Research Opportunity Announcement

Research Opportunity Title: NIH Common Fund Data Ecosystem (CFDE) Cloud Workspace Implementation Center (OT2)

OTA-24-005

Key Dates:

Release date: February 20, 2024

Letter of Intent (LOI) Due Date: March 21, 2024 by 5:00 PM local time of applicant organization. *Submitting an LOI is strongly encouraged but is not required for subsequent submission of a full proposal. Please see Section 8.2 for more details on submitting an LOI*.

Proposal Due Date: April 22, 2024 by 5:00 PM local time of applicant organization. **Late applications to this ROA will not be accepted.**

Earliest Start Date: July 1, 2024

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

Informational Webinar: Webinar information and its date will be posted on the Frequently Asked Questions website https://commonfund.nih.gov/dataecosystem/faqs

Participating Organization(s): National Institutes of Health

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

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

Related Notices:

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

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

Research Opportunity Purpose:
The purpose of this announcement is to invite applications to establish the Cloud Workspace Implementation Center (CWIC) for the Common Fund Data Ecosystem (CFDE). The CWIC will be responsible for developing a cloud workspace that enables users to import their data and co-analyze them together with other CF datasets. Applicants may leverage elements of existing workspaces that meet the CWIC's requirements and branding/identity. The cloud workspace will enable the use of CFDE-constructed pipelines, workflows, and tools, as well as third-party tools of the user's choosing, to perform data analysis. The needs of both novice and expert users should be considered.

The overall goal of CFDE is to build and maintain a thriving ecosystem that enables the research community to (re)use data, knowledge, and other digital resources generated by Common Fund programs to accelerate discovery, enhance health, and reduce illness. Applicants responding to this ROA should familiarize themselves with the other components of CFDE (see below), as the CWIC will be expected to communicate, coordinate, and collaborate with these components.

Background:

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

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

The Common Fund Data Ecosystem (CFDE) is an infrastructure investment made by the CF to address the growing challenges facing scientific programs that leverage data-intensive strategies. To support these programs and downstream data users, CFDE is helping to ensure that all Common Fund data sets are Findable, Accessible, Interoperable, and Reusable (FAIR); ensuring that CF data continue to be available after individual programs are completed; and providing training for users to operate on the data in a cloud environment. This will amplify the impact of many CF programs by enabling discoveries that would be unattainable without interrogation of disparate data sets and application of advanced computational tools, including AI-based algorithms. To further this goal, CFDE is being designed in parallel with NIH IC data platforms to enable crosstalk between CF and IC data sets and address Objectives 1-2 (Connect NIH Data Systems), 2-1 (Modernize the Data Repository Ecosystem), and 3-1 (Support Useful, Generalizable, and Accessible Tools and Workflows) of the NIH Strategic Plan for Data Science.

The CWIC will promote the use and reuse of CF resources by creating and implementing resources and activities addressing three target functions: 1) *CF data* – Provide users access to CFDE data and allow users to import data from other sources; 2) *Tools* – Provide access to tools, workflows, and pipelines developed by CFDE, as well as enable the user to use custom or third-party tools.; and 3) *Evaluation, Outreach, User Experience, and User Training* – Provide evaluation, training, outreach, and engagement to ensure the product is meeting the needs of the users and is appropriate for both novice and expert users.

Additional information on the program and FAQs are available on the program website at https://commonfund.nih.gov/dataecosystem/faqs.

Structure of CFDE:

Building on the successful first phase, CFDE is expanding support of activities that will increase both the use and reuse of CF generated data, knowledge, and tools; and is significantly ramping up outreach, skills development, and training efforts. CFDE is establishing data resource and knowledge portals and cloud

workspaces that will enable users to query and use multiple CF resources. Use and reuse will be increased by expanding outreach and training efforts that bring biomedical researchers to CF resources and to work in the cloud. To accommodate these activities, CFDE will include five tightly integrated centers:

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

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

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

Training Center (TC): This center will be responsible for identifying and addressing the training opportunities and needs of the CFDE community. It will develop targeted training to address gaps in the training landscape, and a mentoring program to support the growing community of CF data users. In addition, it will help coordinate training-related activities across other CFDE centers through a Trainers Working Group, by supporting the analysis and evaluation of training programs, and through engagement with a broad and diverse community for recruitment and outreach. This center will be responsible for developing and maintaining training-related content within the CFDE Portal, created and maintained by the DRC, and providing a web-based mechanism for CFDE Learners to interact and support one another virtually.

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

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

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

Eligibility: See the Eligibility section of this opportunity for further details.

Application budget: The Common Fund may allocate up to $750,000 for the first-year total costs (direct + F&A) for this Center, and up to $1,500,000 total costs per year for years 2-5. The award is contingent upon NIH appropriations and the submission of a sufficient number of responsive and rigorous applications. Future year amounts will depend on annual appropriations.

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

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

Anticipated number of Awards: The Common Fund anticipates making one award to establish the CDFE Cloud Workspace Implementation Center.

Award Project Duration: Initial project duration is anticipated to be up to five (5) years, subject to program needs and availability of funds. Research activities and the associated milestones may be shortened or extended as needed within that period.

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

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Agency Contacts:

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Outline of this Opportunity

1. Overview and goals of the CFDE Cloud Workspace Implementation Center (CWIC)
2. Eligible Organizations
3. Eligibility Requirements
4. Multiple Principal Investigators and Partnerships among Applicant's Institutions
5. Project Manager/Director Requirement
6. Financial and Risk Assessment
7. Cost Sharing
8. Developing Applications
9. Objective Review
10. Application Timeline
11. Special Award Terms and Information

1. Requirements – CFDE Cloud Workspace Implementation Center (CWIC)

The CFDE Cloud Workspace Implementation Center (CWIC) will be responsible for developing a cloud workspace that enables users to import their data and co-analyze them together with other CF datasets, as well as to readily use tools and pipelines developed by participating CFDE resources. Additionally, the cloud workspace will enable users to employ third-party tools and effectively combine CF datasets with other sources of data to drive scientific discovery. It will address the needs of both novice and experienced users by developing and maintaining manuals, tutorials, training materials, and transparent cost estimators. Applicants may leverage elements of existing workspaces that meet the CWIC's requirements and branding/identity. Furthermore, the CWIC will actively collaborate with other components of CFDE.

Goal 1: Provide users access to CFDE data and allow users to import data from other sources.

- The cloud workspace must provide users the ability to set up an account through which cloud compute costs will be covered, must have a mechanism for depositing cloud credits into a user's account (with authorization from the NIH), and must address and maintain security controls that are equivalent to NIST. 800-171.
- The cloud workspace must be linked to the CFDE DRC and KC, and with individual DCCs (where applicable), to allow users to search for CFDE datasets and to enable import of the desired datasets into the workspace. Because data and metadata generated by the CF programs are a mixture of open access and controlled access, the workspace must interface with dbGAP and other relevant controlled-access repositories.
- The cloud workspace must allow the user to import their own datasets for co-analysis with CFDE data. It must also allow the user to import data from third-party data repositories not affiliated with CFDE. Multiple CFDE DCCs have enacted GA4GH-based DRS and unique object identifiers, although implementation specifics may differ.
- The cloud workspace must enable a single sign-on authentication solution, and should enable the use of the NIH Researcher Auth Service (RAS) for controlled access datasets wherever it is required for interoperability.
- The cloud workspace must provide the user with a real-time, transparent estimator of how much it is projected to cost to store the currently imported data over periods of 7 days and 1 year. It must also develop an interface that allows users to optimize storage costs.
- Where practical, the workspace should be interoperable with data and cloud workspace environments provided by other NIH-supported entities, including, but not limited to: All of Us, NCPI, NCBI, dbGAP, SRA, and HEAL.
- CFDE branding, landing page, and other identifying materials will be required to distinguish the CWIC, including any proposals that use elements of existing computational environments.

Goal 2: Provide access to tools, workflows, and pipelines developed by CFDE, as well as enable the user to use custom or third-party tools.

- The cloud workspace must work with the CFDE KC and DRC, and with individual DCCs (where applicable), to enable users to use tools, workflows, and pipelines developed by CFDE. Initially, the priority should be placed on enabling the use of the CFDE Workflow Playbook, and on enabling the use of data analysis and visualization tools (e.g., Azimuth from HuBMAP).
- The cloud workspace must allow the user to securely import and use custom-developed and third-party tools and workflows. The environment should, at a minimum, support the import and integration of tools developed in Python, R, JAVA, and OWL. Integration of Jupyter notebooks is highly desirable.
- The CWIC should Include a selection of widely-adopted pre-configured third party data analysis and visualization tools that can address multiple data types (e.g., genomics, transcriptomics, proteomics,

and/or imaging) that are compatible with widely used data, format standards, and builds.

- The CWIC must, in collaboration with the DRC, KC, and relevant CFDE data resources, support users in implementing their scientific use cases. This includes a system for projecting resources needed to support these activities and prioritizing them.
- The cloud workspace should consider incorporating Workflow Management Systems (e.g., CWL, WDL, Snakemake, Nextflow, etc.).
- The cloud workspace must provide the user with a transparent estimator of compute incurred by executing CWIC-provided workflows or an instance of CWIC-supported analysis/visualization.
- Where practical, the workspace workflows and tools supported by the cloud workspace should be interoperable with workflows and tools provided by other NIH-supported entities, including, but not limited to: All of Us, NCPI, NCBI, dbGAP, SRA, and HEAL.

Goal 3: Evaluation, training, outreach, and engagement.

- In collaboration with the CDFE Integration and Coordination Center (ICC), the CWIC must develop system metrics and user metrics, describe how these metrics will be collected and used, and how feedback from external users will be used to improve the CWIC. The CWIC must also address plans for maintenance of and continuous improvements (e.g., adoption of new technologies) of the cloud workspace.
- The CWIC must develop and maintain good documentation and manuals for the cloud workspace, to provide an environment where new and existing users can have a positive, productive experience without encountering steep learning curves.
- In collaboration with the CFDE Training Center (TC), the CWIC must offer relevant training opportunities targeted at both beginner and advanced users. Beginner training should focus on the productive use of the cloud environment, while advanced training should focus on maximizing the benefits of specific tools and workflows. The latter should be developed in collaboration with the CFDE groups that develop and maintain the tools, as well as the CFDE DRC and KC.
- In collaboration with the CFDE ICC, the CWIC must develop and implement an outreach strategy to bring new users to the cloud workspace. This can be accomplished in a variety of ways, including (but not limited to) presentations at conferences, hosting of webinars, hosting of codeathons, or development of interactive tutorials. The CWIC must participate in the Trainers Working Group administered by the CFDE Training Center. CFDE is in a unique position to make progress toward the goal of increased diversity in NIH-funded bioinformatics research workforce. Through thoughtful and intentional recruitment and outreach, the cloud workspace must attract users, mentors, and collaborators from underrepresented groups and provide the environment and support for a diverse group of investigators and stakeholders to thrive. The web infrastructure developed by the cloud workspace must be accessible to people with disabilities, and all events and materials must include accommodation options for all participants.
- The CWIC will develop a cloud credits program that allows for the use of NIH-funded credits, with controls to prevent overspending. This includes providing, in collaboration with the ICC and the TC, a transparent and easily accessible mechanism for users to apply for free cloud credits to be used while working in the workspace developed by the CWIC.
- The CWIC must actively participate in relevant (as determined by the ICC) CFDE working groups, and must, at a minimum, have representation at the Fall and Spring CFDE meetings. Meetings to date have been held in the vicinity of Bethesda, MD.
- The CWIC must address sustainability, projected costs of operating the cloud workspace functionality, plans for an orderly shutdown, and plans for transferring the cloud workspace functionality to a new product owner.

When submitting a project proposal, applicants must include milestones and timelines. The project must consist of the following minimum features by the end of the first year: a secure workspace (i.e., NIST. 800-171 functionality at minimum) that allows users to import data sets from three different Common Fund programs (with at least one of which must be a controlled access study, e.g., dbGaP), a tool or pipeline for analyzing at least two types of high-throughput data (e.g., genomics, transcriptomics, proteomics, and/or imaging), and provide documentation and a help desk for these features. The platform should also enable billing of computation and storage. Applicants, including those with existing workspaces, are encouraged to propose a more aggressive series of milestones, tools, pipelines, CF data sources, and timelines.

2. Eligible Organizations

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

Non-domestic (non-U.S.) components of U.S. Organizations **are not** eligible to apply.

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

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

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

The following entities are eligible to apply under this ROA:

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

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

Nonprofits Other Than Institutions of Higher Education
- Nonprofits with 501(c)(3) IRS Status (Other than Institutions of Higher Education)
- Nonprofits without 501(c)(3) IRS Status (Other than Institutions of Higher Education)
- Faith-based or Community-based Organizations
- Regional Organizations

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

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

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

3. Eligibility Requirements

A successful CFDE CWIC application will include a team of individuals with expertise in the following:
- Hands-on experience working with biomedical data.
- Understanding the needs of biomedical researchers and the wider user community.
- Development of cloud-based services and workspaces.
- Data management and security, including storage and analysis of personally identifiable data.
- Seamless cross-cloud computing and data migration between different cloud providers.
- DevOps, with an emphasis on Application Programming Interfaces (APIs) and workflow development.
- Management of complex data services delivery projects.
- Development and delivery of data science and cloud computing training.

Since the CWIC team will be directly interacting with the other four core CFDE centers (ICC, DRC, KC, and TC), a PI/MPI for the CWIC may **not** serve as the PI/MPI for either the DRC, the KC, the ICC, or the TC. As long as the PI/MPI holds an award (either active or in a no-cost extension) for one of the these four CFDE centers, they are **ineligible** to receive the CWIC award. PIs/MPIs who have questions concerning their eligibility **are strongly encouraged** to contact the CFDE NIH team to clarify their eligibility before applying.

Applications proposing live vertebrate animal research, human subjects research, and/or clinical trials are not allowed. Specific cloud workspace use cases may involve the use of human data, and must comply with all applicable laws and policies, including IRB review (when required).

4. Multiple Principal Investigators and Partnerships among Applicants' Institutions

More than one individual may be named as Principal Investigator (PI) in the application. One individual must be identified as the contact Principal Investigator. The contact PI must commit **at least 15% effort** to the proposed project; all other individual PIs (if a multiple principal investigators proposal is submitted) must each commit **at least 10% effort** to the proposed project. The contact Principal Investigator must be

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

Partnerships among organizations that bring together teams with complementary skills and expertise needed to meet the requirements of this ROA are not required but are allowed.

5. Dedicated Project Manager/Director (PM/PD) Requirement

NIH expects the proposed project to include an individual that will serve as the primary PM/PD for the project. This individual will have appropriate experience and will provide overall project management and organizational oversight. They must commit **at least 50% effort** to the project.

6. Financial and Risk Assessment

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

7. Cost Sharing

Cost Sharing is not required but may be proposed. Those proposing to develop commercial applications or who are using other state or government resources may consider identifying a cost share percentage. Applicants may voluntarily choose to propose a financial plan that includes non-federal resources. The budget submission must clearly identify and justify the use of these resources. Any voluntary cost share must be supported in the application by including a letter of support from the providing organization(s)/individual(s). Inclusion of cost sharing will **not** be considered during the application selection process.

8. Developing Applications

8.1 Application Submission Instructions

Complete applications must be submitted under **OTA-24-005** via NIH eRA Commons ASSIST no later than the "***Proposal Due Date***" shown at the top of this notice, by 5 PM local time of applicant organization. A single collated PDF must also be e-mailed to CFDE@od.nih.gov and must include the words "CFDE CWIC" in the subject line. **Late applications will not be accepted.**

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

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

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

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

8.2 Letter of Intent

Letters of intent are strongly encouraged but are not required and will not influence eligibility to submit a full proposal. They will be used to optimize the expertise of the Objective Review panel (see Section 9) that will

review applications submitted in response to this ROA. Interested applicants may submit a Letter of Intent (LOI) as a single collated PDF of no more than 4 pages with sections outlining the following:

- A Project Information Summary page (up to 2 pages) as described below for the full application (Section 8.3), which includes the name and email addresses for the Contact PI and the Recipient Business Official/Signing Official.
- A brief description of how the PI(s), their institutional affiliations, and teams meet the eligibility requirements stated in Section 2 and Section 3 of this ROA (up to 1 page).
- An overview of the planned activities and approach (up to 1 page).

LOIs will be reviewed by NIH staff only to assess eligibility of the applicant organization(s) and to identify specific expertise requirements and conflicts of interest for potential reviewers. NIH may provide feedback about any eligibility concerns that are identified through the LOI. ***NIH will not be providing feedback about the scientific and technical content for improvements***. Letters of intent must be submitted by email as a single collated PDF attachment to CFDE@od.nih.gov and must include the words "CFDE CWIC" in the subject line. LOIs submitted by other means may not be considered.

8.3 Full Application

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

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

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

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

- Proposed budgets per year for 5 years (direct, indirect and total costs), including the proposed project period dates.
- Full names (last name, first name) of all key personnel, institutional affiliation, title, and percent effort.
- Confirmation that the work does not involve human subjects or vertebrate animals.

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

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

- **Project Plan:** A full description of the planned activities and approaches that addresses the points listed below (up to 8 pages):
  - A list of goals and an initial approach to their implementation.
  - Advantages and strengths of the proposed approaches.
  - Discussion of potential risks and alternative plans for resolving them.
  - Plans for collaborating with the other CFDE components (DRC, KC, ICC, TC, and individual data resources).
  - Plans for partnerships with complementary non-CFDE programs (e.g., other NIH programs, non- NIH programs) – this is optional but should be included if relevant to the overall proposal.
  - Plans that address sustainability, projected costs of operation, execution of an orderly shutdown, and transfer of the cloud workspace functionality to a new product owner.
  - Description of how the proposed team fulfills the expertise requirements outlined in Section 3, including examples of experience developing cloud-based infrastructure.

- **Milestones and Deliverables** (up to 5 pages): The expected initial project duration is 5 years. Provide a list of detailed milestones and deliverables for the first year and high-level milestones and deliverables for years 2 -5. Please make sure to explicitly associate requested costs with milestones. See Section 8.5 below for additional information on how this document should be prepared. A Gantt chart to illustrate the dependencies between the project milestones and project schedule should be provided. Risks and their mitigation should be addressed in the Project Plan section (see above).

- **Leadership Plan** (up to 4 pages):
  - Organizational and reporting structure, and personnel responsibilities.
  - Relevant prior experience of the team working together.
  - Multiple Principal Investigator (MPI) Leadership Plan, if applicable. This plan should, at a minimum, address the scientific and project management rationale for having multiple PIs, the decision-making process for allocating resources and choosing the direction of the project, and a detailed plan for conflict resolution (may not rely on HHS staff to arbitrate disputes and must be clear how ties are resolved).

- **Equipment and Facilities** (up to 2 pages): Provide the information about the equipment and other physical resources available to the project team to adequately complete the project milestones.
- **Institutional Letter(s) of Support** (up to 2 pages each): The applicant's organization and each identified sub-awardee must provide a letter of support. The letter must indicate institutional commitment for the project (e.g., relaying support for contributions, including, but not limited to, support for training activities or consortium meetings, licenses, and other resources) and preparations to enter into a negotiated Other Transaction Agreement. If cost sharing is proposed, it should be described in these letters.
- **Budget and Budget Justification** (no page limit): All applications should provide detailed budget information for planned activities and partnerships, as described below in Section 8.4. Procurement of hardware, data, cloud computing, and the development of software capabilities to support the proposed activities are allowable costs.
- **Bibliography** (no page limit).
- **Resource Sharing Plan:** Individuals are required to comply with the instructions for the Resource Sharing Plans as provided in the SF424 (R&R) Application Guide. This plan should address relevant licensing an open access goals outlined in this ROA.
- **Data Management and Sharing Plan:** A Data Management and Sharing Plan is not required for the CWIC because the Cloud Workspace Implementation Center is not expected to perform biomedical or social-behavioral research, nor is it expected to generate primary data.
- **Plan for Enhancing Diverse Perspectives (PEDP)** (up to 2 pages): All applicants must include a summary of strategies to advance the scientific impact of the proposed project through expanded inclusivity. Broadly, diverse perspectives can refer to the people who do the research and the places where the research is done, as well as to who participates in the research as part of the study population. Please see NOT-OD-20-031 for additional information. The PEDP should provide a holistic and integrated view of how enhancing diverse perspectives is viewed and how it will be supported as the cloud workspace is implemented and becomes operational. The PEDP will be evaluated as a part of the Appropriateness of Resources category (See Section 9 – Objective Review).

  The PEDP must include the following:

  - Description of defined activities and actionable strategies for enhancing inclusivity in opportunities to participate in and/or conduct NIH-relevant research.
  - Milestones (including a timeline) for the proposed PEDP activities.
  - Planned evaluation and monitoring metrics/activities to identify and measure PEDP progress.

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

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

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

8.4 Budget details

The Common Fund may allocate up to $750,000 for the first-year total costs (direct + F&A) for this Center, and up to $1,500,000 total costs per year for years 2-5. Future year amounts will depend on satisfactory progress by the awardees, the business needs of CFDE, and annual appropriations.

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

Cost share is not required but may be proposed. Including a cost share will **not** impact an applicant's chances of selection. The NIH may elect to negotiate any or all elements of the proposed budget.

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

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

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

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

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

Budget justification must be provided for all budget items.

Budgets must adhere to the latest NIH salary limitation notice https://grants.nih.gov/grants/guide/notice-files/NOT-OD-24-057.html (See Salary Cap Summary/Guidance on Salary Limitation for Grants and Cooperative Agreements).

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

8.5 Milestones and Deliverables

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

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

Example table of milestones and deliverables:
Note 1: Applicants must ensure that the total budget request is consistent with the sum of item budget estimates in Milestones and Deliverables table for the project (see Sections 8.3 and 8.4).
Note 2: Provided costs for the task should include all the costs for personnel, equipment, facilities, other resources, travel, and other associated costs.
Note 3: Total cost (direct and indirect) for the tasks should be provided.

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

8.6 Systems Registration

Applicants must submit a full application via the NIH eRA Commons ASSIST system by 5:00 PM local time on the due date (see Key Dates below). Use **OTA-24-005** in the Funding Opportunity Announcement field. A single collated PDF must also be e-mailed to CFDE@od.nih.gov by 5:00 PM local time on the due date (see Key Dates below) and must include the words "CFDE CWIC" in the subject line. **Late applications will not be accepted.** This link provides instructions for submitting via the NIH eRA ASSIST system. Technical assistance is available from the eRA Service Desk.

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

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

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

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

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

• eRA Commons - Once the unique organization identifier (UEI after April 2022) is established, organizations can register with eRA Commons in tandem with completing their full SAM and Grants.gov registrations; all registrations must be in place by the time of submission of the full application. eRA Commons requires organizations to identify at least one Signing Official (SO) and at least one Program Director/Principal Investigator (PD/PI) account in order to submit an application.

If you encounter a system issue beyond your control that threatens your ability to complete the submission process on-time, you must follow the Dealing with System Issues guidance.

9. Objective Review

The intent of the objective review for the CFDE Cloud Workspace Implementation Center is to determine whether the proposed activities meet the goals and vision of CFDE for this center.

Proposals to Other Transactions Research Opportunity announcements such as this one, are not reviewed by the standard NIH peer review process, but using a custom process referred to as Objective Review. Responsive, full applications submitted in response to the solicitation, will be reviewed by a panel of subject matter experts. Objective review will involve the submission of written critiques by subject matter experts against the Review Criteria described below, and interactive individual discussions between those experts and NIH program staff. The subject matter experts will include NIH staff, other federal staff, and may include individuals external to the federal government. The review will facilitate further dialogue between select applicants, subject matter experts and NIH program staff so that applications are improved by the review process. Components of the full applications may be accepted into the final plan in whole, in part, or may be

omitted. The outcome of each review could result into a modified work plan for each proposal based on reviewers' comments and recommendations. The modified workplan, as shaped by the review process, will serve as a blueprint for the final negotiated terms and milestones for the resulting awards.

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

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

Review of Full Applications

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

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

Scored Review Criteria

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

- **Reasonableness and merit of the proposed plans and approaches (max 30 points)**
  - Are the planned activities likely to advance the goals of the CFDE program and successfully address the primary goals listed in Section 1 of this ROA?
  - Are the proposed milestones and deliverables, as well as the accompanying timelines, reasonable and achievable given the anticipated project duration and budget?
  - Does the proposal describe strategies for identifying and mitigating technical and management risks? Are specific technical and management risks identified and discussed? Are alternative approaches considered (if relevant)?
  - Is an adequate plan and/or documentation for meeting the necessary FISMA-equivalent information security compliance provided?

- **Appropriateness of the key personnel (max 10 points)**
  - Are the expertise, demonstrated capabilities, and past performance of the PI(s), PM/PDs, and key personnel appropriate for the proposed activities and successful execution of the proposed work?
  - Is the necessary expertise illustrated, documented, and shown adequately with relevant examples from past work?
  - Is there adequate Project Management and administrative support to ensure effective execution and monitoring of activities necessary to complete the project milestones?
  - Are the leadership plan and the multiple PI leadership plan (if applicable) appropriate?
  - Are the organizational and reporting structures appropriate?

- **Appropriateness of the equipment and facilities, and other resources (max 5 points)**
  - Are the proposed facilities, computing infrastructure, backup plans, physical security of any data, communication networks, relevant other equipment, and project management tools adequate to support the successful execution of the proposed program?
  - Are the plans for replacing, maintaining, and repairing equipment and critical virtual resources (e.g., software) appropriate?
  - Is the PEDP plan rigorously developed and actionable?

- **Appropriateness of the proposed budget (max 5 points)**
  - Is the proposed budget reasonable and commensurate with the proposed work?
  - Can the goals of the project, as stated, be accomplished with the proposed budget?

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

Post-review Funding Plan

NIH intends to fund one award for the CFDE Cloud Workspace Implementation Center. However, the actual number of awards will depend in on the availability of funds and on how the objectives proposed by the applicants fit the goals of CFDE.

The level of funding for awards made under this solicitation will depend on (1) the objectives for the center proposed by the applicants and how well they fit with the goals of CFDE, (2) the quality of the applications received, (3) availability of funds, and (4) programmatic priorities. The OT mechanism allows for significant flexibility to make budget adjustments as needed to meet NIH's programmatic priorities. Award levels may increase or decrease over time based on funding availability, establishment or termination of sub-contracts, recipient's performance, and other program priorities.

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

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

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

10. Application Timeline

Key Events	**Receipt Dates**	**Action needed by Applicants**
Research Opportunity Announcement (ROA) posted	February 20, 2024	Submit inquiries to anthony.kirilusha@nih.gov and CFDE@od.nih.gov
Informational Webinar	February/March 2024	Webinar information and its date will be posted on the Frequently Asked Questions website
Submission Deadline for Letters of Intent (LOI)	March 21, 2024	Submit LOIs in the form of one collated PDF file to anthony.kirilusha@nih.gov and CFDE@od.nih.gov
Submission Deadline for Full Applications	April 22, 2024	Submit electronically through ASSIST and in the form of one collated PDF file to CFDE@od.nih.gov; **late applications will NOT be accepted**
Award Negotiations expected to begin	May 13, 2024	Respond to written inquiries; attend videoconferences or teleconferences as requested
Earliest Start Date	July 1, 2024	

11. Special Award Terms and Information

NIH Discretion

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

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

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

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

Award Governance

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

NIH Roles and Responsibilities:

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

OT Agreement Governance

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

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

Reporting and Project Meetings

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

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

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

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

Third Parties

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

Management Systems and Procedures

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

Public Policy Requirements and Objectives

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

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

a. Anti-Sexual Harassment

b. Debarment and Suspension

c. Dissemination of Deliberately False or Misleading Information

d. Federal Information Security Management Act (FISMA)

e. Financial Conflict of Interest (FCOI)

f. Fly America Act

g. Foreign Involvement

h. Gun Control

i. Human Embryo Research and Cloning Ban

j. Human Fetal Tissue Research

k. Human Stem Cell Research

l. Intellectual Property

m. Lobbying Prohibition

n. National Environmental Policy Act

o. NIH Data Sharing Requirement

p. NIH Salary Cap

q. Research Involving Recombinant or Synthetic Nucleic Acid Molecules

r. Research Misconduct

s. Restriction on Abortion Funding

t. Research Subjects Protections and Requirements

u. Pro-Children Act of 1994

v. Promotion or Legalization of Controlled Substances

w. Restriction of Pornography on Computer Networks

x. Restriction on Distribution of Sterile Needles

y. Select Agents

z. USA Patriot Act

TERMS AND CONDITIONS (Appendix I)

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

TERMS AND CONDITIONS

OTHER TRANSACTIONS AGREEMENT

BETWEEN

APPLICANT/ADDRESS

AND

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

CONCERNING

Common Fund Data Ecosystem

WITH

CFDE (Insert) Center
Common Fund Data Ecosystem

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

This Agreement is entered into between the National Institutes of Health (NIH), an agency of the United States Government, and (Applicant) pursuant to and under United States Federal law, as applied by the federal courts in the District of Columbia.

Contents

ATTACHMENTS

Attachment 1	**Statement of Milestones**
Attachment 2	**Statement of Budgetary Projections**
Attachment 3	**Reporting Requirements**

ARTICLE I. SCOPE OF THE AGREEMENT

A. Background

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

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

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

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

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

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

Cloud Workspace Implementation Center (CWIC): This center will be responsible for creating a CFDE designated cloud workspace that enables users to import their data and co-analyze them together with other CF data sets

and/or utilize CFDE constructed analysis pipelines, workflows and other analysis and visualization resources. The cloud workspace will meet the needs of both novice and expert users.

Training Center (TC): This center will be responsible for identifying and addressing the training opportunities and needs of the CFDE community. It will develop targeted training to address gaps in the training landscape, and a mentoring program to support the growing community of CF data users. In addition, it will help coordinate training-related activities across other CFDE centers through a Trainers Working Group, by supporting the analysis and evaluation of training programs, and through engagement with a broad and diverse community for recruitment and outreach. This center will be responsible for developing and maintaining training-related content within the CFDE Portal, created and maintained by the DRC, and providing a web-based mechanism for CFDE Learners to interact and support one another virtually.

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

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

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

B. Definitions

In this Agreement, the following definitions apply:

Agreement: This Agreement and any Attachments or other documents that are expressly incorporated in and made a part of the Agreement, including but not limited to Attachments 1-3.

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

Controlled-access Data: Data within this category present a higher risk of patient identification. While stripped of direct patient identifiers as defined by HIPAA, controlled-access data contain specific demographic, clinical, and genotypic information that are excluded in open-access data.

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

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

Deliverables: Any tangible or intangible work product (including third party materials) provided by Recipient to NIH because of the performance of work under the Statement of Milestones (SOM) and identified as a deliverable in the SOM or the Reporting Requirements at Attachment 3.

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

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

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

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

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

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

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

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

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

Other Transactions Agreements (OT): OT awards are not grants, cooperative agreements, or contracts. They are used by the NIH, including the Office of Strategic Coordination, which have been authorized by Congress to use them. They provide considerable flexibility to the government to establish policies for the awards, so policies and terms for individual OT awards may vary between awards. Each award is therefore issued with a specific

Agreement, which is negotiated with the Recipient and details specific terms and conditions for that award. Program and administrative policies and the terms and conditions of individual awards are intended to supplement, rather than substitute for, governing statutory and regulatory requirements. Awards or a specified subset of awards also may be subject to additional requirements, such as those included in executive orders and appropriations acts, including the other transaction legislation cited in the Notice of Award (NoA), as well as all terms and conditions cited in the NoA and its attachments, conditions on activities and expenditure of funds in other statutory or regulatory requirements, including any revisions in effect as of the beginning date of the next funding segment. The terms and conditions of the resulting OT awards are intended to be compliant with governing statutes.

Other Transactions Agreements Officer (OTAO): Individual responsible for legally committing the government to an OT award and to the Agreement through which terms and conditions are established, and for the administrative and financial aspects of the award.

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

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

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

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

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

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

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

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

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

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

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

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

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

C. Award Notice

This award is supported by the NIH Office of Strategic Coordination (OSC) – The Common Fund / Office of the NIH Director pursuant to Research opportunity Announcement OTA-24-005, "NIH Common Fund Data Ecosystem (CFDE) Cloud Workspace Implementation Center (OT2)". Future award segment costs and duration are dependent on scientific advancements, programmatic needs, and availability of funds.

D. Authorization

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

E. CFDE Program Goals and Objectives

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

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

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

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

F. Scope

The recipient shall perform a coordinated research and development project (hereafter referred to as "Project") for CFDE Program. The work shall be carried out in accordance with the Research Opportunity Announcement (OTA-24-005), Notice of Award (NoA), and the Statement of Milestones (SOM) incorporated into this Agreement as Attachment 1.

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

ARTICLE II. TERM

A. Term of this Agreement

The Program commences upon the DATE of the release of the Notice of Award (NOA), or for other such period as mutually agreed to by the Parties, subject to the availability of funds. Provisions of this Agreement, which, by their express terms or by necessary implication, apply for the periods of time other than specified herein, shall be given effect, notwithstanding this Article. If all funds are expended prior to the project end date, the Parties have no obligation to continue performance and may elect to end this Agreement at that point.

B. Termination Provisions

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

C. Enforcement, Termination

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

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

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

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

D. Flow Down

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

E. Extending the Term

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

F. No Cost Extension

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

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

G. Changing the Award Terms

Post-award changes to the terms and conditions are negotiated between the OTAO, in consultation with the NIH OTPO, and the RBO.

H. Unilateral Changes

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

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

I. Prior Approval

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

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

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

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

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

4. Site Changes
Changes to site(s) performing the activities under this Agreement or effort required to achieve stated milestones need prior approval from the OTAO, in consultation with the NIH OTPO.

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

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

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

K. The System for Award Management (SAM)

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

L. Research Integrity Procedures and Plans

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

M. The Notice of Award (NoA)

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

N. Reporting

For detailed reporting requirements, see Attachment 3.

ARTICLE III. MANAGEMENT OF THE PROJECT

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

A. **Modifications**

1. As a result of interactions with the Recipient or at any time during the term of the Agreement, progress or results may indicate that a change in the SOM would be beneficial to program objectives. Recommendations to modify the SOM may be initiated by either Party. The initiating Party will document in writing and submit its recommendations for modifying the SOM to the other Party, including justifications to support the change. The NIH OTAO, in consultation with the NIH OTPO and the RBO, shall approve any Agreement revision (modification).
2. The NIH is not obligated to pay for additional or revised future work to be performed until the SOM is formally revised by the NIH OTAO and made part of this Agreement.
3. The NIH OTPO shall be responsible for the review and verification of any recommendations to revise or otherwise modify the SOM, prospective work, or other proposed changes to the terms and conditions of this Agreement.
4. The NIH OTAO/OTAS and OTPO will be responsible for documenting, communicating, and securing any necessary NIH approvals related to modifications to this Agreement.
5. All requests for NIH approval of revisions must be made in writing by the RBO no less than thirty (30) days prior to the proposed date of change. The NIH will review the request and provide a formal response.

B. **Monitoring**

The Recipient is responsible for managing the day-to-day operations of Agreement activities using their established controls and policies. The NIH OTPO will monitor and identify potential problems and areas where technical assistance might be necessary. NIH OTPO monitoring is accomplished through review of reports provided pursuant to the SOM (Attachment 1) and Reporting Requirements (Attachment 3).

C. **Management Systems and Procedures**

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

ARTICLE IV: AGREEMENT ADMINISTRATION

The NIH will actively engage with Recipients to establish a vision and capabilities for the CFDE program and to oversee the effort of individual Recipients to achieve the vision. NIH may change its representatives named in this Article by written notification to the Recipient. Recipient may change its Recipient Business Official named in this Article by written notification to NIH. Recipient may change its Principal Investigator (PI)/Program Director (PD) only with prior approval as described in Article II(I) (Prior Approval). The NIH will affect the change as stated in this Agreement.

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

A. **NIH Points of Contact**

Other Transactions Agreements Officer (OTAO)
Name
Phone
Email Address

Other Transactions Agreements Specialist (OTAS)
Name, Ph.D.
Phone
Email Address

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

B. **Recipient Points of Contact**

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

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

ARTICLE V: OBLIGATION AND PAYMENT

A. Obligation

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

B. Payment

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

Advances made by Recipients to third parties under the Agreement must conform to substantially the same standards of timing and amount that govern advances to the Recipient.

Operational guidance for the Recipient is provided through training from the DHHS PSC. Inquiries regarding drawdown request, cash management rules, and the disbursement of funds through the Federal Financial Report (FFR) SF 425 should be directed to the DHHS PSC (https://pms.psc.gov/grant-recipients/ffr-updates.html).

C. Interest Earned on Advances

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

D. Limitation of Funds

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

E. Appropriation Mandates

This award must comply with NIH fiscal appropriation mandates.

F. Close out of Fixed Year Appropriations Amounts

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

G. Financial Records and Audits Requirements

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

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

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

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

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

H. Financial Management System Standards

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

I. Unobligated Balances and Actual Expenditures

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

J. Procurement System Standards and Requirements

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

K. Cost Principles

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

Recipients must exercise proper stewardship over Federal funds and ensure that costs charged to awards are allowable, allocable, reasonable, necessary, and consistently applied.

The fact that a proposed cost is awarded as requested by an applicant does not indicate a determination of allowability.

L. Salary Cap

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

M. Other Support

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

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

N. Recovery of Funds

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

O. Debt Collection

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

ARTICLE VI: DISPUTES

A. General

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

B. Dispute Resolution Procedures

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

C. Limitation of Damages

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

ARTICLE VII: INTELLECTUAL PROPERTY RIGHTS

A. General

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

B. Joint Development

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

C. Freedom of Action

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

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

D. Data Protection

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

ARTICLE VIII: PATENT RIGHTS

A. Allocation of Principal Rights

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

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

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

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

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

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

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

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

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

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

C. Conditions When the NIH May Obtain Title

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

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

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

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

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

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

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

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

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

E. Recipient Action to Protect the NIH's Interest

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

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

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

F. Reporting on Utilization of Subject Inventions

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

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

G. Preference for American Industry

Notwithstanding any other provision of this clause, the Recipient agrees that it shall not grant to any person the exclusive right to use or sell any Subject Invention in the United States unless such person agrees that any product embodying the Subject Invention or produced through the use of the subject invention shall be manufactured substantially in the United States. However, in individual cases, the requirements for such an agreement may be waived by NIH upon a showing by the Recipient that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States or that, under the circumstances, domestic manufacture is not commercially feasible.

H. March-in Rights

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

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

ARTICLE IX: SOFTWARE AND DATA RIGHTS

A. Principal Rights

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

B. Derivative Works

The Recipient grants to NIH a royalty-free, nonexclusive, irrevocable right to use, disclose, reproduce, post, link to, prepare derivative works, distribute copies to the public, and perform publicly and display publicly, in any manner and for any purpose, and to have or permit others to do so on NIH's behalf anywhere in the world, any derivative works of the Data or Software provided or developed by Recipient under this Agreement. Derivative works, in this context, includes data (including associated labels, annotations, assertions, inferences, relationships, and indices), queries, graphical and graph representations, data models, topologies, procedural manuals, forms, diagrams, work-flow charts, statistical records, and materials used in training/education.

C. March-In Rights

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

D. Resources Due at Termination

Subject to the timelines within the awarded application or upon termination of the award, whichever comes first, the Recipient shall make all Data (including associated labels, annotations, and indices) and training materials provided or developed under this Agreement available to the NIH under a Creative Commons By (CCBY) or comparable license. Furthermore, in case of an ownership transfer of the CFDE Cloud Workspace, the recipient must transfer all data, technology, and technical specs necessary to keep the workspace operational and maintain at least equivalent functionality post transition. It is the Recipient's responsibility to ensure that any PII or PHI in any Data, Software, tools, resources, training materials, technical solutions, or methods provided or developed under this Agreement are securely archived and transferred to the NIH or to the new CFDE Cloud Workspace owner. A suitable repository or repositories selected in concurrence with NIH (subject to limitations noted) maybe used to facilitate making Data, Software, tools, resources, training materials, technical solutions, and methods available to the public. Repositories selected should have a sustainability plan reviewed by NIH. Resources shall also be provided to NIH via a physical copy at the request of the NIH.

E. Publication and Copyright

The Recipient may copyright any work that is subject to copyright and was developed, or for which ownership was acquired under, a CFDE OT Award, provided that the Recipient agrees to make documents pertaining to education or training available to the public under an open source license, such as a CC-BY license.

The Recipient agrees to notify NIH, in writing, of the assertion of copyright in any publication or other copyrightable work developed under this Award, NIH approval to assert copyright is not required.

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

- An acknowledgment of NIH OT award support such as: “Research reported in this [publication, release] was supported by the Office of the Director, National Institutes of Health under OT award number [1OT2XXXXXXXX-XX]. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.”
- If the recipient plans to issue a press release about research supported by a CFDE OT award, it should notify the NIH OTAO, OTPO and OTAS at least 5 business days in advance to allow for coordination. Publications resulting from work performed under a CFDE OT award-supported project must be included as part of the interim, annual, or Final Research Performance Progress Report (FRPPR) submitted to the NIH OTAO, OTPO and OTAS.

F. NIH Public Access Policy

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

G. Sharing Research Resources

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

NIH Data Sharing Policy: The Recipient agrees to comply with the NIH Policy for Data Management and Sharing[2] that went into effect on January 25, 2023 and the GDS Policy[3]. The NIH Genomic Data Sharing Policy sets forth expectations that ensure the broad and responsible sharing of genomic research data. Sharing research data supports the NIH mission and facilitates the translation of research results into knowledge, products, and procedures that improve human health. For the purposes of this Policy, genomic data includes genome sequence, transcriptomic, epigenomic, immunological and gene expression data. For additional information, see: https://grants.nih.gov/grants/guide/notice-files/not-od-14-124.html. Questions about the GDS policy can be E- mailed to GDS@mail.nih.gov.

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

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

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

they will be unable to meet these data sharing expectations should promptly contact the OTAO and OTPO to discuss the circumstances, obtain information that might enable them to share data, and reach an understanding in advance of an award.

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

ARTICLE X: TITLE TO AND DISPOSITION OF PROPERTY

A. Title to Property

No significant items of property are expected to be acquired under this Agreement. Title to each item of property acquired under this Agreement with an acquisition value of $5,000 or less shall vest in the Recipient upon acquisition with no further obligation of the Parties unless otherwise determined by the OTAO. Should any item of property with an acquisition value greater than $5,000 be required, the Recipient shall obtain prior written approval of the OTAO. All items of property, including equipment, in the approved proposal budget shall be considered pre-approved for the purposes of this clause. Title to this property shall also vest in the Recipient upon acquisition. The Recipient shall be responsible for the maintenance, repair, protection, and preservation of all property at its own expense. The Recipient's deliverable shall not be classified as property. The Government does not accept responsibility for loss or damage to any property or work it has not accepted.

B. Disposition of Property

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

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

C. Property Management System Standards

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

ARTICLE XI: INFORMATION SHARING

A. Public Release or Dissemination of Information

A Recipient planning to issue communications such as a press release concerning the outcome of supported research under this Agreement must notify the NIH Office of the Director, Office of Strategic Coordination (OSC) Communications Team at CFComms@od.nih.gov and the OTPO at CFDE@od.nih.gov least 5 business days in advance to allow for coordination.

B. Prohibition from Confidential Information Release

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

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

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

ARTICLE XII: FOREIGN ACCESS TO TECHNOLOGY

A. General

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

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

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

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

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

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

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

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

OT recipients and subrecipients are prohibited from expending OT funds to:

1. Procure or obtain;
2. Extend or renew an existing OT award; or
3. Enter into a contract (or extend or renew a contract) to procure or obtain equipment, services, or systems that use covered telecommunications equipment or services as a substantial or essential component of any system, or as critical technology as part of any system. As described in Public Law 115-232, section 889, covered telecommunications equipment is telecommunications equipment produced by Huawei Technologies Company or ZTE Corporation (or any subsidiary or affiliate of such entities).

i. For the purpose of public safety, security of government facilities, physical security surveillance of critical infrastructure, and other national security purposes, video surveillance and telecommunications equipment produced by Hytera Communications Corporation, Hangzhou Hikvision Digital Technology Company, or Dahua Technology Company (or any subsidiary or affiliate of such entities).
ii. Telecommunications or video surveillance services provided by such entities or using such equipment.
iii. Telecommunications or video surveillance equipment or services produced or provided by an entity that the Secretary of Defense, in consultation with the Director of the National Intelligence or the Director of the Federal Bureau of Investigation, reasonably believes to be an entity owned or controlled by, or otherwise connected to, the government of a covered foreign country (i.e., the People's Republic of China).

ARTICLE XIII: INFORMATION SECURITY

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

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

a. NIH anticipates that all Data will be equivalent to "low" or "moderate" risk levels, as defined by NIST Federal Information Processing Standards Publication 199 ("FIPS 199").
b. NIH anticipates that all Data will be stored within the Continental United States.
c. NIH does not anticipate storing Data that is subject to the Health Insurance Portability and Accountability Act (HIPAA) at this time. If Recipient does store Data that is subject to the HIPAA, Recipient must comply with HIPAA.
d. Unless otherwise informed in writing by the NIH, all Controlled-Access Data is protected by Section 301(d) of the Public Health Service Act, 42 U.S.C. 241(d).

The Recipient must ensure that data and information systems pertinent to this award are maintained in a manner equivalent to appropriate federal standards such as NIST SP 800-171, and that documented procedures and evidence of administrative processes can be made available to NIH upon request.

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

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

ARTICLE XIV: LOWER TIER AGREEMENTS

A. *Definitions*

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

B. Authorization

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

C. Authorization Process

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

D. *General*

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

ARTICLE XV: HUMAN SUBJECTS RESEARCH

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

ARTICLE XVI: ANIMAL WELFARE

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

ARTICLE XVII: ADDITIONAL ADMINISTRATIVE REQUIREMENTS

A. Financial Conflict of Interest

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

B. Organizational Conflicts of Interest (OCI)

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

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

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

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

D. Closeout

The requirement for timely closeout is a Recipient responsibility. Closeout includes ensuring timely and accurate submission of all required reports and adjustments for amounts due to the Recipient or NIH. Attachment 3: Reporting Requirement will outline the specific timeline requirements for submission of the Final Financial Report, the Final Research Performance Progress Report (FRPPR), and Final Invention Statement and Certification.

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

ARTICLE XVIII: APPLICABLE STATUTES AND REGULATIONS

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

A. Civil Rights Act

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

B. Federal Information Security Management Act (FISMA)

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

C. Harassment and Discrimination Protections

The Recipient shall:

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

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

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

E. Additional Public Policy Requirements

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

ARTICLE XIX: ORDER OF PRECEDENCE

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

ARTICLE XX: EXECUTION

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

ATTACHMENT 1: Statement of Milestones

Statement of Milestones

ID	Milestone	Due Date(s)

The table is intentionally left blank.

ATTACHMENT 2: Statement of Budgetary Projections

The Recipient is authorized to expend funds up to the amounts reflected in the "Federal Funds Authorized" section. This SBP is based on the recipient's approved budget dated MM/DD/YYYY. It is the responsibility of the recipient to manage within this level of obligated resources consistent with the SOM (Attachment 1).							
OT Award / Modifications	**Date**	**Authorization Description**	**Period of Performance**	**Federal Funds Authorized**	**Restricted Funds**	**Unrestricted Funds**	**Budget Period**
			TOTAL				

The table is intentionally left blank.

ATTACHMENT 3: Reporting Requirements

This section consists of information for the following reports:

- Quarterly Status and Financial Reports
- Annual Report(s)
- Final Report(s)

[Project Title] Status Report

Principle Investigator:
Status Report Prepared By:
Award No.: [NIH ID#]

Reporting Period:
Submitted: [*Please submit by the 15th calendar day following the reporting period in a single pdf file.*]

Please note that reports must be submitted via email and uploaded through eRA Commons from the Recipient Business Official (RBO) to the assigned Other Transaction Agreement Officer (OTAO), Other Transaction Agreement Specialist (OTAS), and the Other Transaction Program Officer (OTPO).

Project 1

Please note that "workstream" is a generic term meant to provide flexibility for different awards to define different sub-projects within a single award in whatever way is the most useful for a particular award/program. Awardees should work with their OTPO at the outset of the project to define the workstreams that will be used for reporting purposes throughout the award.

Accomplishments During the Current Reporting Period

- [Focus on reporting achievements and outcomes rather than activity (e.g., to the extent you are able, not convened or attended a working group meeting but what was accomplished or decided at that meeting such as identified an approach to reconciling XYZ or a decision to use ABC standard; etc.]
- [Include a description of any challenges encountered and resulting changes in any tasks, deliverables or milestones]

Priorities for the Upcoming Reporting Period

- [Describe, including any modifications to planned future deliverables needed based on current progress or challenges encountered to date]

Deliverable/Milestone Status

Please add in all funded deliverable and milestones. For those that are complete, you can simply note as complete. For those where work has not yet started, you can simply note "not yet initiated."

Deliverable or Milestone	Due Date	Status
[Please include the numbering provided in your award document, e.g., Y2.101]		[select one of the following: on track, at risk, off track, completed, not yet initiated]

Risk, Issues, and Corrective Action Strategies

Risk/Issue Description	Severity	Mitigation Strategy
	[probability/impact as low, med or high for each]	

Dependencies

A dependency is a task that relies on completion of another task. Please list any dependencies that may impact the completion of the deliverables or milestone. In the "functional team" column, please indicate which team(s) or groups are responsible for completing the dependencies noted.

Description	Functional Team

Award-Generated Products

Please list all outputs from this award including but not limited to publications, patents, tools (e.g., software), and resources (e.g., datasets). This will help enable the NIH program team to track the outputs of this award.

Product Name or ID	Description	Link (as Available/Applicable)
	What it is (e.g., publication) and what it does (e.g., describes the findings of XXX)	

Financial Reporting

The financial reporting schedule is identified below with a due date of the **15th calendar day of the specified month**. The financial reporting frequency for this award is quarterly.

Example of Financial Data Reporting Frequency

Frequency	Reporting Period	Report Due Date
Quarterly	October 1st – December 31st	January 15th

Financial Reporting Guidelines

The Financial Report is to include:

1. Personnel (please note new personnel added - first and last name and title - in "Comments" section)
2. Travel
3. Equipment
4. Other Direct Cost (be specific, e.g., Computing Costs, $4,000)
5. Subawards/subcontractors
6. Indirect Cost Amount
7. Authorization Amount
8. Quarterly Expenditures
9. Quarterly Disbursements (Drawdowns)
10. Cumulative Disbursements (Drawdowns)
11. Unliquidated Obligations
12. Total Costs (Direct + Indirect Costs)
13. Comments, as applicable (e.g., new personnel added, if actual costs/expenses exceed disbursements and vice versa, an explanation is needed)
14. Remaining Balance (of Total Award)
15. Projected and Actual Burn Rates (in $)

Definitions

Authorization Amount
The total amount awarded to the non-Federal entity since the start of the award.

Cumulative Disbursements
The cumulative total of the Federal share of disbursements made against award authorizations from the beginning of the award through the reporting period end date.

Disbursement
Amounts paid for goods and services. Normally, NIH federal funds are considered disbursed when funds have been withdrawn from the Payment Management System (PMS).

Expenditures
Charges made by a non-Federal entity to a project or program for which a Federal award was received.

Unliquidated Obligations
For financial reports prepared on a cash basis, obligations incurred by the non-Federal entity that have not been paid (liquidated). For reports prepared on an accrual expenditure basis, these are obligations incurred by the non-Federal entity for which an expenditure has not been recorded.

Upon completion of the financial report:

1. Save the file as a PDF
2. Use the file naming convention: Include Program Acronym, Award Number, Reporting Month(s) and PI Last name (e.g., ABC – 1 OT2 OD0XXXX – Oct_Dec – Smith).
3. Submit the Financial Report with the Status Report via the Additions tab in eRA Commons and the CFDE Mailbox at CFDE@od.nih.gov from the Recipient Business Official (RBO).
    a. If unable to upload to eRA Commons, please submit the reports via email to the DOTM Mailbox at DOTM@nih.gov and the CFDE Mailbox at CFDE@od.nih.gov from the Recipient Business Official (RBO).

Note: A fillable template will be provided to the recipient(s). Below is a sample of the Quarterly Financial Report.

Quarter: Month X, 20XX - Month XX, 20XX

Category	Authorization Amount*	Quarterly Expenditures	Quarterly Disbursements (Drawdowns)	Cumulative Disbursements (Drawdowns)*	Unliquidated Obligations*	Comments
Total Personnel & Benefits	$ 1,200,000	$ 84,000	$ 40,000	$ 360,000	$ 840,000	*Accounting Office withdrew funds from PMS after the reporting period. Will reflect in next report.*
Travel	$ 3,000	$ 3,000	$ 2,000	$ 2,000	$ 1,000	*Pending receipt of travelers*
Equipment	$ 39,000	$ 5,000	$ 3,000	$ 7,000	$ 32,000	*Pending accounting office drawdown.*
Other Direct Costs (Specify)	$ 5,000	$ 1,300	$ 1,300	$ 3,500	$ 1,500	
Other Direct Costs (Specify)	$ 5,000	$ 1,200	$ 1,200	$ 1,200	$ 3,800	
Subaward #1	$ 1,000,000	$ 45,000	$ 25,500	$ 750,000	$ 250,000	*Pending sub's fulfillment of tasks ($10k) and accounting office drawdown ($10k).*
Subaward #2	$ -	$ -	$ -	$ -	$ -	*N/A*
Indirect Costs (Prime only)	$ 748,000	$ 35,200	$ 30,000	$ 69,000	$ 679,000	
Total Costs/Grand Totals	$ 3,000,000	$ 174,700	$ 103,000	$ 1,192,700	$ 1,807,300	

Total Authorization Amount	$ 3,000,000
Quarterly Expenditures	$ 174,700
Cumulative Disbursements	$ 1,192,700
Remaining Balance	$ 1,807,300
Projected Burn Rate	*(SPECIFY)*
Actual Burn Rate	*(SPECIFY)*

Annual Reporting

1. **SF425:** The SF-425 can be accessed at https://www.grants.gov/forms/. The FFR must be submitted in the Payment Management System (PMS). Instructions for submitting the FFR can be accessed at: https://grants.nih.gov/grants/forms/federal-financial-report and https://www.era.nih.gov/erahelp/Commons/FFR/ffr_intro.htm.
2. **Annual OT Executive Summary Report**: Summary of the major accomplishments under the Agreement and the benefits of using the Other Transactions agreement funding mechanism. Report should be one page and is due July 1st to OTAS/OTAO via Add Additional Materials tab in eRA Commons and CFDE@od.nih.gov from the Recipient Business Official (RBO).
3. **Utilization of Subject Inventions Reporting:** See OTA-24-005, Article VIII: Patent Rights, Section F. All required reporting shall be accomplished, to the extent possible, using the iEdison portal at iEdison.gov. To the extent any such reporting cannot be carried out by use of iEdison, reports and communications shall be submitted to the OTAO via the Add Additional Materials tab in eRA Commons from the Recipient Business Official (RBO).

Final Reporting

Within 120 days of the end or termination of this Agreement, the Recipient shall provide to the NIH the following final reports:

1. **Final Research Performance Progress Report (FRPPR):** Final progress report that includes a general synopsis of the research activity and any noteworthy accomplishments, including results disseminated to the community. At the request of the Government, this may include a summary of lessons learned.
2. **Final Financial Report:** Final Federal Financial Report (FFR), SF-425, for the entire award period. The SF-425 can be accessed at https://www.grants.gov/forms/. The FFR must be submitted in the Payment Management System (PMS). Instructions for submitting the FFR can be accessed at: https://grants.nih.gov/grants/forms/federal-financial-report and https://www.era.nih.gov/erahelp/Commons/FFR/ffr_intro.htm.
3. **Final Invention Statement**: Final Invention Statement and Certification (Form HHS 568). The HHS 568 form can be located at https://grants.nih.gov/grants/hhs568.pdf. Form HHS 568 should be submitted via eRA. Instructions for submitting the HHS 568 can be accessed here: https://era.nih.gov/grantees/submit-final-invention-statement.htm. A negative report is required at the completion of the Agreement, if there are no Subject Inventions. If there were no inventions, the form must indicate "None."