Data Commons Framework will:

a) enable multiple, highly interoperable, and cross-discoverable data commons platforms/efforts.
b) implement use of multiple clouds including on-premise and hybrid clouds.
c) provide services for authentication, authorization, digital IDs, metadata and data access that span multiple commons platforms/clouds so that data can be accessed transparently across commons platforms/clouds (supporting FAIR principles and compliance).
d) provide services for executing reproducible workflows across clouds so analysis tools can be ported easily across commons platforms/clouds, and so queries and analysis pipelines can be distributed across clouds and the results gathered.
e) minimize ingress and egress charges between clouds and, if applicable, make those charges predictable and well understood.
f) support resiliency and high availability of services available in the cloud
g) create a community-driven process for implementing and promulgating existing standards for data, tools, and semantics.

5. Workspaces for Computation

Workspaces for computation should provide users with the ability to store, create, and publish digital objects and analytical pipelines such that they can access and analyze diverse datasets, and visualize results. Workspaces should also provide users with comprehensive and user-friendly interfaces to build and run existing analysis pipelines, to visualize the results, and to allow them to bring their own datasets into the environment.

6. Research Ethics, Privacy, and Security

Approaches to address research ethics, privacy, and security in the context of the Data Commons should incorporate or be consistent with applicable laws, regulations, rules, and policy on human subjects protections, privacy, and information security. Approaches would allow for cloud-based storage of and access to information that alone or in combination with other information may be considered identifiable or otherwise protected information. At a minimum, approaches should address policy considerations associated with the amalgamation of large datasets, controlled-access oversight management, aggregation of informed consent metadata and tracking. To achieve the required level of data transparency and data use, it is

likely that authentication-controlled access solutions will need to be integrated deeply into cloud service providers' Identity and Access Management (IAM) infrastructure and tools. This component is critical to meeting the FAIR compliant goals of the Data Commons. It will also allow NIH supported programs (MODs, TOPMed, and GTEx) to share data with the wider research community, creating research synergies while complying with applicable federal protections for research participants, research participant consents, privacy and security requirements, and NIH security policies.

7. Indexing and Search

The Data Commons will index metadata among different projects through FAIR compliant APIs. This will allow users to search for and identify data of interest in order to create 'synthetic cohorts' and conduct meta-analyses of pooled data. This OT ROA is not intended for the research and development of new methods, rather the modification and deployment of systems that are already available, and have some community support.

8. Scientific Use cases

The Data Commons must enable users to address scientific questions of interest from datasets stored on the cloud platform or be able to bring their data to the cloud platform for analysis against datasets stored there. The DCPPC expects to develop scientific use cases with TOPMed, GTEx, and MODs datasets and tools. NIH expects successful applicants to this OT ROA to work collaboratively with the NIH funded investigators and their groups who manage these datasets as part of the Stage 1 consortium (see details below).

Scientific use cases should enable analysis of individual TOPMed, GTEx, or MODs datasets or enable analysis across these datasets to better support genotype – phenotype associations. The Data Commons should ultimately provide novel ways to interconnect phenotypic, clinical, imaging, biospecimen, and model organism data.

An example use case is shown below. This is meant as an illustration only, additional use cases are expected to be developed.

A collaborative research team is trying to develop a predictive algorithm to identify 'Metabolically Healthy' obese individuals who appear resistant to developing diabetes and cardiovascular disease. This team will use machine learning tools and various methods to define peripheral blood-tissue molecular signatures of the 'Metabolically Healthy Obese' phenotype by linking clinical, genomic, and transcriptomic data in the TOPMed and GTEx datasets. Once the team defines genomic-transcriptomic signatures of the 'Metabolically Healthy Obese' phenotype, they will want to query the Model Organism Databases (MODs) to ascertain whether 'loss-of-function' mutants or gene-knockout animals exhibit a similar 'metabolically healthy obese' phenotype as observed in humans. This cloud based platform with query tools

that can access and link studies or datasets, once again, makes it possible for this collaborative team to find, combine, and analyze the data they need. The platform can also integrate functional annotation and genomic analysis, and support joint analysis of genomic, cellular, tissue-specific and animal model data for a specific gene variant.

3. TWO STAGE PROCESS AND DATA COMMONS PILOT PHASE CONSORTIUM

This solicitation envisions a research and development effort that unfolds over two distinct stages.

In the first stage ("Stage 1"), the NIH expects to award OTs to support multiple projects that are deemed responsive to this solicitation and judged to include high impact, cutting-edge ideas for implementation of the DCPPC.

Awardees will be expected to form a consortium which will also include investigators funded through TOPMed, MOD, and GTEx. The consortium will work closely with NIH staff, and contractors the NIH will engage to assist with administration of the consortium and evaluation of business models and practices.

Although all OT awardees will have submitted compelling ideas for the DCPPC, they must be prepared to adjust, add, or delete items from their proposed plan of action to align with the consortium goals and action plan. This consortium will have 180 calendar days after the initial kickoff meeting with the NIH to provide:

1. A well-documented design/plan for how solutions for the components of the NIH Data Commons can be established, with a detailed budget. Each participating member of the consortium will provide a plan and a budget for their component.
2. A well-justified description of technical, methodological, or other limitations that affect the design/plan, and recommendations (with estimated costs) for additional expertise or approaches that might be added to the consortium if funds are available.
3. A working prototype that follows the principles of a "Minimal Viable Product" designed with just enough features and capabilities to both validate and assess the consortium's design plans.

In the second stage ("Stage 2"), the NIH expects to evaluate, negotiate, and revise terms of existing awards as appropriate or may award additional OTs to extend and fully implement the Data Commons Pilot Phase based on the design strategies and capabilities developed as part of Stage 1.

At the end of Stage 1, all developed material, including prototypes, will be evaluated and reviewed for:

1) overall scientific and technical merit

2) innovation and potential to achieve the NIH vision for the Data Commons

3) cost

Based on this evaluation, OT Agreements for each award will be re-negotiated to detail the goals and milestones for each award and how they will contribute to the overall consortium plan. Additional awards may be issued if limitations in the consortium are identified during the planning phase. Similarly, some awards may be discontinued if they are not deemed critical to the consortium plans.

4. SPECIAL AWARD INFORMATION AND TERMS

Awardees will be selected through an objective review process based on scientific merit, contribution to the requirements of the program, and capabilities of the investigators/key personnel. Multiple awards are anticipated. The level of funding for awards made under this solicitation has not been predetermined but will depend on (1) the objectives proposed by the applicant and how well they fit with the goals of the Data Commons, (2) quality of the proposals received, and (3) availability of funds. Agreements for all awards will be negotiated with eligible entities whose proposals are determined to be the most advantageous and provide the best value to the NIH.

The NIH reserves the right to:

- select for negotiation all, some, one, or none of the proposals received in response to this solicitation;
- segregate portions of resulting awards into pre-priced options;
- accept proposals in their entirety or to select only portions of proposals for award;
- fund proposals in increments and/or with options for continued work at the end of one or more phases;
- fund proposals of two or more applicant entities as part of a reorganized, consolidated consortium operating under an article of collaboration, teaming arrangement, or other means acceptable to the government;
- request additional documentation (certifications, etc.);
- remove proposers from award consideration should the parties fail to reach a finalized, fully executed agreement prior to September 22, 2017, or the proposer fails to provide requested additional information in a timely manner.

Proposals selected for award negotiation are anticipated to result in the issuance of an OT 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 DCPPC awardees to establish a vision and capabilities for the Data Commons and to oversee the effort of individual awardees to achieve the vision. A Steering Committee for the DCPPC will establish Consortium goals, timelines, and milestones. The Steering Committee will include representatives from each award and from the NIH. Decisions from the Steering Committee are subject to review and approval by the NIH Program Manager, with input from External Program Consultants (EPCs).

NIH Roles and Responsibilities:

1. Agreements Officer: 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.
2. Agreement Specialist: A designee of the Agreements Officer for administrative and financial aspects of the award.
3. Program Manager: Individual within the NIH Division of Program Coordination, Planning, and Strategic Initiatives (DPCPSI)/Common Fund responsible for overall scientific and programmatic oversight of the consortium. The Program Manager represents the DCPPC within the NIH and reports to DPCPSI/Common Fund leadership, Institute/Center Directors, and to the NIH Director. The Program Manager seeks input from External Program Consultants to ensure consortium goals and activities are maximally aligned with community needs, requirements, etc.
4. Project Officer: Individual within DPCPSI who provides day-to-day programmatic oversight of individual awards, working closely with the Agreements Officer and with the Program Manager.
5. Science Officers: Individuals within Institutes and Centers who provide scientific expertise to the DCPPC and participate as part of the Steering Committee.

OT Agreement Governance

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 awardee and details specific terms and conditions for that award.

For the awards funded under this OT ROA the NIH will engage in lifecycle negotiations (before, during, and at the end) and all agreed upon terms and conditions will be incorporated into the Agreement.

Intellectual Property

The NIH Data Commons will emphasize creating and using available open source technology and architecture. 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.

Awardees will own the software and data developed under this award, subject to the Government's royalty-free, nonexclusive, irrevocable right 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. In addition, inventions, technical solutions and methods developed under this solicitation will remain the property of the awardees, who may freely use them for their own commercial purposes, subject to a nonexclusive, nontransferable, irrevocable, paid-up license to the Government to practice, or have practiced for or on its behalf, the inventions, technical solutions and methods throughout the world.

Budget

The OT award provides funds for the budget period as appropriate for the negotiated and agreed upon milestones. Subsequent funding periods represent projections of future funding levels contingent on the availability of funds and achievement of agreed-upon milestones.

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 awardee.

Reporting

1. Financial and Progress Reports:

a. Awardees will be asked to provide regular progress reports to the DCPPC Research Program. The frequency and types of technical and financial reports required will be specified in the Agreement document, and will include, as a minimum, quarterly financial status reports and a bi-annual status report.
b. 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

Awardee organizations are expected to have in use clearly delineated roles and responsibilities for their organization's staff, both programmatic and administrative.
Awardees 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

Awardees must have in place accounting and internal control systems that provide for appropriate monitoring of award accounts to ensure that obligations and expenditures are congruent with programmatic needs and are allowable. A list of unallowable costs will be included in the terms and conditions of the award.

Property Management System Standards

Awardees 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

Awardees 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. Awardees 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 subawardees, consultants, etc. Under this section, the proposer is responsible for providing this disclosure with each proposal. The disclosure must include the consortium's, 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 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 proposal and withdraw it from consideration for award.

Human Subjects Research

All research involving human subjects and selected for funding, to include use of human biological specimens and human data, must comply with the federal regulations for human subjects protection at 45 C.F.R. Part 46. Any institution proposing to engage in research involving human subjects must provide documentation that it will comply with the requirements of 45 C.F.R. Part 46, or have a current assurance on file with the Department of Health and Human Services, Office of Human Research Protection – i.e., the Federalwide Assurance (http://www.hhs.gov/ohrp). All institutions engaged in human subjects research and selected for funding, to include consortium member organizations, must hold a valid assurance. In addition, all personnel at these institutions involved in human subjects research must provide documentation of completion of human subjects research training.

Monitoring

Awardees 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 NIH DCPPC 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 awardee.

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 the FFR for the entire competitive segment is submitted. Therefore, awardees 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.

Audit

NIH funding awardees 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 awardee 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 awardee 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 an awardee 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 for cause.

NIH may decide to terminate the award if the awardee does not take appropriate corrective action during the period of suspension. NIH may immediately terminate a DCPPC OT award when necessary, such as to protect the public health and welfare from the effects of a serious deficiency.

An NIH DCPPC OT award also may be terminated, partially or totally, by the awardee. If the awardee decides to terminate a portion of a DCPPC 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 awardee of the possibility of termination of the entire OT award and allow the awardee to withdraw its termination request. If the awardee does not withdraw its request for partial termination, NIH may initiate procedures to terminate the entire award for cause.

Effect of Termination

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

Recovery of Funds

NIH may identify and administratively recover funds paid to an awardee 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 awardee'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 awardees.

Closeout

The requirement for timely closeout is an awardee responsibility. Closeout includes ensuring timely and accurate submission of all required reports and adjustments for amounts due to the awardee or NIH. Terms and conditions of award will outline the specific timeline requirements.

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 awardees. The signature of the AOR/Business Official on the application certifies that the organization complies, or intends to comply, with all applicable policies, certifications and assurances.

5. ELIGIBILITY

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

Foreign Organizations

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

Foreign components, as defined here, **are** allowed:

The performance of any significant scientific element or segment of a project outside of the United States, either by the awardee or by a researcher employed by a foreign organization, whether or not funds are expended, is considered a foreign component. Activities that would meet this definition include, but are not limited to, (1) the involvement of human subjects or animals, (2) extensive foreign travel by project staff for the purpose of data collection, surveying, sampling, and similar activities, or (3) any activity of the awardee that may have an impact on U.S. foreign policy through involvement in the affairs of environment of a foreign country. Examples of other award-related activities that may be significant are:

- Collaborations with investigators at a foreign site anticipated to result in co-authorship;
- Use of facilities or instruments at a foreign site;
- Receipt of financial support or resources from a foreign entity.

Foreign travel for consultation is not considered a foreign component.

Multiple Principal Investigators

More than one individual may be named as Principal Investigator on a single application. One individual must be identified as the contact Principal Investigator.

Organizations

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 and Native American Pacific Islander Serving Institutions (AANAPISIs)

Nonprofits Other Than Institutions of Higher Education

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

For-Profit Organizations

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

Governments

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

Other

- Independent School Districts
- Public Housing Authorities/Indian Housing Authorities
- Native American Tribal Organizations (other than Federally recognized tribal governments)
- Faith-based or Community-based Organizations
- Regional Organizations
- Non-domestic (non-U.S.) Entities (Foreign Institutions)
- Federally funded research and development centers (FFRDC)
- University affiliated research centers (UARC)

Federally Funded Research and Development Centers (FFRDC) and University Affiliated Research Centers (UARC)
FFRDCs and UARCs are eligible to apply and/or participate as partnering organizations. NIH will not award funds specifically for laboratory directed research and development (LDRD) costs. Laboratory contractors may recover LDRD costs within the total funding included in the award. Other costs will be reviewed and negotiated prior to award.

6. APPLICATION CONTENT

Letter of Intent (LOI)
By June 30, 2017 (5:00 PM United States Eastern Time), prospective applicants are required to submit a Letter of Intent that includes the following information:

- Number and title of this research opportunity
- Descriptive title of proposed activity
- For each Key Capability:
  - Designated project lead with address, phone number, email address, and organizational affiliation
  - Name and organizational affiliation for all key personnel
  - Description of relevant expertise for all key personnel, not to exceed 100 words per person
  - Description of planned activity to address the objective(s), not to exceed 800 words
  - Description of resources available to accomplish the activity, not to exceed 500 words
- If the intent is to apply for more than one Key Capability, a description of how objectives will interact, not to exceed 500 words

Submission of a Letter of Intent is required. The LOIs will be reviewed to select an applicant pool and allow NIH staff to plan for the review of invited applications.

Selected individuals or groups will be invited to submit an application by July 12, 2017. Only those who are invited may apply. Appeals of the LOI review will not be accepted.

Applications submitted without an invitation from the NIH will be returned and not reviewed.

Letters of intent should be sent to:

Dr. Vivien Bonazzi,

Email: commonspilot@od.nih.gov

All potential applicants are strongly encouraged to contact this Program Official for guidance and feedback at any stage of the application process, including before submission of a Letter of Intent.

Application

By July 31, 2017 (5:00 PM Eastern Time), invited applicants are required to submit an application with the following information (Arial 11pt, single-spaced with 1" margins).

Cover Page (up to 1 page)

1. Project Title
2. Key Capabilities for which application is intended
3. PI first and last name, title, email address, and phone number. If multiple PIs are named, contact information for Contact PI.
4. Type of applicant (see the Eligibility section above)
5. Name of the applicant organization and department, if any
6. Business Official Authorized to bind the organization legally first and last name, title, email address and phone number
7. Approximate budget (direct and total) for the Stage 1 activities
8. Other key personnel names and organizations (MPIs, co-Investigators, collaborators, etc.)
9. Resources required:
    - o Are Human Subjects Involved: Answer "Yes" or "No"
    - o Are Vertebrate Animals Used: Answer "Yes" or "No"
    - o Are Biohazardous Materials Used: Answer "Yes" or "No"
    - o Are Select Agents Used: Answer "Yes" or "No"
    - o Are Human Embryonic Stem Cells Used: Answer "Yes" or "No"

Summary Vision Statement

Describe in fewer than 500 words how the applicant's expertise and resources will be used to address the objective(s) of the DCPPC.

Detailed Activity Plan for Each Key Capability to be addressed (not to exceed 4000 words and 2 figures per Key Capability)

The activity plan should:

- Identify project leads and other personnel for each Key Capability to be addressed
- Specify contribution levels and specific roles for each person
- Describe objectives that will address the Key Capability
- Describe how key personnel will accomplish the objectives(s)

- Include a project management plan. If the proposal is submitted on behalf of a consortium or teaming arrangement consisting of multiple organizations, the project management plan should describe how the consortium members will operate and work together to carry out the proposed work.
- Provide a task plan, with estimated costs broken out by task. The plan should include milestones with quantifiable metrics at monthly intervals

Include any graphs, pictures, or data tables in the body of the text. Applicants are encouraged to provide links to videos (duration not to exceed 2 minutes total per Objective) and demos/simulations. For this OT3 Research Announcement, applicants should refer to the guidelines described at NOT-OD-12-141, unless superseded by the following. Files must be converted into MPEG4 (.mp4) format and emailed by the AOR to commonspilot@od.nih.gov no later than 5:00 PM local time on the due date. This address only accepts attachments less than 25 MB. If the video file is larger than 25 MB, a file-sharing service may be used. Once the video has successfully been downloaded, you will be emailed to confirm that it has been received.

Please note: applicants submitting files greater than 25 MB must first register for a SEFT account by calling the NIH IT Service Desk (+1-301-496-4357 or +1-866-319-4357 toll free or +1-301-496-8294 TTY). Once registered, notify NIH Data Commons Pilot Phase staff that you have a SEFT account by emailing commonspilot@od.nih.gov. Applicants 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.

Additional information to include in the submission:

- A letter of support from the applicant's organization indicating institutional commitment for the project
- No more than 2 letters of support (encouraged, but not required)
- A bibliography (not to exceed 1 page)

Budget details

Proposals must provide a realistic budget and cost proposal for performing the work for the first 180-day period (Stage 1). 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 with budgets greater than $100,000 need to provide details of cost breakdown.

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 a payment/funding schedule is preferred. This is a scorable selection factor for Stage 1 award.

Applicants need to budget for attending the Kick-off meeting of the DCPPC, to be held in Bethesda, MD, and at least one other face-to-face meeting during the 180-day period. Additionally, applicants need to budget for travel to at least 2 different consortium sites for information exchange.

Institutions with an established Facilities and Administrative (F&A) rate should use the approved rate to calculate indirect costs. Indirect costs on foreign awards will be reimbursed at a rate of 8% of total direct costs, less only equipment. Any applicant that has not negotiated an indirect cost rate may elect to charge a de minimis rate of 40% of modified total direct costs.

Cost Sharing is not strictly required, but due to the likelihood of developing solutions with commercial applications, proposers are encouraged to 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 by a letter of support from the providing organizations/individual.

How to submit the application

Complete applications must be emailed to commonspilot@od.nih.gov. Applications must be submitted in text-recognizable PDF (Adobe) format, and file size must be no greater than 20 MB. Paper applications will not be accepted. Applications from institutions must be submitted by an Authorized Organizational Representative. The Scientific/Research Contact(s) will review your application for completeness and acknowledge receipt within 1 business day.

7. APPLICATION TIMELINE

Key Events	Dates	Action needed by applicants
Call for projects posted	June 15, 2017	
Letter of Intent (LOI) due	June 30, 2017	Email LOI by 5:00 PM United States Eastern Time
Review of LOIs completed	July 11, 2017	
Invitation to submit Applications	July 12, 2017	

Applications due	July 31, 2017	Email completed application by 5pm United States Eastern Time
Review of written applications completed	August 23, 2017	
Negotiations begin	August 28, 2017	
Awards announced	September 29, 2017	
Mandatory Kick-Off Meeting	October 23-25, Bethesda	

Applicants

Applicant 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 **applicants should begin the registration process as soon as possible**.

- Dun and Bradstreet Universal Numbering System (DUNS) – All registrations require that applicants be issued a DUNS number. After obtaining a DUNS number, applicants can begin both SAM and eRA Commons registrations. The same DUNS number must be used for all registrations, as well as on the grant application.
- System for Award Management (SAM) (formerly CCR) – 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.
    - o 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 - Applicants 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 Signing Official (SO) and at least one Program Director/Principal Investigator (PD/PI) account in order to receive an award. Unaffiliated individuals will be registered as "independent scholars" and will also act as the SO, with the same authority in eRA Commons that the Authorized Organizational Representative(s) has in Grants.gov.

Program Directors/Principal Investigators (PD(s)/PI(s))

All PD(s)/PI(s) must have an eRA Commons account prior to award. PD(s)/PI(s) should work with their organizational officials to either create a new account or to affiliate their existing account with the applicant organization in eRA Commons. If the PD/PI is also the organizational Signing

Official, they must have two distinct eRA Commons accounts, one for each role. Obtaining an eRA Commons account can take up to 2 weeks.

8. Objective Review Process

Evaluation of the Letters of Intent (LOIs) and full proposals will be conducted by an appropriate review group convened by NIH.

Letter of Intent (LOI)
Letters of Intent (LOIs) will be evaluated on:

- Expertise of the team members and key personnel [30 points];
- Past performance relevant to the Data Commons [30 points];
- Outline of planned activities [20 points]
- The adequacy and appropriateness of available resources [20 points].

Submission of a Letter of Intent is required. The LOIs will be reviewed to select an applicant pool and allow NIH staff to plan for the review of invited applications.

Selected individuals or groups will be invited to submit an application by July 12. Only those who are invited may apply. Appeals of the LOI review will not be accepted.

Application
The evaluation will be based on:

- The potential impact of the team's vision statement if it were successfully implemented [10 points];
- The plan for developing relevant components of the Data Commons [40 points];
- Plans for engaging the community, including, where relevant, any plan for developing a demonstration project [30 points];
- Past performance and expertise of the team members and complementarity with other awardees [10 points]; and
- The adequacy and appropriateness of the budget, resources, and data 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.

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

9. ADDITIONAL INFORMATION

Following written application, NIH staff may propose to assemble teams from all or parts of proposals to develop the DCPPC. Individual components from distinct applications may be selectively funded to achieve this goal. Additionally, if, over the duration of the project, some of the components either gain relevance or lose relevance, the funding for such components may be increased, decreased, or discontinued.

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 goal. This may mean an awarded activity could be expanded, modified, partnered, not supported, or discontinued based on program needs, emerging methods or approaches, and availability of funds. Performance during the award period will be reviewed on an ongoing basis and course corrections will be made as necessary.