



March 16, 2022

## Research Opportunity Announcement

**Research Opportunity Title:** NIH Cloud Platform Interoperability Administrative Coordinating Center

**OTA-22-004**

**Participating Organization(s):** National Institutes of Health

**Components:** This Other Transactions Research Opportunity Announcement (OT ROA) is to support the *NIH Cloud Platform Interoperability* program ([NCPI](#)) and complements investments by NIH Institutes, Centers, and Offices (ICOs) in secure cloud-based platforms for data storage, sharing, and analysis. This research opportunity will be administered by the Office of Data Science Strategy (ODSS).

**Funding Instrument:** The funding instrument is the Other Transaction (OT) Award mechanism.

OT awards are not grants, cooperative agreements, or contracts, and use an Other Transactions Authority provided by law. Terms and conditions may vary between awards. Each award is therefore issued with a specific Agreement, which is negotiated with the awardee and details the agreed-upon terms and conditions for that award.

**Related Notice:** [\[OT-22-004\]](#)

**Research Opportunity Purpose:** The purpose of this announcement is to invite applications from eligible organizations to engage with the NIH in providing technical, administrative, and coordination support for the *NIH Cloud Platform Interoperability* program ([NCPI](#)). The goal of NCPI is to enable a federated data ecosystem that will facilitate researcher-driven analyses of datasets across multiple cloud-based platforms and repositories. This will be accomplished through testing and implementing standards and approaches for systems interoperability and universal authentication. Current efforts are driven by key scientific data interoperability projects that cut across the Analysis Visualization and Informatics Lab-space ([AnVIL](#)) supported by the National Human Genome Research Institute (NHGRI); [BioData Catalyst](#) supported by the National Heart, Lung, and Blood Institute (NHLBI); the Cancer Research Data Commons ([CRDC](#)) supported by the National Cancer Institute (NCI); the Gabriella Miller [Kids First Data Resource Center](#) (DRC) supported by the NIH Common Fund; and the NIH National Center for Biotechnology Information ([NCBI](#)). Each of these systems are made up of portals or interfaces for searching datasets, repositories for storing and distributing data, and cloud compute platforms that provide private workspaces where researchers can collaborate and run a variety of analysis tools and workflows. Empowering researchers to rapidly and seamlessly co-analyze data from these systems will accelerate biomedical research in pursuit of improving public health.

This announcement aims to establish the NCPI Administrative Coordination Center (ACC), which will provide technical, administrative, coordination, and project management support across NCPI participants and collaborators. The primary responsibility of the ACC will be to support the NIH in identifying, prioritizing, and overseeing *interoperability projects*, which are technical projects that are driven by scientific use cases that leverage datasets from multiple NIH cloud repositories. These



*interoperability projects* should result in the development and/or adoption of foundational technical tools or approaches for an extensible, connected data ecosystem, and ultimately lead to improved findability, accessibility, interoperability, and reproducibility (FAIRness) of data. Additionally, the ACC will have wide-ranging responsibilities that include supporting of the creation and maintenance of communication and training materials, organizing and facilitating events related to NCPI activities, providing project management for NCPI interoperability projects and working groups, monitoring of progress and milestones, supporting the NIH in developing good governance practices, and supporting the onboarding of new partner platforms.

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

**Eligibility:** See the Eligibility section of this opportunity.

**Application budget:** The level of funding for awards made under this solicitation has not been predetermined and will depend on (1) the objectives proposed by the applicants and how well they fit with the goals of NCPI, (2) quality of the applications received, (3) availability of funds and (4) programmatic priorities.

The application budget should reflect the proposed activities and personnel of the ACC. The OT mechanism allows for significant flexibilities 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, awardee performance, and other program priorities. It is anticipated that funds will be allocated on a yearly basis.

NIH is also alerting applicants that the ACC awardee will be expected to establish subawards to support the NCPI-related activities of the participating platforms and collaborators, once approved by the NIH (see the Statement of Milestones (SOM) below for additional details). Currently, the NCPI platforms are those listed above, although other NIH supported platforms and collaborators may be included in the future, as appropriate. Funding for these sub-contracts will be determined based on proposals from the participating platforms, in consultation with NIH.

**Indirect costs for any application funded under this ROA will be capped at 15%.**

Cost share is not required but may be proposed.

**Anticipated number of Awards:** One. While the intention is to select a single applicant to carry out the required work, it is possible that elements from two or more proposals will, if effectively combined, offer the best solution. In that case, an attempt will be made to negotiate with multiple applicants to gauge the possibility of a joint effort.

**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.



**Release Date of this Research Opportunity Announcement:** March 16, 2022

**Frequently Asked Questions:** <https://datascience.nih.gov/nih-cloud-platform-interoperability-effort/administrative-coordinating-center>

**Letters of Intent (LOI) Due Date:** April 15, 2022 by 5:00 PM local time of applicant organization. **Please note that only those applicants that submit an LOI and an receive an invitation from the NIH NCPI program will be eligible to submit a full proposal.**

**Proposal Due Date:** June 1, 2022 by 5:00 PM local time of applicant organization. Late applications to this ROA will not be accepted.

**Earliest Start Date:** July 31, 2022

**Kick-off Meeting:** To Be Determined

**Agency Contacts:**

Scientific Research Contact: [ncpi-info@od.nih.gov](mailto:ncpi-info@od.nih.gov)

LOI/proposal submission: [ncpi-info@od.nih.gov](mailto:ncpi-info@od.nih.gov)

## Outline of this Opportunity

- Overview of the NIH Cloud Platform Interoperability Program
- Statement of Milestones – The NCPI Administrative Coordinating Center
- Eligibility Requirements
- Organizations
- Multiple Principal Investigators and Partnerships among Applicant’s Institutions
- Project Manager/Director Requirement
- Financial and Risk Assessment
- Cost Sharing
- Developing Applications
- Peer Review
- Application Timeline
- Special Award Terms and Information

### 1. Overview of the NIH Cloud Platform Interoperability Program

Connecting NIH’s many data systems is a critical step toward improving researchers’ access to all types of data. NIH has invested significant resources into the generation of large-scale datasets, such as human genomic, clinical, and imaging data. Many of these data are stored in different cloud-based repositories (a.k.a. cloud platforms) that are stewarded by multiple ICs across the NIH. This can cause researchers to struggle to find, access, aggregate, and co-analyze datasets across different data repositories. For example, when a researcher is interested in studying a specific disease, pertinent data may reside on multiple cloud platforms. It is difficult to discover where all of the relevant data reside, and there is often no efficient mechanism to combine data that are not all



hosted by the same repository or to perform an integrated analysis. Doing so on a case-by-case basis is costly, time-consuming, and requires expertise in cloud computing and computer programming.

The goal of the NIH Cloud Platform Interoperability (NCPI) program is to enable a federated data ecosystem that will facilitate researcher-driven analyses of datasets across multiple cloud-based platforms and repositories. This will be accomplished through testing and implementing standards and approaches for systems interoperability and universal authentication. To achieve this, technical cohesion among the participating platforms will need to be maintained while solving cutting-edge interoperability and cloud engineering problems. Current work is driven by key scientific data interoperability projects that cut across AnVIL, supported by the National Human Genome Research Institute (NHGRI), BioData Catalyst supported by the National Heart, Lung, and Blood Institute (NHLBI), the Cancer Research Data Commons (CRDC) supported by the National Cancer Institute (NCI), the Gabriella Miller Kids First Data Resource Center supported by the NIH Common Fund, and the NIH National Center for Biotechnology Information (NCBI). Empowering researchers to co-analyze data from these systems will accelerate biomedical research in pursuit of improving public health. Furthermore, NCPI will develop a governance structure and implement guidelines that will allow additional interested repositories with applicable interoperability projects to be integrated into the federated data ecosystem.

To date, NCPI has had several successes, including enabling researchers to co-analyze data from multiple cloud-based repositories leveraging standards such as the GA4GH Data Repository Service API, and enabling exchange of clinical data using the HL7 FHIR standard. Expanding these efforts to address additional high priority interoperability projects in pursuit of more complex capabilities warrants robust coordination within NCPI and with additional collaborators. This announcement aims to establish the NCPI Administrative Coordination Center (ACC), which will provide technical, administrative, coordination, and project management support across NCPI partners and collaborators to address the evolving needs of the program.

## [2. Statement of Milestones – The NCPI Administrative Coordinating Center](#)

NIH key expectations for the NCPI ACC:

- (i) The ACC shall work under the management and oversight of the ODSS Program Office (PO), with scientific and strategic guidance from the NIH NCPI Steering Committee (SC) composed of NIH staff from ODSS and NCPI partners.
- (ii) The ACC must effectively and productively collaborate with the investigators representing the NCPI partners, which is essential to the success of both the ACC and NCPI during the performance of their activities.
- (iii) The ACC is expected to provide technical, administrative, coordination, and project management support for the five primary task areas outlined below.

**2.1 Establish, facilitate, and monitor the technical implementation of interoperability projects.**

- a. Establish a fair and transparent process for soliciting proposals for interoperability projects. Develop a broad solicitation for interoperability projects that considers the scientific impact, near-, medium- and long-term feasibility, and the potential to develop extensible, foundational capabilities for a FAIR data ecosystem. An example of the latter would be the development, testing, or implementation of interoperability tools, standards, and approaches across NCPI partners and potential new partners. Potential areas of interest underlying the interoperability projects may include but are not limited to: the ability to search across the NCPI datasets in different NIH platforms; executing the same analysis workflows on different platforms and validating the workflow equivalency; testing new IT standards to foster cross-platform analysis; creating resources for estimating cloud computing costs for popular workflows in various platforms; and improving semantic and syntactic interoperability to support a specific combined analysis.
- b. Support the full solicitation cycle, which includes addressing questions from the applicants, receiving the applications, organizing and conducting the review, and providing reviews to NIH for funding consideration.
- c. Establish subcontract awards to participants of each approved NCPI interoperability projects and provide support for resolving technical challenges. Monitor progress, project timelines, and milestones. Milestones, key performance parameters and deadlines should be made viewable across the NCPI partners and NIH through a dashboard, or equivalent.
- d. Provide a synthesis of interoperability projects' progress reports, timeline and milestone updates and other information to the PO and to the SC on a regular, and an as-needed basis. This information will be used by NIH staff when making decisions regarding the approval, continuation, and termination of work associated with interoperability projects.

**2.2 Provide project management and coordination for NCPI partners and collaborators.**

- a. Organize NCPI meetings (e.g., partner kick-offs, all hands workshops, Steering Committee meetings, NCPI Leadership Group meetings, Working Group meetings), define meeting agendas, document meeting minutes, action items, decisions and ensure follow-ups.
- b. Maintain NCPI project documentation.
  - Develop and update NCPI documentation and materials (including recordings and videos), and maintain the document management system
  - Collate and share NCPI training materials as they relate to cross-platform functionalities, standards, and use cases
  - Migrate existing NCPI documentation to the NCPI website, collate content based on input from the NIH Steering Committee, ODSS, platform representatives, and NCPI Working Groups
- c. Establish a dashboard, or an equivalent solution, accessible to the NIH and across the NCPI, to track interoperability projects' activities, roadmaps, timelines and milestones, generate progress reports on a regular or as needed basis, and facilitate the identification and management of risk.
- d. Establish evaluation criteria and metrics for training, interoperability projects, and other activities of the NCPI with regular reporting to NIH.
- e. Facilitate onboarding of new NCPI partners. This includes developing and maintaining the relevant documentation.



- f. Support the use of cloud services provided by NIH STRIDES or through other cloud service providers, including the provision of cloud accounts and credits for NCPI related program activities, such as for researchers involved in NCPI interoperability projects, event participants (e.g., NCPI code-a-thons), students of hands-on training offerings, (e.g. NCPI fellows – see below), including supporting review/approval procedures for cloud credit requests, establishing and managing bill groups, monitors credits spending, and documenting feedback and lessons learned from users.
- g. Serve as liaison with other relevant efforts, committees and organizations within and outside the NIH (e.g., potential new NCPI partners at other ICOs, NIH RAS, OSP, GA4GH, CFDE, FDA, etc.).
- h. Identify and support engagements, pilot projects, and capacity building with current NCPI partners, as well as new partners, as approved by NIH. The ACC must manage these relationships and associated contractual arrangements in partnership with NIH as subject to the OTA award.

### **2.3 Support training, outreach, and other community building activities**

- a. Facilitate the logistics of training events in coordination with NCPI partners.
- b. Provide administrative support for code-a-thons to test or implement NCPI standards or help researchers contribute additional workflows and tools to NCPI environments.
- c. Evaluate the current [NCPI website](#), establish the new website including a standalone URL, further develop its structure and content, and maintain it as a central location for the public to learn about NCPI. At a minimum, the website should contain up-to-date information about the NCPI mission, partners, progress, products, onboarding documentation, technical documentation (e.g., link to GitHub repositories), training materials, and a schedule of events.
- d. Establish and maintain NCPI social media accounts and other forms of communication with the public.
- e. Establish an NCPI Fellows program. This program is to support community driven efforts on NCPI platforms. The ACC should solicit applications, review and make awards for fellows, to include salary support, assistance with development and tracking of the projects proposed by fellows, dissemination of cloud credits to support the fellows' analyses, soliciting input and feedback.
- f. Engage, document, address and resolve user feedback on NCPI interoperability solutions.

**2.4 Support NCPI's governance structure and coordinate working groups.** The NCPI activities are organized through several working groups and governance bodies. The ACC will support these, and other groups, as needed to meet NCPI goals. This task includes, and is not limited, to the following:

- a. Establish and coordinate the NCPI Leadership Group which should include the principal investigators and other senior representatives from participating NCPI partners and collaborators. The NCPI Leadership Group will serve as a leadership nexus for the technical working groups. It will provide a forum for coordinating technical implementation of integration projects across partner repositories, identifying new opportunities, and identifying both existing and emerging technical risks.
- b. Develop and maintain an organizational, reporting, and accountability structure for the overall NCPI program.
- c. Monitor and facilitate the resolution of conflicting priorities across different NCPI partners and their associated NIH Institutes and Centers.



- d. Address administrative concerns and facilitate conflict resolution.
- e. Establish a Scientific Consultant Group (SCG) of individuals without conflicts of interest, and with the relevant subject matter expertise to provide periodic guidance to the ACC about its administrative, scientific and technical operations.

### 2.5 Support, facilitate, and monitor adoption of RAS by NCPI.

- a. Support the initial technical implementation of the Researcher Auth Service (RAS) to advance interoperability goals of NCPI approved by the NIH PO and SC.
- b. Provide ongoing technical support of RAS in the NCPI ecosystem by documenting and monitoring RAS adoption; and implementing projects that improve and promote RAS services (i.e., authentication, authorization, auditing) and features (e.g., account linking).
- c. Provide the ability to monitor progress on milestones, key performance parameters and deadlines associated with the activities outlined in (a) and (b). Ideally, this should take the form of a dashboard, or an equivalent solution, accessible to the NIH and across the NCPI participating platforms. Some milestones and key performance parameters will be derived directly from the NIH RAS integration review process, and approval of key deliverables (i.e., RAS Partner System Development Team SOP).
- d. Provide support to member platforms and CIT staff to facilitate technical progress on milestones and deliverables, as outlined in NIH guidance for RAS adoption. Activities include submission of technical design documentation, completion of end-to-end testing and a tabletop exercise, proper deployment and audits of key services and features (including evaluation of security access logs), and participation in forums to share best practices, common challenges and other relevant information within NCPI and with other integrating systems.

## 3. Eligibility Requirements

A successful NCPI ACC application will include individuals with expertise in:

- management and security of biomedical research data (e.g., genomics, other omics, phenotypic and clinical data, imaging)
- cloud computing
- interoperability solutions (e.g., APIs, data standards and ontologies, portable workflow languages)
- computer security (e.g., single sign-on, multi-factor authentication, authentication and authorization audit logging)
- development and delivery of data science training, particularly cloud-based training
- administration and project management of complex biomedical research projects (ideally trans-NIH projects)

**NOTE 1:** Since the ACC will be directly involved in facilitating the solicitation for interoperability projects, the primary institution of current NCPI partners is **not** eligible to apply for this opportunity.

Current NCPI partners and primary institution ineligible for the ACC:

- a. NHGRI/AnVIL: Broad Institute, Johns Hopkins



- b. NHLBI/BioData Catalyst: Seven Bridges Genomics Inc., Harvard Medical School, Broad Institute, University of Chicago, RENCI
- c. CF/Kids First DRC: Children's Hospital of Philadelphia, University of Chicago, Seven Bridges Genomics Inc, University of Colorado Denver, Centre Hospitalier Universitaire Sainte Justine, Ann & Robert H. Lurie Children's Hospital of Chicago, Children's Research Institute
- d. NCI/CRDC: Broad Institute, Seven Bridges Genomics, Institute for Systems Biology, University of Chicago, Johns Hopkins, ICF (icf.com), Brigham and Women's Hospital, Harvard Medical School
- e. NIH NLM/NCBI

Applications from these institutions will be deemed non-responsive and will not receive further consideration.

**NOTE 2:** The ACC awardee will be ineligible to apply for the NCPI interoperability projects, or otherwise receive NCPI funding not related to the activities of the ACC.

**NOTE 3:** To ensure the best balance of expertise and capabilities, the NIH may decide to make an ACC award that includes one or more applicants from this solicitation.

**NOTE 4:** To be considered eligible, the applicants must first submit a Letter of Intent (see section 9.2 for detailed instructions) by the listed due and be invited to apply. Full applications that do not include an invitation to apply will not be considered eligible and will not be reviewed.

**NOTE 5:** Applications proposing human subjects research and/or clinical trials are not allowed. Specific integration projects may involve the use of human data, and must comply with all applicable laws and policies, including IRB review.

## 4. Organizations

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

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/awardees, 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.

Foreign components, as defined in the [NIH Grants Policy Statement](#), **are** allowed.

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

The following entities are eligible to apply under this ROA:



#### Higher Education Institutions

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

The following types of Higher Education Institutions are always encouraged to apply for NIH support as Public or Private Institutions of Higher Education:

- Hispanic-serving Institutions
- Historically Black Colleges and Universities (HBCUs)
- Tribally Controlled Colleges and Universities (TCCUs)
- Alaska Native and Native Hawaiian Serving Institutions
- Asian American Native American Pacific Islander Serving Institutions (AANAPISIs)

#### Nonprofits Other Than Institutions of Higher Education

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

#### For-Profit Organizations

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

#### Governments

- State Governments
- County Governments
- City or Township Governments
- Special District Governments
- American Indian/Native American Tribal Governments (Federally Recognized)
- American Indian/Native American Tribal Governments (Other than Federally Recognized)
- Eligible Agencies of the Federal Government
- U.S. Territory or Possession Other
- Independent School Districts
- Native American Tribal Organizations (other than Federally recognized tribal governments)

## 5. Multiple Principal Investigators and Partnerships among Applicants' Institutions

More than one individual may be named as Principal Investigator (PI) in the application. Each individual PI must commit at least 10% level of effort to the proposed project. One individual must be identified as the contact Principal Investigator. The contact Principal Investigator must be employed by or affiliated with the applicant organization. If a multiple Principal Investigator (MPI) proposal is submitted, an MPI Leadership plan is required.

Partnerships among institutions with investigators having complementary skills and expertise to meet the requirements of this ROA's Statement of Milestones are acceptable.



## 6. Project Manager/Director (PM/PD) Requirement

NIH expects the proposed project to include an individual that will serve as the PM/PD for the project, with the appropriate scientific expertise and project management responsibilities, who would support the PI(s) with project management and organizational oversight. Such individual should commit at least 90% level of effort to the project.

## 7. Financial and Risk Assessment

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

## 8. Cost Sharing

Cost Sharing is not required but maybe 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).

## 9. Developing Applications

### 9.1 Application Submission Instructions and Contact Information

For best consideration, complete applications should be submitted under **OTA-22-004** via eRA ASSIST no later than the “Proposal Due Date” shown at the top of this notice, **by 5 PM local time of applicant organization. Late applications submitted to this ROA will not be accepted.**

For further information, please consult the NCPI FAQ page: <https://datascience.nih.gov/nih-cloud-platform-interoperability-effort/administrative-coordinating-center>

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

Letters of Intent (LOIs), due by the “**Letters of Intent Due Date**” shown at the top of this notice, will be used to select individuals or groups who will be invited by NIH staff to submit a full application. Only those who are invited may apply with a full application. If invited to submit a full application, the Authorized Business Official (ABO) and contact PI will be notified and will be provided with guidance on submission of an application.

Full applications are due by the “**Proposal Due Date**” shown at the top of this notice. NIH may also share, with PI agreement, applications between or among teams to ensure optimal configuration of funding, partnerships, and activities. For more details on the review process, see the **Objective Review** section below. Late applications submitted to this ROA will not be accepted.



### 9.2 Letter of Intent

Interested applicants should submit a Letter of Intent (LOI) of no more than 3 pages, outlining the following:

- A cover page as described below for the full application, which includes the name and email addresses for the Contact PI and the Authorized Organizational Representative. NIH will contact the Contact PI and Authorized Organizational official to invite a full proposal.
- A brief description of how the PI(s), their institutional affiliations, and teams meet the eligibility requirements stated above.
- An overview of the planned activities and approach.
- Estimated overall annual budgets, for all 5 years of the award, excluding the costs of the subcontracts to support interoperability projects, but including any anticipated administrative costs associated with establishing and overseeing subcontracts.

LOIs will be reviewed by NIH staff only to assess eligibility and responsiveness and to determine which applicants will be invited to submit full proposals.

NIH is not responsible for providing feedback on unsuccessful LOIs.

Letters of intent must be submitted by email as a PDF attachment to [ncpi-info@od.nih.gov](mailto:ncpi-info@od.nih.gov). LOIs submitted by other means may not be considered.

### 9.3 Full Application

Applications will be accepted only from entities listed in the Organizations section of this Announcement, who meet the criteria listed in Eligibility Requirements, submit a Letter of Intent, and are invited by the NIH to apply. Applications must be prepared and submitted using NIH's eRA [ASSIST](#). The NIH will not review applications submitted from organizations not included in the Eligibility section. 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). 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):

- Cover page (1 page): see below for additional information.
- Invitation to apply, issued by the NCPI Program in response to the LOI.
- A summary of the planned activities and approaches (1 page).
- A full description of the planned activities and approaches to provide administrative support for the five primary areas described above, under the guidance and with oversight by the NIH NCPI Steering Committee, including the following sections (12 pages total):
  - a. Support for the establishment and monitoring of the technical implementation of the interoperability projects.
  - b. Support for project management and coordination of NCPI partners and collaborators.
  - c. Demonstrate expertise to identify and mitigate project management risks.
  - d. Support for training and other community building activities.
  - e. Support for NCPI's governance structure and coordination working groups.



- f. Support, facilitate, and monitor adoption of RAS by NCPI.
- g. Leadership plan, organizational and reporting structure, and personnel responsibilities. Include relevant past performance for the team and any prior experience working together. Describe how the proposed team meets the eligibility requirements stated above.
- Milestones and deliverables for the **first three years** of the project. See below for additional information (up to 3 pages).
- List of PI(s), PM, Key Personnel, other significant contributors and their proposed level of effort, as well as the biosketch of each named individual (3 pages per individual). The information in the biosketch should include the name and position title, education/training (including institution, degree, date (or expected date), and field; list of positions and employment in chronological order (including dates); list of relevant publications, proposed level of effort and a personal statement that briefly describes the individual's role in the project and why they are well-suited for this role. The format (<https://grants.nih.gov/grants/forms/biosketch-blankformat.docx>) used for an NIH grant application is acceptable.
- List of Equipment and facilities (2 pages).
- Institutional Letter of Support (1 page): A letter of support from the applicant's organization indicating institutional commitment for the project (e.g., relaying support for contributions, including, but not limited to, support for training activities or consortium meetings, licenses, and other resources) and preparations to enter into a negotiated Other Transaction Agreement.
- MPI Leadership Plan, if applicable.
- Budget request and justification (no page limitation): All applications should provide detailed budget information for planned activities and partnerships, as described below. Procurement of hardware, data, and the development of software capabilities to support the proposed activities are allowable costs.
- Bibliography (no page limitation).

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

Applications must be submitted both to eRA [ASSIST](#) and to [ncpi-info@od.nih.gov](mailto:ncpi-info@od.nih.gov) by the due date, in one text-recognizable PDF (Adobe) file, use 11-point font with 1" margins, single-spaced.

#### Cover page

- Number and title of this Research Opportunity Announcement.
- Project Title (must be the same as the one used for the LOI).
- First and last name, title, institution, department, mailing address, email address, phone number, and email address for the Contact PI and Authorized Organizational Representative (must be the same as those used for the LOI).
- Names of all key personnel, institutional affiliation, title, and percent effort.
- Approximate budget per year for 5 years (direct and total), excluding costs for establishing interoperability project subawards.
- Confirmation that the work does not involve human subjects or vertebrate animals.
- Agreement that any or all parts of the application can be shared among other applicants.



9.4 Budget details

The level of funding for awards made under this solicitation has not been predetermined and will depend on (1) the objectives proposed by the applicants and how well they fit with the goals of NCPI, (2) quality of the applications received, (3) availability of funds and (4) programmatic priorities.

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

**Indirect costs for any application funded under this OT mechanism will be capped at 15%.**

Applicants can model their budgets on SF424 budget pages for this section of the application which are available as optional forms in [ASSIST](#) or a format that best fits their program. All budgets must be readable by [ASSIST](#). The budget should address costs associated with the Applicant’s organization and its third parties.

**The detailed budget request should provide the overall expected cost for each of the following categories:** personnel, equipment, travel, funds for consortium partners or other stakeholders (if applicable), third parties (subcontracts) other direct costs, and total cost (with indirect costs included). Provide a budget justification. Third parties are required to provide details of cost breakdown and any federally negotiated rate will not be considered. Third party F&A costs may be negotiated as explicit line items in the proposed budget, provided they are well documented, and deemed appropriate for the proposed work.

9.5 Milestones and Deliverables

The expected initial project duration is five (5) years. Given the dynamic nature of NCPI, applicants must provide a description of the goals and milestones **for the first three (3) years** of the proposed project, completion criteria, due dates, how success is defined for a given milestone (e.g., Go/No-Go criteria), and payment/funding schedule (example provided below). While agreements may be fixed price or expenditure-based, subject to negotiation, the use of fixed price milestones with discrete deliverables and a payment/funding schedule is encouraged.

Applicants should plan to attend a mandatory kick-off meeting of the NCPI program, to be held either in person or virtually no earlier than September 1, 2022.

Example table of milestones and deliverables. Applicants must ensure that the total budget request for the first three (3) years is consistent with the sum of the estimates in the table.

Milestone	Task(s)	Due Date (Months after award)	Milestone Definition	Estimated budget, including personnel, equipment/facilities



				and other resources.
1	1.1	3	Milestone Name/Description <ul style="list-style-type: none"> <li>Bulleted list of tasks completed</li> </ul> Deliverables: <ul style="list-style-type: none"> <li>Bulleted list (including data sharing)</li> </ul>	
1	1.2	3	Milestone Name/Description <ul style="list-style-type: none"> <li>Bulleted list of tasks completed</li> </ul> Deliverables: <ul style="list-style-type: none"> <li>Bulleted list (including data sharing)</li> </ul>	
2	2.1	6	Milestone Name/Description <ul style="list-style-type: none"> <li>Bulleted list of tasks completed</li> </ul> Deliverables: <ul style="list-style-type: none"> <li>Bulleted list (including data sharing)</li> </ul>	

### 9.6 eRA Registration

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

Dun and Bradstreet Universal Numbering System (DUNS) - All registrations require that applicants be issued a DUNS number. After obtaining a DUNS number, applicants can begin both SAM and eRA Commons registrations. The same DUNS number must be used for all registrations, as well as on the grant application.

System for Award Management (SAM) – 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.

NIH will use the eRA Commons system to administer OT awards. If you are selected to participate, you may need to submit additional information in eRA [ASSIST](#), you will need to be registered in eRA Commons, which can take some time to complete – as many as several weeks in some cases. Applicants must have an active DUNS number to register in eRA Commons. Organizations can register with the eRA Commons as they are working through their SAM or Grants.gov registration. Therefore, if you are considering submitting an application and are not yet registered in eRA, it is highly recommended that you begin the process of registering your organization, Program



Director/Principal Investigator (PD/PI) and Signing Official (SO) in eRA Commons as soon as possible to avoid possible award processing delays. To register, please follow the instructions via this website: <https://public.era.nih.gov/commons/public/registration/registrationInstructions.jsp>.

1. Complete the online Institution Registration Form and click Submit.
2. The NIH database will send you an email with the link to confirm your email address.
3. Once your email address is verified, the NIH will review your request and let you know of the result via email.
4. If your request is denied, you will get an email notifying you of the reason.
5. If your request is approved, you will get an email with your Commons User ID and temporary password.
6. Log into Commons with the temporary password and the system will prompt you to change temporary password to a permanent one. Your SO will be prompted to electronically sign your registration request. (Please review your registration information carefully.)
7. Once your SO has electronically signed the request, your organization will be active in eRA Commons and you may create and maintain additional accounts for your institution staff.

To complete the registration above, use the following: <https://grants.nih.gov/grants/how-to-apply-application-guide/prepare-to-apply-and-register/registration/org-representative-registration/sam-org-registration.htm>

All Principal Investigators (PIs) will need an eRA Commons account. If they do not already have one, PIs should work with their organizational officials to either create a new account or to affiliate their existing account with the proposer organization in eRA Commons. If the PI is also the organizational Signing Official (SO), they must have two distinct eRA Commons accounts, one for each role. Obtaining an eRA Commons account can take up to 2 weeks.

## 10. Objective Review

The intent of the objective review for the NCPI Administrative Coordinating Center (ACC) is to determine whether the proposed activities meet the goals of NCPI.

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.**

### Review of Full Applications

Full proposals will undergo objective review by 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 ranging between 0 (worst score) - 40 (best score). The following individual review criteria and their scores will contribute to the final cumulative score.**

1. Reasonableness and merit of the proposed plans and approaches (Max 20 pts)
  - a. To what extent are the planned activities likely to advance the goals of the NCPI program and successfully address each of the five primary tasks of the Statement of Milestones:
    - Establish, facilitate, and monitor the technical implementation of interoperability projects.
    - Provide project management and coordination for NCPI partners and collaborators.
    - Support training, outreach, and other community building activities.
    - Support NCPI's governance structure and coordinate working groups.
    - Support, facilitate, and monitor adoption of RAS by NCPI.
  - b. Adequacy of the milestones and deliverables for the first three years of the project.
  - c. Ability to identify and mitigate technical and management risks.
2. Appropriateness of the key personnel (Max 10 pts)
  - a. 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 complex program? Is the leadership plan appropriate? Is the organizational and reporting structure appropriate? What expertise, if any, is missing from the team?
  - b. Is there adequate administrative support to ensure an effective execution and monitoring of subawards for interoperability projects and other projects that are necessary to accomplish the tasks of the statement of milestones?
3. Appropriateness of the equipment and facilities, and other resources (Max 5 pts)
  - a. Are the proposed facilities, computing infrastructure and project management tools adequate to support the successful execution of the proposed program?
4. Appropriateness of the proposed budget (Max 5 pts)
  - a. Is the proposed budget reasonable and commensurate with the proposed work?
  - b. Are there any areas where less funding is needed, or areas where more funding would improve the overall impact?

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



**Post-review funding plan**

The level of funding for awards made under this solicitation has not been predetermined and will depend on (1) the objectives proposed by the applicants and how well they fit with the goals of NCPI, (2) quality of the applications received, (3) availability of funds and (4) programmatic priorities.

Following the review of applications, NIH may assemble teams from all or parts of applications to establish the Administrative Coordinating Center (ACC). Individual components from distinct plans may be selectively funded to achieve the goals set forth herein. Additionally, if, over the duration of the project, some of the components either gain relevance or lose relevance to programmatic goals, the funding for such components may be increased, decreased, or discontinued.

NIH intends to fund one award through this solicitation. 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 NCPI.

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

- 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;
- Share applications between and among any proposer(s) as necessary for configuring teams, economizing work, and prioritizing activities;
- Select for negotiation all, some, one, or none of the applications received in response to this solicitation;
- Accept applications in their entirety or to select only portions of the proposal for award.

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

**Application Timeline**

Key Events	Receipt Dates	Action needed by Applicants
Research Opportunity Announcement (ROA) posted	March 16, 2022	Submit inquiries to <a href="mailto:ncpi-info@od.nih.gov">ncpi-info@od.nih.gov</a>
Submission Deadline for Letters of Intent (LOI)	April 15, 2022	Submit to <a href="mailto:ncpi-info@od.nih.gov">ncpi-info@od.nih.gov</a>
Submission Deadline for Full Applications from invited applicants	June 1, 2022	Submit to ASSIST and to <a href="mailto:ncpi-info@od.nih.gov">ncpi-info@od.nih.gov</a> ; <b>late applications will NOT be accepted</b>
Negotiations expected to begin	July 1, 2022	Respond to written inquiries; attend videoconferences or teleconferences as requested



Award(s) announced	July 31, 2022	
--------------------	---------------	--

## 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.); and
4. Remove participants from award consideration should the parties fail to reach a finalized, fully executed agreement prior to a date determined by the NIH, or the proposer fails to provide requested additional information in a timely manner.

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 NCPI 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 OTA. The OTPO ensures the successful implementation of the NCPI program by integrating input from the NIH-NCPI Steering Committee, ODSS leadership, 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 OTA.
- NIH-NCPI Steering Committee: Consists of NIH staff, including program leaders from the NCPI participating platforms, to include program representatives from newly onboarded repositories in the future, and ODSS representatives. Provides scientific and strategic guidance for the NCPI.

### OT Agreement Governance

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

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

### Reporting and Progress Meetings

The awardee will be required to:

- Participate in an initial virtual kick off meeting with NIH staff and NCPI stakeholders.
- Participate in a monthly (or more frequent) virtual progress meetings with NIH staff to ensure program continues to achieve objectives and to discuss progress and strategies.
- Submit a written monthly progress report.
- Submit written quarterly (or more frequent if there is a change of scope) budget and milestone reports.



### Indirect Costs

**Indirect costs for any application funded under this ROA will be capped at 15%.**

### Enjoined Collaborations

While the intent is to select a single applicant to carry out the work outlined in this ROA, it is possible that elements from two or more proposals will, if effectively combined, offer the best solution. If that is the case, an attempt will be made to negotiate with multiple applicants to assess the feasibility of a joint effort.

### Third Parties

With mutual consent of the awardee and the NIH, the NCPI may be expected to issue third party contracts to entities identified and approved by the NIH.

### Limitation of Damages

Party's claim for damages will be limited to direct damages pursued under this Agreement shall be limited to direct damages only up to the aggregate amount of the NIH funding disbursed as of the time the dispute arises. SUBJECT TO APPLICABLE LAW IN NO EVENT SHALL EITHER PARTY BE LIABLE FOR CLAIMS FOR CONSEQUENTIAL, PUNITIVE, SPECIAL OR INCIDENTAL DAMAGES, CLAIMS FOR LOST PROFITS, OR OTHER INDIRECT DAMAGES. These limitations of damages do not apply to gross negligence or willful misconduct; breaches of confidentiality obligations under the Agreement; or violations of the other party's Intellectual Property Rights.

### Intellectual Property

Specific terms with respect to intellectual property will be negotiated at the time of award; however, any negotiation will consider other laws (as relevant) that affect the government's issue and handling of intellectual property, such as the Bayh-Dole Act (35 U.S.C. 200-212); the Trade Secrets Act (18 U.S.C. 1905) the Freedom of Information Act (5 U.S.C. 552); 10 U.S.C. 130; 28 U.S.C. 1498; 35 U.S.C. 205 and 207-209; and the Lanham Act, partially codified at 15 U.S.C. 1114 and 1122. Joint development of intellectual property is not explicitly intended, but to create Joint IP a separate schedule must identify the joint IP which will address terms of ownership and other Terms & Conditions before development of Joint IP begins.

### Foreign Access to Technology

Awardees will provide timely notice (60 days) to NIH of sale of company or sales of licensing of technology to foreign firms. If NIH determines there will be adverse consequences to national security interests, parties will jointly endeavor to find alternatives to proposed transfer or mitigate potential adverse consequences. If transfer is not approved by NIH, awardees will refund the NIH funds paid for the development of the technology and the governments shall retain a nonexclusive, nontransferable, irrevocable, paid-up license to practice the technology on behalf of the US.

### Budget



The OT award provides funds for the budget period as appropriate for the negotiated and agreed upon statement of milestones, and deliverables. Subsequent funding periods represent projections of future funding levels contingent on the availability of funds, achievement of agreed-upon activities, and continued alignment with programmatic goals.

### Payment

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

### Reporting

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

- Awardee will be asked to provide regular progress reports to the OT Program Official and Agreements Officer. The frequency and types of technical and financial reports (e.g., Federal Financial Reports) required will be specified in the Agreement document.
- A final Federal Financial report is required for all Other Transactions awards. A final report that summarizes the project and tasks will be required at the end of the Agreement period. The reports shall be prepared and submitted in accordance with the terms and conditions.
- i-Edison: Agreement terms and conditions will contain a requirement for patent reports and notifications to be submitted electronically through the i-Edison Federal patent reporting system at <https://public.era.nih.gov/iedison>.

### Management Systems and Procedures

Awardee organizations are expected to have systems, policies, and procedures in place by which they manage funds and activities. Awardees 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, awardee organizations are expected to have in use clearly delineated roles and responsibilities for their organization's staff, both programmatic and administrative; written policies and procedures; training; management controls and other internal controls; performance assessment; administrative simplifications; and information sharing.

### Financial Management System Standards

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



are identified. An awardee's failure to establish adequate control systems constitutes a material violation of the terms of the award.

### Property Management System Standards

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

### Organizational Conflicts of Interest (OCIs)

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

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

### Monitoring

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

Monitoring of a project or activity will continue for as long as NIH retains a financial interest in the project or activity as a result of property accountability, audit, and other requirements that may



continue for a period of time after the OT award is administratively closed out and NIH is no longer providing active OT award support.

### Record Retention and Access

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

### Audit

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

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

### Noncompliance or Enforcement Actions: Suspension, Termination, and Withholding of Support

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

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

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

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

### Recovery of Funds

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

### Debt Collection

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

### Closeout

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

### Public Policy Requirements and Objectives

NIH intends to uphold high ethical, health, and safety standards in both the conduct of the research it funds and the expenditure of public funds by its awardee. 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.

1. Animal Welfare Requirements (PHS Policy on Humane Care and Use of Laboratory Animals)
2. ClinicalTrials.gov Requirements



3. Comptroller General Access
4. Debarment and Suspension
5. Dissemination of False or Deliberately Misleading Information
6. Federal Information Security Management Act
7. Financial Conflict of Interest
8. Fly America Act
9. Gun Control
10. Human Embryo Research and Cloning Ban
11. Human Fetal Tissue Research
12. Human Subjects Protections
13. Human Stem Cell Research (NIH Guidelines)
14. Lobbying Prohibition
15. Metric System
16. National Environmental Policy Act
17. Pro-Children Act of 1994
18. Prohibition on Promotion or Legalization of Controlled Substances
19. Research Involving Recombinant or Synthetic Nucleic Acid Molecule
20. Research on Transplantation of Human Fetal Tissue
21. Restriction of Abortion Funding
22. Restriction on Distribution of Sterile Needles
23. Restriction of Pornography on Computer Networks
24. NIH Salary Cap/Salary Limitation
25. Research Misconduct
26. Select Agents
27. Trafficking in Persons
28. USA Patriot Act

### Relevant NIH Resources

1. NIH ODSS: <https://datascience.nih.gov/>
2. NCPI Program pages: <https://datascience.nih.gov/nih-cloud-platform-interoperability-effort>
3. NCPI portal: <https://anvilproject.org/ncpi>
4. NHGRI AnVIL: <https://anvilproject.org>
5. NHLBI BioData Catalyst: <https://biodatacatalyst.nhlbi.nih.gov/>
6. NCI CRDC: <https://datascience.cancer.gov/data-commons>
7. NIH Common Fund-supported Gabriella Miller Kids First program: <https://kidsfirstdrc.org/>
8. NCBI: <https://www.ncbi.nlm.nih.gov>
  - a. dbGaP: <https://www.ncbi.nlm.nih.gov/gap/>
  - b. SRA: <https://www.ncbi.nlm.nih.gov/sra>
9. NIH RAS: <https://datascience.nih.gov/researcher-auth-service-initiative>
10. NIH STRIDES: <https://datascience.nih.gov/strides>

### Key Definitions

- *Interoperability projects*: technical projects that are driven by scientific use cases and leverage datasets from multiple NIH cloud repositories. Interoperability projects include testing or implementing standards and approaches for systems interoperability.