U.S. Department of Health and Human Services

Office of the National Coordinator for Health Information Technology

Notice of Funding Opportunity
Leading Edge Acceleration Projects (LEAP) in Health Information Technology

Assistance Listings (CFDA) Number
93.345

Application Due Date: August 15, 2022

Anticipated Award Date: September 26, 2022

Program Contact	Grants Contact
Wei Chang Anastasia Perchem Office of the National Coordinator 330 C Street SW Washington, D.C., 20201 ONC-LEAP@hhs.gov	Carmel Halloun Office of the National Coordinator 330 C Street SW Washington, D.C., 20201 ONCGrants@hhs.gov

Table of Contents

Executive Summary

This Notice of Funding Opportunity (NOFO) seeks Leading Edge Acceleration Projects (LEAP) in Health Information Technology (Health IT) to address well-documented and fast emerging challenges that inhibit the development, use, and/or advancement of well-designed, interoperable health IT. Project solutions are expected to further a new generation of innovative health IT research and inform the development, implementation, and refinement of standards, methods, and techniques for overcoming major barriers in health information access, exchange, and use.

This NOFO outlines two Areas of Interest that are a priority for the Office of the National Coordinator for Health Information Technology (ONC):

- Area 1: Address health equity and social determinants of health through innovative, open-source technology tools, and electronic health records; and

- Area 2: Demonstrate the use of equity-enhancing patient-generated health data for clinical care and research.

ONC expects to issue one cooperative agreement award per area of interest (the "Area of Interest"), up to $1 million per award, totaling up to $2 million for the two awards in fiscal year 2022. These awards will have a two-year project and budget period at initial award. However, applicants are encouraged to submit their applications based on a five-year budget period. Additional funding for years three to five may be provided, contingent upon availability of funds, meaningful progress, and ONC priorities.

This funding opportunity will have a five-year open application period. ONC may issue future awards under this NOFO to other eligible applicants for future areas of interest.

A. Program Description/Purpose

Background Description

Created in 2004 through Executive Order 13335[1] and statutorily authorized by the Health Information Technology for Economic and Clinical Health Act (HITECH Act) of 2009, ONC is the principal federal entity charged with coordination of nationwide efforts to implement the most advanced health IT and the electronic exchange of health information. At the forefront of the administration's health IT efforts, ONC is a resource to the entire health system to support the adoption of health IT and the promotion of nationwide, standards-based health information exchange to improve healthcare.

In 2010, through the HITECH Act, ONC created the Strategic Health Information Technology Advanced Research Projects (SHARP) cooperative agreement program.[2] The SHARP program was created to support advanced research activities to address short- and long-term challenges to the implementation of HITECH and its programs, with a focus on solving currently known, as well as anticipated challenges to the adoption and the meaningful use of health IT.

Since the HITECH Act was enacted and the SHARP program was created, the healthcare ecosystem and the technology supporting it have rapidly evolved. Many providers have implemented electronic health record (EHR) systems,[3] and sophisticated health IT tools and applications are quickly coming to market. As the electronic exchange of health information has matured, the amount and types of health data available has expanded. Data standards such as Health Level Seven International (HL7®)'s Fast Healthcare Interoperability Resources (FHIR®)[4] and application programming interfaces (APIs) are making it easier for consumers to seamlessly access and share their health data with providers and allow health systems to integrate disparate data sources.

Passage of the 21st Century Cures Act[5] (Cures Act) in 2016 strengthened ONC's mandate to improve the interoperability of health information, facilitate information exchange, address barriers to interoperability, and reduce provider burden when using EHRs.

Purpose

While working to implement Cures Act provisions, ONC identified gaps with respect to leveraging EHR data to support population-level analyses and delivery of services, as well as integrating clinical knowledge into routine clinical practice.[6] The reasons for these gaps range from a lack of data standards and interoperability to the digitization, integration, and presentation of new evidence into clinical workflows in safe, useful, and useable ways.

[1] https://www.gpo.gov/fdsys/pkg/FR-2004-04-30/pdf/04-10024.pdf
[2] https://www.healthit.gov/buzz-blog/sharp/health-it-challenges-and-the-future-of-healthcare/
[3] https://www.healthit.gov/sites/default/files/2016_report_to_congress_on_healthit_progress.pdf
[4] http://www.hl7.org/fhir/
[5] 21st Century Cures Act, Pub. L. No. 114-255, 130 Stat. 1033 (December 13, 2016).
[6] https://www.healthit.gov/sites/default/files/jsr-17-task-002_aiforhealthandhealthcare12122017.pdf

Therefore, this funding opportunity will support innovative and breakthrough solutions critical to maximize the potential of health IT and achieve the goal of a transformed healthcare delivery system through various methods, such as:

- Determining the fundamental questions, the answers to which will identify barriers to nationwide interoperability and electronic exchange of health data.
- Engaging the health IT industry, along with academic researchers, to identify and develop innovative solutions that address barriers to interoperability.
- Disseminating findings from research while fostering collaboration, advancement, and implementation of solutions and lessons learned with the health IT industry.

Structure and Approach

ONC expects to award two cooperative agreements for a project period of two years for each recipient to focus on areas where breakthrough improvements are needed to address problems that have impeded the innovative use of health IT and thereby accelerate progress in the areas identified.

Areas of Interest

The two Areas of Interest identified below describe priorities ONC is interested in continuing to explore and advance. The descriptions include ways in which applicants may approach developing a project. The Areas of Interest have been assigned numbers for ease of reference, not for prioritization. While there are many challenges associated with the use of health IT, these two Areas of Interest have been identified as critical priority areas for ONC.

Area 1: Address health equity and social determinants of health through innovative, open-source technology tools, and electronic health records

Background

Social determinants of health (SDOH) refer to the conditions in which people live, learn, work, and play, and affects a wide range of health risks and outcomes while health equity is everyone attaining their full potential for health and well-being.[7] An integral part of healthcare delivery involves understanding the social and environmental factors of patients' lives outside of the healthcare system. Addressing inequities in these conditions may be supported by the collection, exchange, and use of SDOH data.[8] This data can be used to identify and help eliminate health disparities by improving health outcomes at an individual and population level. Advancing the use and interoperability of SDOH data is a priority for ONC in keeping with our mission to improve the health and well-being of individuals and communities through the use of technology and health information that is accessible when and where it matters most.

In January of 2021, the President issued an Executive Order on Advancing Racial Equity and Support for Underserved Communities to address barriers to equity via program delivery and stakeholder engagement. Taking a comprehensive approach to address barriers to health equity across the federal government as well as among private and public stakeholders will be fundamental to improving health and reducing health inequities. As part of that approach, ONC is committed to advancing the development and use of health IT, establishing expectations for standardizing and sharing data, and ensuring that these benefits are available to communities that have historically faced structural barriers

[7] https://www.who.int/health-topics/health-equity#tab=tab_1
[8] https://www.healthit.gov/sites/default/files/page/2020-10/Federal%20Health%20IT%20Strategic%20Plan_2020_2025.pdf

to accessing healthcare and health IT. More specifically, ONC is focused on improving data collection through the development and adoption of standards to mitigate some of the challenges encountered in the collection and the equity-focused analysis of race, ethnicity, and SDOH data.[9,10,11]

Project Goals

Through this Area of Interest, ONC aims to advance the adoption and use of SDOH-related standards and data in underserved communities to address disparities, and to identify the challenges and opportunities inherent in scaling health IT solutions across communities.

In alignment with the Executive Order on Advancing Racial Equity and Support for Underserved Communities, this Area of Interest seeks to help address barriers to health equity by implementing innovative, scalable, and easily replicable data-system based, non-proprietary health IT solutions to support SDOH data collection, exchange, and use among individuals who belong to underserved communities (including Black, Latino, and Indigenous and Native American persons, Asian Americans and Pacific Islanders and other persons of color; members of religious minorities; lesbian, gay, bisexual, transgender, and queer (LGBTQ+) persons; persons with disabilities; persons who live in rural areas; and persons otherwise adversely affected by persistent poverty or inequality).[12]

Using open, non-proprietary standards, the awardee shall create and implement a comprehensive technology solution that supports 1) the collection and analysis of SDOH data in an EHR to identify population-level use cases for addressing health disparities, 2) closed loop referrals between an EHR and appropriate Community Based Organizations (CBOs) [13] supporting human and social services, and 3) patient-facing technology, such as, but not limited to web-based platforms and applications (apps) that allows patients to manage their data, provide consent for various purposes, and share sensitive information with other organizations. The comprehensive technology solution may include, without limitation, a combination of apps, web-based platforms, and directories via APIs to allow data to be shared between an EHR, a CBO, and a patient.

Key Objectives

1) Create specific use cases for the technology platform based on high-risk population factors like chronic diseases (which may include, but are not limited to, heart disease, hypertension, and cancer) and/or social risk factors (which may include, but are not limited to housing instability, food insecurity, and transportation insecurity) in underserved communities. While creating the use cases, the applicant must use standardized SDOH data collected within the EHR.

2) Create and implement non-proprietary technical solutions for referring patients to CBOs that interface seamlessly with a health system or community health center's EHR.

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[9] https://www.healthit.gov/sites/default/files/page/2021-07/Standards_Bulletin_2021-3.pdf
[10] https://www.healthit.gov/isa/sites/isa/files/2021-07/USCDI-Version-2-July-2021-Final.pdf
[11] https://www.healthit.gov/buzz-blog/interoperability/onc-health-it-framework-for-advancing-sdoh-data-use-and-interoperability
[12] https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/20/executive-order-advancing-racial-equity-and-support-for-underserved-communities-through-the-federal-government/
[13] A CBO refers to public or private not-for-profit resource hubs that provide specific services to the community or a targeted population within the community.
https://www.phe.gov/Preparedness/planning/abc/Pages/engaging-CBO.aspx

3) Create and implement technology that supports patient engagement that at minimum allows patients to manage their data by suggesting edits to their SDOH data and provide consent and authorization to use sensitive data.

4) Coordinate forums to share implementation strategies, lessons learned, and recommendations with other healthcare providers and CBOs.[14] Forums may include, but are not limited to, workshops, webinars, and documents.

Applicants shall include the following activities in the project plan that they will develop[15]:

- Assess current SDOH data collection and use activities to ensure efforts are aligned with prior work, including, but not limited to, previous ONC LEAP projects, the Gravity Project, and 360X.
- Collect SDOH data using nationally recognized[16] open standards (e.g., United States Core Data for Interoperability (USCDI), US Core Implementation Guide , 360X, and the Social Determinants of Health Clinical Care Implementation Guide (SDOHCC IG)).
- Utilize innovative analysis techniques and real data to identify patients with negative health outcomes among underserved populations with a need for human and social services, such as, but not limited to, elderly and aging services, access to medicine, and shelter assistance.

  Innovative analysis techniques could include linking different types of data, stratifying data, natural language processing.
- Use findings from the above analysis to develop at least one use case for referring patients to CBOs using non-proprietary EHR-embedded or third party closed loop referral technology. CBOs that are expected to use this technology shall be included in the development of the use case. This may require a CBO to understand the feasibility of developing the use case and the technology, which may require education from the project team.
- Create and implement closed loop referral technology in a real-world environment involving at least one health system or community health center, their EHR developer, and at least one CBO.[17] The awardee will be expected to provide feedback on the challenges and successes that the health system or community health center and CBO experience while using the technology in underserved communities.[18]
- Create and implement patient-facing technology that allows a patient to indicate changes in social risk factors and allows those changes to be incorporated into an EHR.[19]
- Develop, publish, and disseminate training and education tools (such as, but not limited to, white papers, blog posts, and reports) that document implementation strategies, lessons learned, and best practices for implementation. The strategies, lessons learned, and best practices should reflect input from implementers, CBO sites, developers, and health IT experts. The training tools should include guidance for using the technology solution.[20]

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[14] https://www.phe.gov/Preparedness/planning/abc/Pages/engaging-CBO.aspx
[15] The Project Activities and Performance Goals and Objectives sections of this NOFO describe the project plan requirement.
[16] https://www.healthit.gov/isa/
[17] https://www.ahrq.gov/chsp/chsp-reports/resources-for-understanding-health-systems/defining-health-systems.html
[18] https://www.healthit.gov/topic/leading-edge-acceleration-projects-leap-health-information-technology-health-it
[19] https://www.healthit.gov/topic/leading-edge-acceleration-projects-leap-health-information-technology-health-it
[20] May also include an overview of SDOH data collection, use, and exchange and its impact on health equity. The awardee may work in collaboration with awardees from the Public Health Informatics & Technology (PHIT) Workforce Development Program.

- Conduct forums to educate participants on implementation strategies, lessons learned, and best practices from the project to allow the work to expand across communities.
- Develop and implement evaluation tools that measure and document the outcomes of the implementation of the technology platform and the return on investment of the technology in supporting underserved communities.

An applicant's proposal shall not rely on proprietary technology for apps or web portals. The proposed technical solution for this Area of Interest should leverage previous work funded by ONC (such as, but not limited to ONC LEAP projects, the Gravity Project, 360X) and not duplicate efforts.

Area 2: Demonstrate the use of equity-enhancing patient-generated health data for clinical care and research

Background

Patient-generated health data (PGHD) is increasingly becoming critical for both clinical care and research. PGHD are health-related data that are created, recorded, or gathered by or from patients (or family members or other caregivers) to help address a health concern.[21] PGHD related technologies such as mobile phones, apps, remote monitoring devices, and wearable technology (such as, but not limited to fitness trackers, smart watches, and body-mounted sensors) are more accessible now than before and can be cost effective methods to monitor and track health outside of the clinical care setting. PGHD can also support patients' healthcare goals by providing patients, providers, and researchers with more information about a patient's conditions or health situation.

The 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program Final Rule adopted the United States Core Data for Interoperability (USCDI) version 1 as a standard.[22] USCDI version 1 sets a foundation for broader sharing of electronic health information to support patient care[23]and USCDI version 2 reinforced the importance of incorporating SDOH in healthcare settings. SDOH may prevent or make it difficult for some patients to appropriately follow up with providers, have their conditions monitored[24], or obtain and adhere to medical care. It is also well documented that these types of factors disproportionately affect underserved communities when they try to access care and that these communities are underrepresented in research.[25,26]

PGHD technologies may ease some of these barriers. For example, PGHD technologies can facilitate patient engagement by providing patients the opportunity to monitor and track their condition outside of the clinical care setting via multiple avenues such as a patient portal or via a third-party app on their smartphone. Patients can also decide when and with whom to share their clinical data. Improving the interoperability of PGHD can also increase patient knowledge, access to care, and control of their conditions.[27] Providers can use PGHD to monitor aspects of their patients' healthcare from a distance and between visits. Providers can also use these data to facilitate joint decision-making, resulting in the provision of better care over time. Currently, the integration of PGHD into EHR and clinical workflows

[21] https://www.healthit.gov/topic/otherhot-topics/what-are-patient-generated-health-data
[22] https://www.federalregister.gov/documents/2020/05/01/2020-07419/21st-century-cures-act-interoperability-information-blocking-and-the-onc-health-it-certification
[23] https://www.healthit.gov/cures/sites/default/files/cures/2020-03/USCDI.pdf
[24] https://pubmed.ncbi.nlm.nih.gov/22092449/
[25] https://muse.jhu.edu/article/430672
[26] https://www.nature.com/articles/d41586-018-05049-5
[27] https://www.healthit.gov/sites/default/files/onc_pghd_final_white_paper.pdf

is not robust. Subsequently, it is often difficult for researchers to access PGHD that are connected to EHR data they may already be requesting. Researchers will often have to set up separate systems to collect PGHD.

The ONC National Health IT Priorities for Research: A Policy and Development Agenda (the Agenda) highlighted key several of which are related to the enhancement of PGHD.[28] Specifically, Priority 5 spotlights the need to integrate emerging health and health-related data sources.[29] Improvements in the collection, use, and sharing of PGHD will contribute to the types of data that can be leveraged for research and the advancement of a health IT infrastructure that supports research. Not only has the usefulness of PGHD technologies been identified in literature and in practice, but ONC has also highlighted its value in previous work as well. Projects such as Advancing Standards for Precision Medicine and the Patient-Centered Outcomes Research (PCOR) project on PGHD have examined the collection, use, and standardization of PGHD and demonstrated the opportunities that PGHD can provide.[30,31] PGHD technologies offer a unique opportunity to leverage health IT to directly support the Biden Administration's priority of ending "disparities in healthcare access and education", particularly by addressing barriers to health equity among underserved communities (i.e. Black, Latino, and Indigenous and Native American persons, Asian Americans and Pacific Islanders and other persons of color; members of religious minorities; lesbian, gay, bisexual, transgender, and queer (LGBTQ+) persons; persons with disabilities; persons who live in rural areas).[32]

Despite the innovative possibilities that the use of PGHD brings to care and research, there are also several challenges associated with the advancement of PGHD. Difficulties experienced by patients include a lack of access to PGHD technologies, varying health and technology literacy levels, and data privacy and security concerns.[33] Clinician and researcher challenges include apprehension regarding the accuracy of PGHD and specifically for providers, the impact on clinical workflow.[34] In addition, the sharing of PGHD for research is still nascent. Though many wearable technology and apps use APIs, the capture, use, and sharing of PGHD are not standardized.[35] For example, many PGHD related technologies have not adopted standards, such as FHIR, and the interoperability of PGHD, though emerging, is still relatively new.[36] Even with the promising use of PGHD for greater health equity, there is also the concern that collection of PGHD may have unintended consequences on underserved communities, based on a potential "digital divide" resulting from the use of costly PGHD related technologies.

Project Goals

The goal of this project is to develop the infrastructure and standards-based PGHD technologies needed to demonstrate the scalable use of equity enhancing patient-generated health data for clinical care and research from the point of care to the researcher. The proposed PGHD technology solution can be comprised of apps, remote monitoring devices, or wearable technology that collect data to monitor and

[28] https://www.healthit.gov/topic/scientific-initiatives/national-health-it-priorities-research-policy-and-development-agenda
[29] https://www.healthit.gov/topic/scientific-initiatives/national-health-it-priorities-research-policy-and-development-agenda
[30] https://www.healthit.gov/topic/advancing-standards-precision-medicine
[31] https://www.healthit.gov/topic/scientific-initiatives/pcor/patient-generated-health-data-pghd
[32] https://www.whitehouse.gov/priorities/
[33] https://www.healthit.gov/sites/default/files/onc_pghd_final_white_paper.pdf
[34] https://www.healthit.gov/sites/default/files/onc_pghd_practical_guide.pdf
[35] https://www.healthit.gov/sites/default/files/page/2021-01/Advancing-Standards-in-Precision-Medicine.pdf
[36] Hussein, R., Crutzen, R., Gutenberg, J., Kulnik, S. T., Sareban, M., & Niebauer, J. (2021). Patient-Generated Health Data (PGHD) Interoperability: An Integrative Perspective. In Public Health and Informatics (pp. 228-232). IOS Press.

track health outside of the clinical care setting. Additionally, the awardee of the project shall do the following:

- Examine the capabilities of current health IT infrastructure that is available to support PGHD technologies and identify standards-based technology that needs to be developed to effectively integrate PGHD into one or multiple EHRs and for PGHD to subsequently be used by both clinicians and researchers.
- Identify and propose a PGHD technology solution that is most useful for healthcare research with an emphasis on underserved communities and their unique needs, while considering the accuracy of the type of PGHD that is collected.
- Demonstrate the use of a PGHD solution that leverages nationally recognized open standards (e.g. USCDI[37] and the Interoperability Standards Advisory (ISA)[38]) and standards-based approaches or resources (e.g. FHIR "Write" APIs, HL7 FHIR, Substitutable Medical Applications and Reusable Technologies (SMART) on FHIR, and Mobile Health Implementation Guides) for integrating PGHD with clinical EHR data, with the appropriate privacy, security, and other data provenance considerations.
- Demonstrate a path to scalability by implementing the proposed PGHD technology solution in at least two separate healthcare locations or by demonstrating how the same proposed PGHD technology solution can be used for two different use cases.
- Capture and document lessons learned, challenges encountered, and recommendations for a blueprint that can be used by others to advance the use of PGHD for research and in clinical care.

Key Objectives

1) Perform a landscape analysis/environmental scan to understand the current standards and interoperability of PGHD technologies related to the proposed PGHD technology solution (such as across device manufacturers and different EHRs).
2) Per the above landscape analysis/environmental scan, identify at least two separate healthcare locations and at least two use cases around clinical care and research that require PGHD and incorporate the needs of underserved communities.
3) Create and develop plans for at least two demonstration projects with consideration on reuse and scalability of the proposed PGHD technology solution. To result in two demonstration projects, the proposed PGHD technology solution should be implemented at two separate healthcare locations affiliated with the awardee, and the proposed PGHD technology solution should be implemented for two different use cases (e.g. high blood pressure and respiratory diseases) that use the same underlying technology. This will show how the solution can be reused.
4) Convene a coalition of key stakeholders (e.g. clinicians, researchers, technical experts, and/or patients) that will be directly involved in the development and implementation of the demonstration projects.
5) Engage standards development organizations (SDOs) to identify opportunities and practical solutions for the advancement of standards that are necessary to capture, exchange, integrate, and use PGHD in clinical and research settings. This includes leveraging and testing existing standards for the proposed PGHD technology solution and can also include balloting and updating implementation guides with information resulting from the demonstration projects.
6) Develop the proposed PGHD technology solution (incorporating standards-based solutions) that collects and shares PGHD among patients, providers, and researchers.

[37] https://www.healthit.gov/isa/united-states-core-data-interoperability-uscdi
[38] https://www.healthit.gov/isa/

7) Prepare a final report that includes lessons learned and recommendations that provide experiential insights for others who wish to implement similar types of PGHD technology solutions at their organizations.
8) Develop at least one manuscript that details the demonstration project results and submit to appropriate journal.

Project Activities

Awardees shall carry out at a minimum, the following set of activities:

- Define a project plan that will include all key objectives
    - The project plan will identify key issues and potential challenges.
    - The project plan will map all project activities to a two-year timeframe.
    - Engage with ONC and other federal HHS partners as identified by ONC, to establish and refine key issues and potential challenges in the project's Area of Interest.
- Document and report progress throughout the project timeframe.
- Utilize research methods to inform the demonstration projects.
- Publish (e.g., manuscript, report, blog post, and white paper) and disseminate project findings in a way that translates project outcomes into useable knowledge and insights for federal partners, health IT industry, SDOs, CBOs, developers, healthcare systems, and providers to maximize the accessibility of this knowledge to the entire health IT community.
- Select measurable outcomes that are specific to the project's Area of Interest and key objectives.
- Conduct virtual mid-point demonstrations and provide an update regarding any proposed approaches, prototype(s), and/or revisions to the project plan to illustrate their progress on the Area of Interest.

In addition, applicants will provide a draft project plan as an appendix to the application, with a corresponding table of key dates and objectives to demonstrate that key objectives can be met within the two-year period (see Section D, Application and Submission Information).

Performance Goals and Objectives

A performance goal is a target level of performance expressed as a tangible, measurable objective, against which actual achievement can be compared.

ONC will utilize the following objectives to assess project performance and progress:

- The quality of the two-year project plan and the description of how performance goals and objectives will be met.
- The identification and securement of subject matter experts (SMEs), as appropriate, to provide guidance and review strategies, research methods, and results.
- Scheduling, conducting, and participating in status, strategy and/or SME meetings with ONC and the coalition of key stakeholders.
- Communicating findings and providing quarterly programmatic progress reports, including a risk register to ensure timely deliverables.

B. Funding Opportunity Award Information

Key Award Parameters

Title: Leading Edge Acceleration Projects (LEAP) in Health Information Technology

Federal Funding Agency: Department of Health and Human Services
Office of the National Coordinator for Health Information Technology

Announcement Type: *Cooperative Agreement*

Application Type: *New*

Funding Opportunity Number: *NAP-AX-22-001*

Catalog of Federal Domestic Assistance (CFDA) Number*: 93.345*

Eligible Applicants:

This is a competitive funding opportunity open to public or non-profit private institutions, such as a university, college, or a faith-based or community-based organization; units of local or state government, eligible agencies of the federal government, Indian/Native American Tribal Governments (federally recognized, other than federally recognized, and tribally designated organizations).

For-profit organizations may participate in projects as members of a consortia or as a sub-recipient only. Because the purpose of this NOFO is to improve healthcare in the United States, foreign institutions may participate in projects as members of a consortia or as a sub-recipient only. Applications submitted by for-profit organizations or foreign institutions will not be reviewed. Organizations described in section 501(c)4 of the Internal Revenue Code that engage in lobbying activities are not eligible.

HHS grants policy requires that the grant recipient perform a substantive role in the conduct of the planned project activity and not merely serve as a conduit of funds to another party or parties. If consortium/contractual activities represent a significant portion of the overall project, the applicant shall justify why the applicant organization, rather than the party(s) performing this portion of the overall project, should be the recipient and what substantive role the applicant organization will play.

Applicant organizations may submit more than one application, provided that each application is scientifically distinct.

Legislative Authority: Consolidated Appropriations Act, 2022, Pub. L. 117-103, Division H, Title II

Approximate Amount of Available Funding (inclusive of direct and indirect costs):

Anticipated Number of Awards: *2 (1 award per Area of Interest)*

Approximately Amount of Each Award: *$1,000,000*

Project Period: *September 26, 2022-September 25, 2027*

Budget Period(s): *September 26, 2022-September 25, 2024*

Under this announcement, as new emerging issues and vexing problems/challenges are documented, program will call attention to these specific areas of interest for further investigation via a special emphasis notice (SEN). This funding opportunity will have a 5-year open application period. ONC may issue future awards to other eligible applicants for future priority areas of interest to address emerging challenges in the field, via SEN; again, contingent on the availability of funds and ONC priorities. Any SENs will be issued at least 60 days prior to the due date of applications.

Funding of future non-competing continuation awards will be determined by ONC and is conditioned on the availability of funds, satisfactory progress by the recipient, and an awarding office determination that continued funding of the award is in the best interests of the Government.

Cooperative Agreement and Substantial ONC Involvement

The funding instrument used for this program will be the cooperative agreement, an assistance mechanism, in which substantial ONC programmatic involvement is anticipated during the project period. Under the cooperative agreement, the ONC purpose is to support and stimulate the recipient's activities by involvement in, and otherwise working jointly with, each recipient in a partnership role. It is not to assume direction, prime responsibility, or a dominant role in the activities. Consistent with this premise, the dominant role and prime responsibility resides with the recipient for the project as a whole. To facilitate appropriate involvement, during the period of this cooperative agreement, ONC and the recipient will be in contact monthly and more frequently when appropriate.

ONC involvement may include, but is not limited to:

- Participating in monthly (minimum) check-in meetings
- Ensuring compliance of timely programmatic reporting, project progress, and other terms and conditions of the award
- Review and approve quarterly programmatic progress reports on Confluence
    - Quarterly programmatic progress reports are due one month after each quarter (January, April, July, and October)
- Participating in the selection of key personnel
- Releasing funds based on achievement of performance goals and objectives
- Agency review and approval of substantive provisions of proposed subawards or contracts
- Reviewing and approving deliverables
- Selecting meeting/panel members and subject matter experts
- Participating in communities of practice
- Providing tactical guidance and feedback during project execution
- Engaging with leadership of the recipient's organization to ensure successful execution of the cooperative agreement
- Ending an activity if performance specifications are not met

Program Income
There are four potential ways in which ONC may require that a recipient apply program income as specified in the Notice of Grant Award (NGA): 1) **deduct** it from total allowable program costs to determine the net allowable costs on which the Federal share of costs is based; 2) **add** it to funds otherwise available for the program, generally resulting in an increase to the total approved budget; 3) use it to meet a **matching or cost sharing** requirement; or 4) a **combination** of these alternatives.

Costs paid by program income generally are subject to the applicable cost principles and other Federal requirements and shall be disbursed for program purposes **before** requesting additional payments of Federal funds. In the event program income remains at the end of the award, the additional income is considered part of the award funding and shall be returned to ONC. **If program income is generated, the recipient shall use the additive method.**

Intergovernmental Review

Applications for this Cooperative Agreement are not subject to review by states under Executive Order 12372, "Intergovernmental Review of Federal Programs" (45 CFR 100). Please check box "C" on item 19 of the SF 424 (Application for Federal Assistance) as Review by State Executive Order 12372, does not apply to this Cooperative Agreement.

Key Dates

Milestone	Date
NOFO Released	*June 14, 2022*
Informational Session	*June 28, 2022*
Letters of Intent Due	*June 30, 2022*
Applications Due	*August 15, 2022*
Anticipated Award Date	*September 26, 2022*
Anticipated Project Start Date	*September 26, 2022*

Informational Session

ONC will conduct an informational session, via a webinar, to:

- Discuss the background, purpose, scope, terms and conditions and other provisions in the NOFO;
- Explain the eligibility and application requirements;
- Describe the application review process; and
- Provide an opportunity for interested parties to ask questions.

Further details about the informational session – including the date, time, and instructions for joining – are available at https://us06web.zoom.us/meeting/register/tZMtf-yurDgvH9wNRzED7Sm0MZR76l8vs0Nq

To ensure that ONC addresses all comments and questions regarding this announcement during the information session, please submit any comments and questions, via email, to *ONC-LEAP@hhs.gov* no later than three days prior to the call.

Letter of Intent

Although not required, applicants are strongly encouraged to submit a non-binding e-mail letter of intent to apply for this funding opportunity. This letter of intent will assist ONC in planning for the application review process.

The Letter of Intent is requested by 11:59 P.M. Eastern Standard Time on June 30, 2022 and should be sent to *ONC-LEAP@hhs.gov.* The notice should identify the name of the applicant organization, the city and state in which the applicant organization is located, and the Notice of Funding Opportunity title and number.

C. Eligibility Information

See Section B, Funding Opportunity Award Information, for eligibility, cost-sharing, and other key award information.

Priority will be given to applicants who demonstrate provision of services to primarily underserved communities (i.e. Black, Latino, and Indigenous and Native American persons, Asian Americans and Pacific Islanders and other persons of color; members of religious minorities; lesbian, gay, bisexual, transgender, and queer (LGBTQ+) persons; persons with disabilities; persons who live in rural areas) and provide evidence of this in the application.

D. Application and Submission Information

Application Package

The following documents comprise, as applicable, the application package. Additional information regarding each of these documents is further provided.

- Project Abstract
- Project Narrative
- Appendices
    - Form SF-424, Application for Federal Assistance
    - Form SF-424A, Budget Information for Non-Construction Programs
    - Form SF-424B, Assurances for Non-Construction Programs
    - Form SF-LLL, Disclosure of Lobbying Activities
    - Budget Narrative
    - Letters of Commitment
    - Proof of Non-Profit Status (if, applicable)
    - Indirect Cost Agreement(s) – including recipient, sub-recipient, and contractors' agreements (if applicable)

Appendix A, Tips for Writing a Strong Application, can be used as a resource.

The project narrative and budget narrative sections of the application shall be double-spaced, on 8-1/2" X 11" plain white paper with 1" margins on all sides and use either Cambria or Times New Roman font size of not less than 11 point. Smaller font sizes may be used to fill in the Standard Forms, exhibits, and figures, though all text in forms, exhibits, and figures shall not be smaller than 8-point font.

Project Abstract
Applicants shall include a one-page abstract that is no more than 500 words. This abstract is often distributed to the public and Congress and represents a high-level summary of the project. As a result, applicant should prepare a clear, accurate, concise abstract that can be understood without reference to other parts of the application and that provides a description of the proposed project, including: the project's goal(s), objectives, overall approach, anticipated outcomes, products, and duration.

The applicant shall place the following information at the top of the Project Abstract (this information is not included in the 500-word maximum):

- Project Title
- Applicant Name
- Physical Address
- Contact Name
- Contact Phone Numbers (Voice, Fax)
- E-Mail Address
- Web Site Address, if applicable

Project Narrative
The project narrative should describe the proposed project in a clear and concise manner. The project narrative should address the elements articulated in the Areas of Interest section of this NOFO. The project narrative should also align with the Performance Goals and Objectives and Merit Review criteria presented in this NOFO.

The project narrative shall be double-spaced, formatted to 8 ½" x 11" (letter-size) pages, 1" or larger margins on all sides, and using no less than 11-point font size. The maximum length allowed for the project narrative is *35* pages. A project narrative that exceeds the *35*-page limit will not be accepted. Resumes of key personnel (personnel required for the project), are not counted as part of the project narrative and are not included in the *35*-page limit.

Your project narrative should include the following components. These components will be counted as part of the page limit. The suggested lengths of the components, given below, are guidelines to help applicants create a balanced document. They are not mandatory restrictions:

1. Understanding of Project Purpose (2-3 pages)
2. Proposed Approach and Activities (10-14 pages)
3. Applicant Capabilities (9-15 pages)
4. Budget Narrative (2-3 Pages)

1. Understanding of Project Purpose
This section should offer the applicant's conceptualization of the selected Area of Interest. This should include, from the applicant's perspective, a specific delineation of the objectives and research challenges the proposed project will address, specifically distinguishing between challenges that can be addressed in the self-contained project period (two years) and challenges requiring a longer period (three to five years). Applicants shall clearly state which Area of Interest the proposed project will address. (2-3 pages).

2. Proposed Approach and Activities
This section should provide a clear and concise description of the approach the applicant is proposing to use to conduct the research and development work, including identifying the major challenges and proposed activities used in the approach. This section should be organized so that each element of the project plan is clear and aligns to the project's key objectives and project goals. The applicant should include the usage of novel concepts, approaches, methodologies, tools, and/or technologies and provide insight as to how their usage will inform the field of health IT. Additionally, the approach should include proposed strategies on how the results of the project may be disseminated and transitioned to field at large.

Each key objective being addressed should be described as a discrete activity, and each activity should have a separately itemized budget as described below. The applicant shall clearly identify each activity and denote whether it is a short-term objective (two years) or a long-term objective (three to five years).

The approach should include as much details as possible given the page limitation. Notwithstanding, the plan for each activity, at a minimum, **shall state**, (a) specific aims, (b) previous work of the investigative team on which the proposed research is **directly** based, (c) the methods that will be applied, the anticipated outcomes of the work, and their potential significance in addressing the

challenges of the selected Area of Interest, and (d) the key personnel who will be involved. Statements of previous work should not be redundant with general statements of experience in the "Organizational Capability Statement" section described below.

Applications should justify the project's proposed approaches through relevant scholarly articles and other literature. Up to 100 citations may be included. Citations will be judged by quality, not quantity. Applicants should avoid multiple, partially redundant citations. Where an assertion in the narrative is supported by a large number of citations, we recommend applicants consider stating in the narrative the number of citations that support the assertion and then including in the citation list only the most important exemplars. (10-14 pages)

3. Applicant Capabilities

Project Team. This section should describe the applicant's project team, personnel qualifications, and past performance demonstrating experience consistent with successfully meeting the goals of the cooperative agreement. This section should discuss the overall project management approach and the types and level of staffing, resources, and infrastructure in place to support the project. This would include identifying the roles of key staff, identifying the roles of subcontractors and/or any other external consultants or subject matter experts, as well as communication strategy with ONC to provide updates and progress reports. The applicant must provide the names of staff that will be overseeing the analysis of the data and preparation of the ongoing reports. This section should also include any quality assurance or quality control processes your organization plans to conduct throughout the project. It is recommended that the project team be comprised of, but is not limited to, the following roles:

- Project Director/Principal Investigator (PD/PI):
    - Only one PD/PI may be designated on the application.
    - An eligible PD/PI may come from a variety of areas including, but not limited to, nurses, pharmacists, medical doctors, health service researchers, economists, health system administrators, health IT experts, industrial and systems engineers, computer and cognitive scientists, human factors professionals, and health informatics professionals. Any individual with the skills, knowledge, and resources necessary to carry out the proposed research is invited to work with their institution to develop an application for support.
    - The PD/PI is expected to contribute a minimum of 20% effort annually throughout the course of the cooperative agreement. If less time is allocated, an explicit justification of the lower level of effort shall be included.
- At least one person on the proposed team shall possess health IT expertise.
- *For Area of Interest 1*: Address health equity and social determinants of health (SDOH) through innovative, open-source technology tools, and electronic health records:
    - Discuss the proposed project team's expertise in the following areas:
        - Data standards development and balloting
        - API development and EHR integration
    - Discuss the proposed project team's knowledge in the following areas:
        - Implementation of EHRs and collection of SDOH data and electronic patient consent and authorization.
        - Stakeholder coordination and project management with clinical care providers and CBOs.
        - Patient engagement, information dissemination, and education.

        - Workflow and technical architecture development supporting referral management, patient engagement, and privacy and security.
        - Data analysis such as, but not limited to, outcomes measurement, population health, and health disparities.
        - Work directly on health disparities in collaboration with specific historically marginalized communities and/or community organizations that represent the perspectives and interests of historically marginalized communities.
    - To be considered for an award in Area of Interest 1, an applicant's proposal shall include a collaborative team of key stakeholders who will be directly involved in the project, which we refer to as the coalition. Coalition members shall include stakeholders such as healthcare providers, CBOs, human and social service organizations, health information exchanges (HIEs), health IT developers and vendors, and state/local agencies. An applicant's proposal shall include letters of commitment from stakeholders who will be part of the coalition.
- *For Area of Interest 2*: Demonstrate the use of equity-enhancing patient-generated health data for clinical care and research
    - Discuss the proposed project team's expertise in the following areas:
        - User-centered design
        - Workflow design
        - Data visualization
        - Cognitive support
    - Discuss the proposed project team's knowledge in the following areas:
        - Use of nationally recognized health IT standards and standards development to support the exchange of PGHD.
        - Stakeholder coordination with patients/patient advocates, clinicians, and researchers.
        - Excellent project management of large projects with multi-stakeholder facets and workflows.
        - Workflow and technical architecture development that supports the sharing of PGHD from collection to researchers.
        - Data analysis such as, but not limited to, population health, health disparities, and other relevant types of research and analysis.
    - To be considered for an award in Area of Interest 2, an applicant's proposal shall include a collaborative team of key stakeholders who will be directly involved in the project, which we refer to as the coalition. Coalition members shall include healthcare providers or professionals across healthcare settings (e.g. Physicians, Nurses, and Physical Therapists, health information exchanges (HIEs), health IT developers or vendors, and researchers). An applicant's proposal shall include letters of commitment from stakeholders who will be part of the coalition.

Plan for Disseminating and Transitioning Appropriate Research Results into Practice. This section should include a plan for engaging industry stakeholders to adopt, disseminate, and transition findings from the project into data standards, data infrastructures, health IT products, tools, and best practices. Collaborative arrangements with industry and other groups outside of the applicant institution should be accompanied by appropriate letters of support.

In the event an applicant's solution include the development of a prototype, the applicant should also submit a plan for approval by ONC, illustrating how the prototype will be made and maintained in a publicly available and acceptable domain at no cost to the general public. (2-3 pages)

Stakeholder Coordination. This section should describe plans to establish and operate a technical expert panel of relevant and appropriate stakeholders, including names of members who have committed to join or proposed to join to help inform the work to be conducted on the relevant Area of Interest. (2-3 pages)

Project Management. This section should include a clear delineation of the roles and responsibilities of the principal investigator, participating researchers, project staff, consultants, and collaborating organizations, and how they will contribute to achieving the research objectives and outcomes. If the application includes subcontractors, plans for coordinating activities across multiple organizations should be described. This section should specify who would have day-to-day responsibilities for key tasks such as: leadership of project, monitoring the project's on-going progress, preparation of reports, and communications with other collaborating organizations and ONC. Recipients will be required to maintain information relevant to executing the proposed project plan and performance-based outcomes. The application should describe the approach that will be used to assess project performance and monitor and track progress toward meeting key objectives. The application should include a detailed project timeline as an appendix that incorporates those objectives. The project timeline will not count towards the narrative page limit. The applicant should also include an organizational chart as an appendix that reflects roles and responsibilities. The organizational chart will not count towards the narrative page limit. (3-5 pages)

Organizational Capability Statement. The statement should describe the organization's capabilities, qualifications, and approach to address the work to be completed. Applicants are strongly encouraged to propose the development of technology using open-source approaches (freely available without a license) and share the outcomes of their research in open-source communities. The statement should highlight potential strategies the organization may employ to sustain research efforts and activities beyond the scope of the project timeframe.

The statement should include the relevant organizational resources available to perform the proposed project (e.g., facilities, equipment, and other resources). Also, the applicant should include information about any organization(s) that will have a significant role(s) in the research project and achieving research goals, including those proposed to receive sub-awards. Applicants who are working with project counterparts as part of a consortia shall also provide letters of commitment from them. The letters of commitment shall be included with the appendices and will not count towards the page limit. (2-4 pages)

4. **Budget Narrative**
   This section should include a detailed breakdown of how the applicant plans to spend the allotted resources to complete the activities detailed in the NOFO. More details about the requirements of this section can be found in the Budget Narrative section on page 24. (2-3 Pages)

Appendices

Applicants may submit no more than 30 pages of appendix material. Appendix material should be used to provide additional materials (for example, key papers or reports or excerpts) that will be of assistance in evaluating the merit of the application. Do not use the Appendix to circumvent the page limitations of

the project narrative component. Applications that use appendix material as a mechanism to exceed the page length limitations of the project narrative will not be considered for award.

Form SF-424, Application for Federal Assistance
Appendix B provides line-by-line instructions to complete the form. Please note that the SF-424 is used for a wide variety of Federal grant programs, and Federal agencies have the discretion to require some or all of the information on these forms. Accordingly, when completing the form, please use the instructions in Appendix B in lieu of the standard instructions attached to SF-424.

Form SF-424A, Budget Information for Non-Construction Programs
Appendix C provides line-by-line instructions to complete the form. Please note that the SF-424A is used for a wide variety of Federal grant programs, and Federal agencies have the discretion to require some of or all the information on these forms. Accordingly, when completing the form, please use the instructions in Appendix C in lieu of the standard instructions attached to SF-424A. All direct and indirect costs shall be allowable, allocable, reasonable, and necessary.

Form SF-424B, Assurances for Non-Construction Programs
This form contains laws and other assurances applicants shall comply with under the discretionary funds programs administered by the Office of the National Coordinator for Health Information Technology. Please note that a duly authorized representative of the applicant organization shall certify that the organization is in compliance with these assurances.

Form SF-LLL, Disclosure of Lobbying Activities
This form contains the name and address of lobbying registrants. Please note that a duly authorized representative of the applicant organization shall sign the disclosure form. Failure to complete and sign the form may result in civil penalties ranging from $10,000 to $100,000.

Budget Narrative
The budget narrative describes how the proposed budget, as articulated in the SF-424A, aligns with the applicant's project narrative. That is to ensure that costs are realistic (not artificially too low) and reasonable (not inflated) in view of programmatic requirements. Appendix D provides a template to complete the budget narrative populated with *sample* information.

When more than 33% of a project's total budget falls under a contractual expense, a detailed budget narrative/justification shall be provided for each sub-contractor or sub-recipient. Applicants requesting funding for multi-year grant programs are required to provide a combined multi-year budget narrative/justification, as well as a detailed budget narrative/justification for each year of potential grant funding. A separate budget narrative/justification is also required for each potential year of grant funding requested.

The full budget narrative/justification should be included in the application immediately following the SF 424 forms. The budget narrative shall be double-spaced, formatted to 8 ½" x 11" (letter-size) pages, 1" or larger margins on all sides, and a font size of not less than 11 point.

Letters of Commitment
Include letters of commitment confirming the support to the project (should it be funded) made by key collaborating organizations and agencies. Any organization that is specifically named to have a significant coordination role in carrying out the project should be considered an essential collaborator

such as interstate, intrastate, and regional partners. At a minimum, the letter shall explain the demonstrated commitment to the project and how they will advance coordination and collaboration among critical stakeholders. See Appendix E for an example letter of commitment.

Applicants will also provide a letter of commitment from entities that will be responsible for generating reports based on transactional data (e.g. health information service providers, technology developers or vendors, or others). These entities should have the capacity and resources to produce required reports on adoption and use in a timely manner. See Appendix E for an example letter of commitment.

These letters should not be considered as part of the page limit. Signed letters of commitment should be scanned and included as attachments.

Proof of Non-Profit Status
Non-profit applicants shall submit proof of non-profit status. Any of the following constitutes acceptable proof of such status:

- A copy of a currently valid IRS tax exemption certificate.
- A statement from a state taxing body, state attorney general, or other appropriate state official certifying that the applicant organization has a non-profit status and that none of the net earnings accrue to any private shareholders or individuals.
- A certified copy of the organization's certificate of incorporation or similar document that clearly establishes non-profit status.

Indirect Cost Agreement(s)
Applicants that have included indirect costs in their budgets shall include a copy of the current indirect cost rate agreement approved by the Department of Health and Human Services or another federal agency. This is optional for applicants that have not included indirect costs in their budgets. Further, if any sub-contractors or sub-recipients are requesting indirect costs, copies of their indirect cost agreements shall also be included with the application. Cost allocation plans are not accepted.

Application Submission Instructions

1) You shall access the electronic application for this program via http://www.grants.gov. You can search the downloadable application page by the Notice of Funding Opportunity Number *NAP-AX-22-001* or CFDA number *93.345*.
2) Applicants will be able to download a copy of the application packet and complete it off-line. In order to complete the application, an organization shall have a Unique Entity Identifier (UEI). A UEI can be obtained via registering at http://SAM.gov and typically takes 7 to 10 business days. Please plan accordingly.
3) Completed applications are uploaded into Grants.gov. APPLICATIONS WILL NOT BE ACCEPTED THROUGH ANY OTHER WEBSITE, AND WILL NOT BE ACCEPTED THROUGH PAPER MAIL, COURIER, OR DELIVERY SERVICE.

   In order to upload applications into Grants.gov:
   a) An applicant shall be registered in the System for Award Management (SAM), at sam.gov and use their UEI. The SAM registration process takes 7 to 10 business days so please plan

accordingly. If you have already registered with the SAM, but have not renewed your registration in the last 12 months, you will need to renew your registration.

b) Please note that entities registering in SAM shall submit a notarized letter appointing their authorized Entity Administrator. This will not impact the registration approval process, but is required as part of your registration. For additional information, read SAM's updated FAQs to learn more about changes to the notarized letter review process and other system improvements.

The following website depicts the SAM registration process: http://www.grants.gov/web/grants/applicants/organization-registration.html

c) An applicant shall be registered in Grants.gov which can take several days. To that end, applicants are strongly encouraged to register and test Grants.gov logins and passwords well in advance of the application deadline date. For assistance with www.grants.gov, please contact them at support@Grants.gov or 1-800-518-4726. Resources are available 24 hours a day/7 days a week.

A depiction of the Grants.gov application process can be found at http://www.grants.gov/web/grants/applicants/apply-for-grants.html

4) After electronically submitting your application, Grants.gov will generate an email a tracking number and date of receipt verification confirming that the application was received, the date and time the application was received, and a tracking number. This notification does not ensure that your application could be opened and read -- only that the application was received.

The deadline for the submission of applications under this Funding Opportunity is 12:00PM Eastern Standard Time on August 15, 2022. Applications that fail to meet the application deadline will not be reviewed and will receive no further consideration.

Restrictions on Oral Conversations

This funding opportunity is subject to restrictions on oral conversations during the period of time commencing with the submission of a formal application by an individual or entity and ending with the award of the competitive funds. Federal officials may not participate in oral communications initiated by any person or entity concerning a pending application for a competitive grant or other competitive form of federal financial assistance, whether the initiating party is a federally registered lobbyist or not.

This restriction applies unless:

- The communication is purely logistical
- The communication is made at a widely attended gathering
- The communication is to or from a federal agency official and another federal Government employee
- The communication is to or from a federal agency official and an elected chief executive of a state, local, or tribal government, or to or from a federal agency official and the Presiding Officer or Majority Leader in each chamber of a state legislature
- The communication is initiated by the federal agency official

Funding Restrictions

Funds cannot be used for the following purposes:

- To supplant or replace current public or private funding
- To supplant ongoing or usual activities of any organization involved in the project
- To purchase or improve land, or to purchase, construct, or make permanent improvements to any building
- To reimburse pre-award costs

E. Application Review Information

Screening Review

Applicants that do not meet the following screening criteria will be eliminated and will not be sent forward for merit review:

- The application is received by the required deadline through http://www.grants.gov
- The application contains all required components (e.g. Project Abstract, project narrative, SF-424 etc.)
- The application meets the formatting and length requirements. The project narrative shall not exceed *35* pages. The Project Abstract and resumes do not count as part of the project narrative length limitation.
- Appendices and attachments are not used as a mechanism to exceed page limits of the project narrative

Merit Review

An independent review panel will evaluate applications that meet the screening review criteria identified above. These reviewers will be experts in their fields from academic institutions, private and non-profit organizations, and state, tribal, local, territorial, and federal government agencies. Panelists will review, evaluate, and score applications, in accordance with the criteria identified below.

- Understanding of Project Purpose (10 points)
- Proposed Approach and Activities (40 points)
- Applicant Capabilities (30 points)
- Budget Narrative (20 points)

Understanding of Project Purpose (10 points)

- The extent to which the application addresses the objectives and project goals of this NOFO.
- The extent to which the application identifies a project plan and activities that align with one of the two identified Areas of Interest within the NOFO.
- The extent to which the application identifies barriers and ways to mitigate those barriers with one of the two identified Areas of Interest within the NOFO.
- The extent to which the applicant describes how the project, expected outcomes, and results will inform future health IT development, research, and implementation.

Proposed Approach and Activities (40 points)

- The extent to which the approach, design, methods, and analyses are specifically stated, adequately developed, well-integrated, well-reasoned, and appropriate to the project goals/key objectives of the Area of Interest **(20 points)**, to include:
    - The extent to which proposed activities for achieving the research objectives are clear, feasible, and appropriate.
    - The extent to which development or utilization of novel concepts, approaches, methodologies, tools, or technologies, or a combination of common elements, are described and generate insight to inform the field of health IT.
- The extent to which the applicant proposes a clear and detailed plan for disseminating and

transitioning appropriate research results into practice. This section of the application should include a plan for engaging industry stakeholders to adopt, disseminate, and transition findings from the project to stakeholders who will continue to advance the work. **(15 points)**

- The extent to which the plan describes a project management approach for ensuring project success. **(5 points)**

Applicant Capabilities (30 points)

- The extent to which the applicant identifies all the resources necessary to perform the proposed work and outline strategies to complete this work within a two-year time frame. **(5 points)**
- The extent to which the scientific environment(s) in which the work will be done contributes to the probability of success, employs useful collaborative arrangements, and has evidence of institutional support. **(5 points)**
- The extent to which the project proposal integrates and provides an appropriate level of research and technical knowledge and subject matter expertise. **(20 points)**.
    - Does the application include a project team drawing from diverse fields? Are needed expertise or relevant disciplines adequately represented across the project team?
    - Does the application demonstrate that the project team will have adequate administrative structure and processes in place to oversee the successful conduct of the proposed project, which includes addressing weaknesses encountered during the project?
    - *For Area of Interest 1*: Address health equity and social determinants of health (SDOH) through innovative, open-source technology tools, and electronic health records:
        - Does the proposed project team have expertise in the following areas?
            - Data standards development and balloting
            - API development and EHR integration
        - Is the proposed project team able to demonstrate knowledge in the following areas?
            - Implementation of EHRs and collection of SDOH data and electronic patient consent and authorization.
            - Stakeholder coordination and project management with clinical care providers and CBOs.
            - Patient engagement, information dissemination, and education.
            - Workflow and technical architecture development supporting referral management, patient engagement, and privacy and security.
            - Data analysis such as, but not limited to, outcomes measurement, population health, and health disparities.
            - Work directly on health disparities in collaboration with specific historically marginalized communities and/or community organizations that represent the perspectives and interests of historically marginalized communities.
        - To be considered for an award in Area of Interest 1, an applicant's proposal shall include a collaborative team of key stakeholders who will be directly involved in the project, which we refer to as the

coalition. Coalition members shall include stakeholders such as healthcare providers, CBOs, human and social service organizations, health information exchanges (HIEs), health IT developers and vendors, and state/local agencies. An applicant's proposal shall include letters of commitment from stakeholders who will be part of the coalition.

- *For Area of Interest 2*: Demonstrate the use of equity-enhancing patient-generated health data for clinical care and research
    - Does the proposed project team demonstrate expertise in the following areas?
        - User-centered design
        - Workflow design
        - Data visualization
        - Cognitive support
    - Is the proposed project team able to demonstrate knowledge in the following areas?
        - Use of nationally recognized health IT standards and standards development to support the exchange of PGHD.
        - Stakeholder coordination with patients/patient advocates, clinicians, and researchers.
        - Excellent project management of large projects with multi-stakeholder facets and workflows.
        - Workflow and technical architecture development that supports the sharing of PGHD from collection to researchers.
        - Data analysis such as, but not limited to, population health, health disparities, and other relevant types of research and analysis.
    - To be considered for an award in Area of Interest 2, an applicant's proposal shall include a collaborative team of key stakeholders who will be directly involved in the project, which we refer to as the coalition. Coalition members shall include healthcare providers or professionals across healthcare settings (e.g. Physicians, Nurses, and Physical Therapists, health information exchanges (HIEs), health IT developers or vendors, and researchers). An applicant's proposal shall include letters of commitment from stakeholders who will be part of the coalition.

Budget Narrative (20 points)

- Does the application provide the proposed levels of effort of the project team and consultants (if needed) and describe how they are adequate and appropriate to advance the project in accordance with the project plan?
- Does the application include an explanation of how the proposed budget supports the project and is cost-efficient and reasonable for meeting the project activities?

Pre-Award Risk Assessment

ONC is required to conduct a risk assessment to assess the risk posed by a potential recipient, prior to issuing an award. In doing so, ONC will consider the applicant's financial stability, quality of

management systems, history of performance, reports and findings from audits, and the applicant's ability to effectively implement statutory, regulatory, or other requirements imposed on non-Federal entities. To facilitate this assessment, ONC may review information available in systems, review documentation, such as previous audits, and/or desk reviews or site visits conducted from previous awards. ONC may elect not to fund applicants with management or financial instability that directly relates to the organization's ability to implement statutory, regulatory, or other requirements (45 CFR 75.205).

For any Federal award issued under a Notice of Funding Opportunity (NOFO), if the HHS awarding agency anticipates that the total Federal share will be greater than the simplified acquisition threshold on any Federal award under a notice of funding opportunity may include, over the period of performance (see §75.2 Simplified Acquisition Threshold), this section shall also inform applicants:

- That the HHS awarding agency, prior to making a Federal award with a total amount of Federal share greater than the simplified acquisition threshold, is required to review and consider any information about the applicant that is in the designated integrity and performance system accessible through SAM (currently FAPIIS) (see 41 U.S.C. 2313).

- ONC is required to review and consider any information about the applicant that is in the Federal Awardee Performance and Integrity Information System (FAPIIS), www.fapiis.gov/, before making any award greater than the simplified acquisition threshold over the period of performance. An applicant may review and comment on any information about itself that a federal awarding agency has previously entered into FAPIIS. ONC will consider any commentsby the applicant, in addition to other information in FAPIIS, in making a judgment about the applicant's integrity, business ethics, and record of performance under federal awards when completing the review of risk posed by applicants as described in 45 CFR § 75.205(a)(2) Federal Awarding Agency Review of Risk Posed by Applicants.

Award Decisions

The final award decision will be made by ONC or an authorized designee, taking into consideration several factors such as the results of the merit review process; results of the pre-award risk assessment; compliance with programmatic and grants management requirements; the reasonableness of the estimated costs, available funding, geographical dispersion, program priorities, any mandatory statutes or regulations associated to this program; and the likelihood that the proposed project will result in the benefits expected. All applicants will receive a summary of the independent review panel's assessment of the application's strengths, weaknesses, and score.

F. Federal Award Administration Information

Federal Award Notices

Successful applicants will receive a letter of notification acknowledging that an award was funded but does not provide authorization for the applicant to begin performance and expend funds associated with the award.

Following this notice, successful applicants will receive a Notice of Award (NOA). The NOA will include, at a minimum, the following:

- Legal name and address of the organization or institutions to whom ONC has issued an award
- Award number assigned by ONC
- Project period, specifying the amount of time ONC intends to support the project without requiring re-competition for funds
- Total amount of financial assistance approved by ONC during the project period
- Budget period, specifying the increments in which the project will be funded, subject to the availability of funds
- Applicable award terms and conditions
- Performance goals, indicators, objectives, or expected outcomes (such as outputs, or services performed or public impacts of any of these) with an expected timeline for accomplishment

The successful applicants' Authorized Representatives will receive the NOA electronically from ONC. The recipient accepts the award by drawing down funds. By accepting an ONC award, the recipient assumes legal, financial, administrative, and programmatic responsibility for administering the award in accordance with the terms and conditions of the award, as well as applicable laws, rules, regulations, and Executive Orders governing HHS assistance awards, all of which are to be incorporated into the award by reference. Failure to comply with these requirements may result in suspension or termination of the awards and/or ONC's recovery of award funds.

Terms and Conditions

Administrative and National Policy Requirements
Awards issued under this announcement are subject to 45 CFR Part 75 - Uniform Administrative Requirements, Cost Principles, and Audit Requirements for HHS Awards currently in effect or implemented during the period of award, other Department regulations andpolicies in effect at the time of award, and applicable statutory provisions. The Code of Federal Regulations (CFR) is available at www.ecfr.gov.

An application funded with the release of federal funds through a grant award does not constitute, or imply compliance with federal regulations. Funded organizations are responsiblefor ensuring that their activities comply with all applicable federal regulations.

HHS Grants Policy Statement
The HHS Grants Policy Statement (HHS GPS) is the Department of Health and Human Services' single policy guide for discretionary grants and cooperative agreements. ONC grant awards are subject to the requirements of the HHS GPS, which covers basic grants processes, standard terms and conditions, and points of contact, as well as important agency-specific requirements. The general terms and conditions in the HHS GPS will apply as indicated unless there are statutory, regulatory, or award-specific requirements to the contrary that are specified in the Notice of Award (NOA). The HHS GPS is available at https://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf

Specific terms and conditions are further delineated below due to their importance in terms of integrity, achieving programmatic objectives, and/or sound financial stewardship of federal funds.

Non-Discrimination Legal Requirements for Recipients of Federal Financial Assistance
Per Executive Order (E.O.) 13985 entitled Advancing Racial Equity and Support for Underserved Communities Through the Federal Government (Jan. 20, 2021), should you successfully compete for an award, recipients of federal financial assistance (FFA) from HHS shall administer their programs in compliance with federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, disability, age and, in some circumstances, religion, conscience, and sex (including gender identity, sexual orientation, and pregnancy). This includes ensuring programs are accessible to persons with limited English proficiency and persons with disabilities. The HHS Office for Civil Rights provides guidance on complying with civil rights laws enforced by HHS. See https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html and https://www.hhs.gov/civil-rights/for-individuals/nondiscrimination/index.html.
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- Recipients of FFA shall ensure that their programs are accessible to persons with limited English proficiency. For guidance on meeting your legal obligation to take reasonable steps to ensure meaningful access to your programs or activities by limited English proficient individuals. See https://www.hhs.gov/civil-rights/forindividuals/special -topics/limited-english-proficiency/fact-sheet-guidance/index.htmland https://www.lep.gov.

- For information on your specific legal obligations for serving qualified individuals with disabilities, including reasonable modifications and making services accessible to them, see http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html.

- HHS funded health and education programs shall be administered in an environment free of sexual harassment, see https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html.

- For guidance on administering your program in compliance with applicable federal religious nondiscrimination laws and applicable federal conscience protection and associated anti-discrimination laws, see https://www.hhs.gov/conscience/conscience-protections/index.html and https://www.hhs.gov/conscience/religious-freedom/index.html.

Performance Reporting
ONC Program Progress Reports (PPR) are due quarterly. The PPR will address, to the extent applicable:

- Degree to which performance goals were attained (actual performance versus targeted performance)
- Data source and validation method for performance measures
- Opportunities to address performance deficiencies
- Accomplishments
- Next steps
- Challenges/barriers
- Recommendations to address challenges and barriers

ONC will provide specific guidance regarding the content, format, and deadlines for submitting the PPRs before each report is due.

Each report will be due throughout the fiscal year as follows:

Reporting Period	**Reporting Due Date**
October 1 through December 31	No later than January 31
January 1 through March 31	No later than April 30
April 1 through June 30	No later than July 31
July 1 through September 30	No later than October 31

Additional programmatic requirements, include, but not limited to:

- A Kick-Off Meeting no later than two (2) weeks after award date with members of each recipient team and ONC is required. The purpose of this meeting is to establish points of contacts, expectations, and set-up regular check-in calls.

- A monthly (minimum) check-in meeting to be scheduled with project team and your ONC Project Officer to discuss implementation trajectory, accomplishments, next steps, challenges, barriers, and recommendations to address challenges and barriers.

- Draft of the Final Report shall be submitted to ONC at least three (3) months prior to the end of the grant period of performance project period in Microsoft Word and include the following elements:
    - Title Page that includes the following:
        1. Title of Project
        2. Principal Investigator and Team Members
        3. Organization
        4. Project Dates
        5. Federal Project Officer
        6. Acknowledgment of Agency Support
        7. Grant Award Number

    <u>Final Report Components</u>
    Include the following six components using these headings:

1. Structured Abstract not to exceed 500 words and with the following sections
    a. Purpose
    b. Scope
    c. Methods
    d. Results
    e. Key Words
2. Purpose (Project Objectives)
3. Scope (e.g., Background, Context, Settings, Participants, Incidence, Prevalence)
4. Approach (e.g., Study Design, Data Sources/Collection, Interventions, Measures, Limitations)
5. Results (Principal Findings, Outcomes, Discussion, Conclusions, Significance, Implications)
6. List of Publications and Products (Bibliography of Published Works and Electronic Resources from Study)

- A final version of report that incorporates project official feedback shall be submitted to ONC for review and approval by your project by no later than 90 days after the end of the grant.

Additional closeout information and requirements may be disseminated prior to the expiration of the period of performance.

Final Prototype Development
In the event an applicant's solution include the development of a prototype, the applicant will obtain ONC's approval and make the prototype publicly available at no cost to the general public.

Financial Reporting
Expenditures shall be reported, on a semi-annual basis, using the SF-425, Federal Financial Report (FFR). Reports are due to HHS no later than April 30 of each year the award is active for funds expended between October and March, and no later than October 31 for funds expended between April and September. The semi-annual FFR will be submitted using the Payment Management System (PMS). ONC will not accept reports sent directly to the ONC Grants mailbox.

Federal Funding and Accountability and Transparency Act of 2006
The Federal Funding Accountability and Transparency Act of 2006 (Transparency Act) includes a requirement for recipients of Federal grants to report information about first-tier sub-awards and executive compensation under Federal assistance awards issued in FY2011 or later. All recipients of ONC grants and cooperative agreements are required to report to the Federal Subaward Reporting System (FSRS) available at www.fsrs.gov on all sub-awards over $25,000.

Federal Recipient Performance and Integrity Information System (FAPIIS)
As of January 1, 2016, recipients of Federal grants and cooperative agreements are subject to mandatory disclosure requirements. Recipients that have Federal contracts, grants, and cooperative agreement awards from all Federal awarding agencies with a cumulative total value greater than $10,000,000 shall maintain the currency of information reported to the System for Award Management (SAM) that is made available in the designated integrity and performance system (currently FAPIIS), any information about criminal, civil, and administrative proceedings that reached its final disposition during the most

recent five-year period in connection with the award or performance of a grant, cooperative, agreement, or procurement contract from the Federal Government. Reporting shall specifically include the following:

Proceedings About Which You Shall Report

Submit the information required about each proceeding that:

a. Is in connection with the award or performance of a grant, cooperative agreement, or procurement contract from the Federal Government;
b. Reached its final disposition during the most recent five year period; and
c. If one of the following:

(1) A criminal proceeding that resulted in a conviction, as defined in paragraph 5 of this award term and condition;
(2) A civil proceeding that resulted in a finding of fault and liability and payment of a monetary fine, penalty, reimbursement, restitution, or damages of $5,000 or more;
(3) An administrative proceeding, as defined in paragraph 5 of this award term and condition, that resulted in a finding of fault and liability and your payment of either a monetary fine or penalty of $5,000 or more or reimbursement, restitution, or damages in excess of $100,000; or
(4) Any other criminal, civil, or administrative proceeding if:

(i) It could have led to an outcome described in paragraph 2.c.(1), (2), or (3) of this award term and condition;
(ii) It had a different disposition arrived at by consent or compromise with an acknowledgement of fault on your part; and
(iii) The requirement in this award term and condition to disclose information about the proceeding does not conflict with applicable laws and regulations.

Reporting Procedures
Enter in the SAM Entity Management area the information that SAM requires about each proceeding described in paragraph 2 of this award term and condition. You do not need to submit the information a second time under assistance awards that you received if you already provided the information through SAM because you were required to do so under Federal procurement contracts that you were awarded.

Reporting Frequency
During any period of time when you are subject to this requirement in paragraph 1 of this award term and condition, you shall report proceedings information through SAM for the most recent five-year period, either to report new information about any proceeding(s) that you have not reported previously or affirm that there is no new information to report. Recipients that have Federal contract, grant, and cooperative agreement awards with a cumulative total value greater than $10,000,000 shall disclose semiannually any information about the criminal, civil, and administrative proceedings.

For purposes of this award term and condition:

a. Administrative proceeding means a non-judicial process that is adjudicatory in nature in order to make a determination of fault or liability (e.g., Securities and Exchange Commission Administrative proceedings, Civilian Board of Contract Appeals proceedings, and Armed Services Board of Contract Appeals proceedings). This includes proceedings at the Federal and State level but only in connection with performance of a Federal contract or grant. It does not include audits, site visits, corrective plans, or inspection of deliverables.

b. Conviction, for purposes of this award term and condition, means a judgment or conviction of a criminal offense by any court of competent jurisdiction, whether entered upon a verdict or a plea, and includes a conviction entered upon a plea of nolo contendere.
c. Total value of currently active grants, cooperative agreements, and procurement contracts includes -

(1) Only the Federal share of the funding under any Federal award with a recipient cost share or match; and

(2) The value of all expected funding increments under a Federal award and options, even if not yet exercised

This is a statutory requirement under section 872 of Public Law 110-417, as amended (41 U.S.C. 2313). All information posted in the designated integrity and performance system on or after April 15, 2011, except past performance reviews required for Federal procurement contracts, will be publicly available.

Conflict of Interest

The term "organizational conflict of interest" means that the applicant, including its chief executives, directors, consultants, sub recipients, or any other personnel that are substantially involved in the performance of this assistance agreement, has interests which:

- May diminish its capacity to give impartial, technically sound, objective assistance and advise in performing this task.
- May otherwise result in a biased work product under this assistance agreement; or,
- May result in an unfair competitive advantage to itself or others.

In accordance with 45 CFR 75.112 of the Uniform Administrative Requirements, Cost Principles, and Audit Requirements for All Federal Awards, all applicants and non-federal entities shall disclose, in writing, any potential conflict of interest (COI) that they have with the awarding agency and/or any other pass-through entities. The applicant shall notify the ONC grants management officer (GMO) when they believe an actual or potential COI may exist.

If, after award, a recipient discovers a COI, with respect to the assistance agreement, it shall make an immediate and full disclosure in writing to the ONC GMO. The disclosure shall include identification of the actual or potential conflict, the manner in which it arose, and a description of the action the recipient has taken, or proposed to take, to avoid, eliminate, or neutralize the conflict.

In the event the recipient was aware of an organizational COI, prior to award of the assistance agreement, and did not disclose the conflict to the GMO, or becomes aware of an organizational COI after award of this assistance agreement and does not disclose the COI within ten (10) days of becoming aware of such conflict, the Government may terminate the assistance agreement and the recipient shall not be entitled to reimbursement of any costs incurred in performing the assistance agreement.

The rights and remedies of the Government, under this term and condition, shall not be exclusive and are in addition to any other rights and remedies provided to the Government under law, regulation, or any other available enforcement mechanism.

Non-Disclosure Requirements

The federal award may require the recipient to have access to information relating to any and all aspects of grants management operations that may be of a technical, legal, sensitive and/or confidential nature and which may be the sole property of the U.S. Government. To mitigate risks associated with such access, the recipient shall ensure that all its personnel, including chief executives, directors, consultants,

sub recipients, or any other personnel substantially involved in the performance of this award sign a non-disclosure agreement prior to the commencement of any work on the award.

In addition, recipients shall put in place appropriate procedures for the protection of such information and shall be liable to the Government for any misuse or unauthorized disclosure of such information by its personnel.

The rights and remedies of the Government, under this term and condition, shall not be exclusive and are in addition to any other rights and remedies provided to the Government under law, regulation, or any other available enforcement mechanism.

Mandatory Disclosures
In accordance with 45 CFR 75.113, Mandatory Disclosures, of the Uniform Administrative Requirements, Cost Principles, and Audit Requirements for HHS Awards. The non-Federal entity or applicant for a Federal award shall disclose, in a timely manner, in writing to the Federal awarding agency or pass-through entity all violations of Federal criminal law involving fraud, bribery, or gratuity violations potentially affecting the Federal award. Failure to make required disclosures can result in any of the remedies described in Section 75.371 of the Uniform Requirements including suspension or debarment.

Health IT Coordination Requirements
Title XIII of the HITECH Act provides for the advancement of health information technology and health information exchange through the use of standards and implementation specifications, and through health information technology certification criteria established by the Secretary.

For grants or cooperative agreements where funding will be used to implement, acquire, upgrade, or utilize health information technology for activities involving health care providers in ambulatory or hospital settings (as such health care providers are defined as eligible under Sections 4101, 4102 and 4201 of the HITECH Act), the recipient must implement, acquire, upgrade, or utilize health information technology certified under the ONC Health IT Certification Program if certified technology can support the activity and such technology has been certified to the standards and implementation specifications adopted under section 3004 of the Public Health Service Act.

For all grants or cooperative agreement activities involving the adoption or use of health information technology standards and systems, or the interoperability (as defined 45 C.F.R. 170.102) of health information technology, the recipient must implement, acquire, upgrade, or utilize health information technology that meets standards and implementation specifications adopted under section 3004 of the Public Health Service Act (PHSA) (identified in 45 CFR Part 170, Subpart B "Standards and Implementation Specifications for Health Information Technology" (170.200-170.299)) if standards and implementation specifications in 45 CFR Part 170, Subpart B can support the activity. If standards and implementation specifications adopted under Section 3004 of the Public Health Service Act cannot support the activity, the recipient should implement, acquire, update, or utilize technology that meets non-proprietary standards and implementation specifications that are developed by consensus-based standards development organizations. This may include standards identified in the ONC Interoperability Standards Advisory (Link: https://www.healthit.gov/isa/).

Intangible Property and Copyrights
Intangible property, as defined in 45 CFR 75.2 means property having no physical existence, such as trademarks, copyrights, patents and patent applications and property, such as loans, notes and other debt instruments, lease agreements, stock, and other instruments of property, ownership (whether the property is tangible or intangible).

(a) Title to intangible property (see 45 CFR §75.2 Intangible property) acquired under a Federal award vests upon acquisition in the non-Federal entity. The non-Federal entity shall use that property for the originally authorized purpose, and shall not encumber the property without approval of the HHS awarding agency. When no longer needed for the originally authorized purpose, disposition of the intangible property shall occur in accordance with the provisions in 45 CFR §75.320(e).

(b) The Non-Federal entity may copyright any work that is subject to copyright and was developed, or for which ownership was acquired, under a Federal award. **The HHS awarding agency reserves a royalty-free, nonexclusive and irrevocable right to reproduce, publish, or otherwise use the work for Federal purposes, and to authorize others to do so. (Please note, for the purpose of this funding opportunity "work" can be considered as: writings, films, sound recordings, pictorial reproductions, drawings, designs, or other graphic representations, procedural manuals, forms, diagrams, work flow charts, equipment descriptions, data files, data processing or computer programs (software), statistical records, and other technical research data.)**

(c) The Non-Federal entity is subject to applicable regulations governing patents and inventions, including government-wide regulations issued by the Department of Commerce at 37 CFR part 401.

(d) The Federal Government has the right to:

(1) Obtain, reproduce, publish, or otherwise use the data produced under a Federal award; and
(2) Authorize others to receive, reproduce, publish, or otherwise use such data for Federal purposes

(e) Freedom of Information Act (FOIA). (1) In response to a Freedom of Information Act (FOIA) request for research data relating to published research findings produced under a Federal award that were used by the Federal Government in developing an agency action that has the force and effect of law, the HHS awarding agency shall request, and the non-Federal entity shall provide, within a reasonable time, the research data so that they can be made available to the public through the procedures established under the FOIA. If the HHS awarding agency obtains the research data solely in response to a FOIA request, the HHS awarding agency may charge the requester a reasonable fee equaling the full incremental cost of obtaining the research data. This fee should reflect costs incurred by the Federal agency and the non-Federal entity. This fee is in addition to any fees the HHS awarding agency may assess under the FOIA (5 U.S.C. 552(a)(4)(A)).

(2) Published research findings means when:
(i) Research findings are published in a peer-reviewed scientific or technical journal; or
(ii) A Federal agency publicly and officially cites the research findings in support of an agency action that has the force and effect of law. "Used by the Federal Government in developing an agency action that has the force and effect of law" is defined as when an agency publicly and officially cites the research findings in support of an agency action that has the force and effect of law.

(3) Research data means the recorded factual material commonly accepted in the scientific community as necessary to validate research findings, but not any of the following: Preliminary analyses, drafts of scientific papers, plans for future research, peer reviews, or communications with colleagues. This "recorded" material excludes physical objects (e.g., laboratory samples). Research data also do not include:

(i) Trade secrets, commercial information, materials necessary to be held confidential by a researcher until they are published, or similar information which is protected under law; and

(ii) Personnel and medical information and similar information the disclosure of which would constitute a clearly unwarranted invasion of personal privacy, such as information that could be used to identify a particular person in a research study.

(f) The requirements set forth in paragraph (e)(1) of this section do not apply to commercial organizations.

For any work owned by a third party that was licensed by the recipient under this award, recipient will assure that said license also reserves for the Government a royalty free, nonexclusive, and irrevocable right to reproduce, publish, or otherwise use the work for Federal purposes and to authorize others to do so.

Records Retention

Recipients generally shall retain financial and programmatic records, supporting documents, statistical records, and all other records that are required by the terms of an award, or may reasonably be considered pertinent to a grant/cooperative agreement, for a period of three years from the date the final FFR is submitted. For awards where the FFR is submitted at the end of the competitive segment, the three-year retention period will be calculated from the date the final FFR, for the entire competitive segment, is submitted.

45 CFR Part 75.361 provides exceptions and qualifications to the three-year retention requirement. For example, if any litigation, claim, financial management review, or audit is started before the expiration of the three-year period, the records shall be retained until all litigation, claims, or audit findings involving the records have been resolved and final action taken. This section also specifies the retention period for other types of grant-related records, including indirect cost proposals and property records. See 45 CFR Part 75.335 for record retention and access requirements for contracts under grants/cooperative agreements.

Modifications

Modifications and/or amendments to the cooperative agreement shall be effective upon the mutual agreement of both parties, except where ONC is authorized under the Terms and Conditions of award, 45 CFR Part 75, or other applicable regulation or statute to make unilateral amendments.

Audit Requirements

OMB's Uniform Administrative Requirements, Cost Principles, and Audit Requirements, Subpart F, Audit Requirements sets forth standards for obtaining consistency and uniformity among Federal agencies for the audit of non-Federal entities expending Federal awards. In general, a non-Federal entity that expends $750,000 or more during the non-Federal entity's fiscal year in Federal awards shall have a single or program-specific audit. Subpart F provides further guidance including the manner in which

expenditures are determined, the distinction between a single audit and a program-specific audit, frequency of audits, and roles and responsibilities in the conduct of audits.

Enforcement Actions/Termination

Per 45 CFR Part 75.371, ONC will generally allow the recipient an opportunity to take appropriate corrective action before terminating a program. ONC may terminate the Cooperative Agreement if the recipient does not take appropriate corrective action. ONC may also terminate the award, without the option for corrective action, if the deficiency is so serious as to warrant immediate termination or if public health or welfare concerns require immediate action.

ONC or the recipient may mutually terminate a Cooperative Agreement, partially or totally, if the two parties agree upon the termination conditions, including the effective date and the portion to be terminated. If the recipient decides to terminate a portion of a Cooperative Agreement, ONC may determine that the remaining portion of the Cooperative Agreement will not accomplish the purposes for which the Cooperative Agreement was originally awarded. The recipient shall contact the ONC representative should it decide to terminate all, or part of its Cooperative Agreement as outlined in 45 CFR Part 75.372.

When an award is terminated or partially terminated, the recipient is still responsible for closing out the award per 45 CFR Part 75.381. The recipient is required to contact their assigned Grants Management Specialist to obtain closeout instructions. In the event of termination, the recipient will be required to continue supporting functions of the Cooperative Agreement throughout a 90-day closeout period. This support includes the transfer of all Work Products created under the Cooperative Agreement to ONC immediately upon completion/termination of the award.

For the purpose of this program, if the recipient is terminated, the recipient agrees to the transfer of and future use by ONC and any successor recipient of any Work Products developed under this Cooperative Agreement.

Please review all HHS regulatory provisions for Termination at 45 CFR Part 75.372.

Steven's Amendment
When issuing statements, press releases, requests for proposals, bid solicitations, and other documents describing projects or programs funded in whole or in part with Federal money, all receiving Federal funds included in this Act, including but not limited to State and local governments and recipients of Federal research grants, shall clearly state—

(1) the percentage of the total costs of the program or project which will be financed with Federal money;
(2) the dollar amount of Federal funds for the project or program; and
(3) percentage and dollar amount of the total costs of the project or program that will be financed by non-governmental sources.

Recipients are required to use the following acknowledgement and disclaimer on all products produced by ONC grant funds:
"This project is/was supported by the Office of the National Coordinator for Health Information Technology (ONC) of the U.S. Department of Health and Human Services (HHS) under grant number and title for grant amount (specify grant number, title, total award amount and percentage financed with nongovernmental sources). This information or content and conclusions are those of the author and should not be construed as the official position or policy of, nor should any endorsements be inferred by ONC, HHS or the U.S. Government."

Recipients are required to use this language when issuing statements, press releases, requests for proposals, bid solicitations, and other ONC supported publications and forums describing projects or programs funded in whole or in part with ONC funding. Examples of ONC supported publications include, but are not limited to, manuals, toolkits, resource guides, case studies, and issues briefs.

508 Compliance
ONC requires its recipients to ensure that any material meant for public release developed by way of ONC funding is in compliance with Section 508 of the Rehabilitation Act of 1973 (29 U.S.C. 794d) accessible to people with disabilities.

Whistleblower Protections
Recipients of this award must comply with the National Defense Authorization Act (NDAA) for Fiscal Year (FY) 2013 (Pub. L. 112-239, 41 U.S.C. § 4712) "Enhancement of contractor protection from reprisal for disclosure of certain information," and 48 CFR part 3 subpart 3.9, "Whistleblower Protections for Contractor Employees." For more information see:
https://oig.hhs.gov/fraud/whistleblower/

G. Appendix

Appendix A

Tips for Writing a Strong Application

Include your organization's Unique Entity Identifier (UEI). You shall include a UEI to have your application reviewed. For additional information regarding UEI, please access https://www.gsa.gov/about-us/organization/federal-acquisition-service/office-of-systems-management/integrated-award-environment-iae/iae-systems-information-kit/unique-entity-identifier-update.

Keep your audience in mind. Reviewers will use only the information contained in the application to assess the application. Be sure the application and responses to the program requirements and expectations are complete and clearly written. Do not assume that reviewers are familiar with the lead recipient organization. Keep the review criteria in mind when writing the application.

Prepare early. Start preparing the application early. Allow plenty of time to gather required information from various sources.

Follow the instructions in this guidance carefully. Place all information in the order requested in the guidance. If the information is not placed in the requested order, you may receive a lower score.

Be brief, concise, and clear. Make your points understandable. Provide accurate and honest information, including candid accounts of problems and realistic plans to address them. If any required information or data is omitted, explain why. Make sure the information provided in each table, chart, attachment, etc., is consistent with the proposal narrative and information in other tables.

Be organized and logical. Many applications fail to receive a high score because the reviewers cannot follow the thought process of the lead recipient or because parts of the application do not fit together.

Be careful in the use of attachments. Do not use the attachments for information that is required in the body of the application. Be sure to cross-reference all tables and attachments to the appropriate text in the application.

Carefully proofread the application. Misspellings and grammatical errors will impede reviewers in understanding the application. Be sure that page limits are followed. Limit the use of abbreviations and acronyms, and define each one at its first use and periodically throughout application. Make sure you submit your application in final form, without markups.

Print out and carefully review an electronic application to ensure accuracy and completion. When submitting electronically, print out the application before submitting it to ensure appropriate formatting and adherence to page limit requirements. Check to ensure that all attachments are included before sending the application forward.

Ensure that all information is submitted at the same time. We will not consider additional information and/or materials submitted after your initial submission, nor will we accept e-mailed applications or supplemental materials once your application has been received.

Appendix B

Instructions – SF-424, Application for Federal Assistance

This is a standard form required for use as a cover sheet for submission of pre-applications and applications and related information under discretionary programs. Some of the items are required and some are optional at the discretion of the applicant or the federal agency (agency). Required fields on the form are identified with an asterisk (*) and are also specified as "Required" in the instructions below.

Item	Field Name	Information
1.	Type of Submission:	(Required) Select one type of submission in accordance with agency instructions. • Pre-application • Application • Changed/Corrected Application - Check if this submission is to change or correct a previously submitted application. Unless requested by the agency, applicants may not use this form to submit changes after the closing date.
2.	Type of Application:	(Required) Select one type of application in accordance with agency instructions. • New - An application that is being submitted to an agency for the first time. • Continuation - An extension for an additional funding/budget period for a project with a projected completion date. This can include renewals. • Revision - Any change in the federal government's financial obligation or contingent liability from an existing obligation. If a revision, enter the appropriate letter(s). More than one may be selected. If "Other" is selected, please specify in text box provided. A. Increase Award B. Decrease Award C. Increase Duration D. Decrease Duration E. Other (specify)
3.	Date Received:	Leave this field blank. This date will be assigned by the Federal agency.
4.	Applicant Identifier:	Enter the entity identifier assigned by the Federal agency, if any, or the applicant's control number if applicable.
5a.	Federal Entity Identifier:	Enter the number assigned to your organization by the federal agency, if any.
5b.	Federal Award Identifier:	For new applications leave blank. For a continuation or revision to an existing award, enter the previously assigned federal award identifier number. If a changed/corrected application, enter the federal identifier in accordance with agency instructions.

Item	Field Name	Information
6.	Date Received by State:	Leave this field blank. This date will be assigned by the state, if applicable.
7.	State Application Identifier:	Leave this field blank. This identifier will be assigned by the state, if applicable.
8.	Applicant Information:	Enter the following in accordance with agency instructions:
	a. Legal Name:	(Required) Enter the legal name of applicant that will undertake the assistance activity. This is the organization that has registered with the Central Contractor Registry (CCR). Information on registering with CCR may be obtained by visiting www.Grants.gov.
	b. Employer/Taxpayer Number (EIN/TIN):	(Required) Enter the employer or taxpayer identification number (EIN or TIN) as assigned by the Internal Revenue Service. If your organization is not in the US, enter 44-4444444.
	c. Unique Entity Identifier:	(Required) Enter the organization's UEI received from SAM.gov, upon registering. Information on obtaining a UEI may be obtained by visiting https://www.gsa.gov/about-us/organization/federal-acquisition-service/office-of-systems-management/integrated-award-environment-iae/iae-systems-information-kit/unique-entity-identifier-update
	d. Address:	Enter address: Street 1 (Required); city (Required); County/Parish, State (Required if country is US), Province, Country (Required), 9-digit zip/postal code (Required if country US).
	e. Organizational Unit:	Enter the name of the primary organizational unit, department or division that will undertake the assistance activity.
	f. Name and contact information of person to be contacted on matters involving this application:	Enter the first and last name (Required); prefix, middle name, suffix, title. Enter organizational affiliation if affiliated with an organization other than that in 7.a. Telephone number and email (Required); fax number.
9.	Type of Applicant: (Required) Select up to three applicant type(s) in accordance with agency instructions.	A. State Government B. County Government C. City or Township Government D. Special District Government E. Regional Organization F. U.S. Territory or Possession G. Independent School District H. Public/State Controlled Institution of Higher Education I. Indian/Native American Tribal Government (Federally Recognized) J. Indian/Native American Tribal Government (Other than Federally Recognized) K. Indian/Native American Tribally Designated Organization L. Public/Indian Housing M. Nonprofit N. Private Institution of Higher Education O. Individual P. For-Profit Organization (Other than Small Business)

Item	Field Name	Information
		Q. Small Business R. Hispanic-serving Institution S. Historically Black Colleges and Universities (HBCUs) T. Tribally Controlled Colleges and Universities (TCCUs) U. Alaska Native and Native Hawaiian Serving Institutions V. Non-US Entity W. Other (specify)
10.	Name of Federal Agency:	(Required) Enter the name of the federal agency from which assistance is being requested with this application.
11.	Catalog of Federal Domestic Assistance Number/Title:	Enter the Catalog of Federal Domestic Assistance number and title of the program under which assistance is requested, as found in the program announcement, if applicable.
12.	Funding Opportunity Number/Title:	(Required) Enter the Funding Opportunity Number and title of the opportunity under which assistance is requested, as found in the program announcement.
13.	Competition Identification Number/Title:	Enter the competition identification number and title of the competition under which assistance is requested, if applicable.
14.	Areas Affected by Project:	This data element is intended for use only by programs for which the area(s) affected are likely to be different than the place(s) of performance reported on the SF-424 Project/Performance Site Location(s) Form. Add attachment to enter additional areas, if needed.
15.	Descriptive Title of Applicant's Project:	(Required) Enter a brief descriptive title of the project. If appropriate, attach a map showing project location (e.g., construction or real property projects). For pre-applications, attach a summary description of the project.
16.	Congressional Districts Of:	15a. (Required) Enter the applicant's congressional district. 15b. Enter all district(s) affected by the program or project. Enter in the format: 2 characters state abbreviation - 3 characters district number, e.g., CA-005 for California 5th district, CA-012 for California 12 district, NC-103 for North Carolina's 103 district. If all congressional districts in a state are affected, enter "all" for the district number, e.g., MD-all for all congressional districts in Maryland. If nationwide, i.e. all districts within all states are affected, enter US-all. If the program/project is outside the US, enter 00-000. This optional data element is intended for use only by programs for which the area(s) affected are likely to be different than place(s) of performance reported on the SF-424 Project/Performance Site Location(s) Form. Attach an additional list of program/project congressional districts, if needed.
17.	Proposed Project Start and End Dates:	(Required) Enter the proposed start date and end date of the project.
18.	Estimated Funding:	
(Required) Enter the amount requested, or to be contributed during the first funding/budget period by each contributor. Value of in-kind contributions should be included on appropriate lines, as applicable. If the		

Item	Field Name	Information
action will result in a dollar change to an existing award, indicate only the amount of the change. For decreases, enclose the amounts in parentheses. Applicants should review matching principles contained in 45 CFR _art 75 before completing Item 18. All budget information entered under item 18 should cover the upcoming budget period. For sub-item 18a, enter the federal funds being requested. Sub-items 18b-18e is considered matching funds. The dollar amounts entered in sub-items 18b-18f shall total at least *[cite percentage or fraction]* of the amount of federal funds being requested (the amount in 18a). For sub-item 18f, enter only the amount, if any, which is will be used as part of the required match. There are two types of match: 1) non-federal cash and 2) non-federal in-kind. In general, costs borne by the applicant and cash contributions of any and all third parties involved in the project, including sub-recipients, contractors and consultants, are considered matching funds. Generally, most contributions from sub-contractors or sub-recipients (third parties) will be non-federal in-kind matching funds. Volunteered time and use of facilities to hold meetings or conduct project activities may be considered in-kind (third party) donations. Examples of non-federal cash match include budgetary funds provided from the applicant agency's budget for costs associated with the project. ***ONC's Match Requirement – (Sample Language)*** *Under this program, the applicant's match requirement is $1 for every $3 Federal dollars In other words, for every three (3) dollars received in Federal funding, the applicant shall contribute at least one (1) dollar in non-Federal resources toward the project's total cost. This "three-to-one" ratio is reflected in the following formula which you can use to calculate your minimum required match:* *Federal Funds Request/3 = Minimum Match Requirement* *For example, if you request $100,000 in Federal funds, then your minimum match requirement is $100,000/3 or $33,333. In this example the project's total cost would be $133,333.* *If the required non-Federal share is not met by a funded project, ONC will disallow any unmatched Federal dollars.* Indirect charges may only be requested if: (1) the applicant has a current indirect cost rate agreement approved by the Department of Health and Human Services or another federal agency; or (2) the applicant is a state or local government agency. State governments should enter the amount of indirect costs determined in accordance with HHS requirements. If indirect costs are to be included in the application, a copy of the approved indirect cost agreement shall be included with the application. Further, if any sub-contractors or sub-recipients are requesting indirect costs, copies of their indirect cost agreements shall also be included with the application.		
19.	Is Application Subject to Review by State Under Executive Order 12372 Process?	(Required) Applicants should contact the State Single Point of Contact (SPOC) for Federal Executive Order 12372 to determine whether the application is subject to the State intergovernmental review process. Select the appropriate box. If "a." is selected, enter the date the application was submitted to the State.
20.	Is the Applicant Delinquent on any Federal Debt?	(Required) Select the appropriate box. This question applies to the applicant organization, not the person who signs as the authorized

Item	Field Name	Information
		representative. Categories of federal debt include but, may not be limited to: delinquent audit disallowances, loans and taxes. If yes, include an explanation in an attachment.
21.	Authorized Representative:	To be signed and dated by the authorized representative of the applicant organization. Enter the first and last name (Required); prefix, middle name, suffix. Enter title, telephone number, email (Required); and fax number. A copy of the governing body's authorization for you to sign this application as the official representative shall be on file in the applicant's office. (Certain federal agencies may require that this authorization be submitted as part of the application.)

Appendix C

Instructions – SF-424A, Budget Information for Non-Construction Programs

Standard Form 424A is designed to accommodate applications for multiple grant programs; thus, for purposes of this program, many of the budget item columns and rows are not applicable. You should only consider and respond to the budget items for which guidance is provided below. Unless otherwise indicated, the SF 424A should reflect a two-year budget.

Section A Budget Summary
Line 5: Leave columns (c) and (d) blank. Enter TOTAL federal costs in column (e) and total nonfederal costs (including third party in-kind contributions and any program income to be used as part of the recipient match) in column (f). Enter the sum of columns (e) and (f) in column (g).

Section B Budget Categories
Column 3: Enter the breakdown of how you plan to use the federal funds being requested by object class category (see instructions for each object class category below).

Column 4: Enter the breakdown of how you plan to use the non-federal share by object class category.

Column 5: Enter the total funds required for the project (sum of Columns 3 and 4) by object class category.

Separate Budget Narrative/Justification Requirement

You shall submit a separate budget narrative/justification as part of your application. When more than 33% of a project's total budget falls under a contractual expense, a detailed budget narrative/justification shall be provided for each sub-contractor or sub-recipient. Applicants requesting funding for multi-year grant programs are required to provide a combined multi-year budget narrative/justification, as well as a detailed budget narrative/justification for each year of potential grant funding. A separate budget narrative/justification is also required for each potential year of grant funding requested.

In your budget narrative/justification, you should include a breakdown of the budgetary costs for all of the object class categories noted in Section B, across three columns: federal; non-federal cash; and non-federal in-kind. Cost breakdowns, or justifications, are required for any cost of $1,000 or more. The budget narratives/justification should fully explain and justify the costs in each of the major budget items for each of the object class categories, as described below. Non-federal cash as well as, sub-contractor or sub-recipient (third party) in-kind contributions designated as match shall be clearly identified and explained in the budget narrative/justification. The full budget narrative/justification should be included in the application immediately following the SF 424 forms. This should include a budget narrative for the entire period of performance.

Line 6a: Personnel: Enter total costs of salaries and wages of applicant/recipient staff. Do not include the cost of consultants. Consultant costs should be included under 6h, Other. In the budget narrative/justification: Identify the project director, if known. Specify the key staff, their titles, brief summary of project related duties, and the percent of their time commitments to the project in the budget narrative/justification.

Some Points to Consider:

- ♦Is the basis for determining each employee's compensation described (annual salary and % time devoted)?
- ♦Is each position identified by title/responsibility?
- ♦Are time commitments and the amount of compensation stated and reasonable?
- ♦Are salary increases anticipated during the grant period and are they justified (COLA, etc.)?
- ♦Are any personnel costs unallowable?
    - o Dual Compensation
    - o Federal Employee

Line 6b: Fringe Benefits: Enter the total costs of fringe benefits unless treated as part of an approved indirect cost rate. In the justification: Provide a breakdown of amounts and percentages that comprise fringe benefit costs, such as health insurance, FICA, retirement insurance, etc.

Some Points to Consider:

- ♦Is the amount specified as a separate line item?
- ♦Is each type of benefit indicated separately or does the organization have an approved fringe benefit rate?
- ♦Are fringe increases contemplated during the grant period?
- ♦Are any fringe costs unallowable?

Line 6c: Travel: Enter total costs of out-of-town travel (travel requiring per diem) for staff of the project. Do not enter costs for consultant's travel - this should be included in line 6h. In the justification: Include the total number of trips, destinations, purpose, and length of stay, subsistence allowances and transportation costs (including mileage rates).

Line 6d: Equipment: Enter the total costs of all equipment to be acquired by the project. For all recipients, "equipment" is nonexpendable tangible personal property having a useful life of more than one year and an acquisition cost of $5,000 or more per unit. If the item does not meet the $5,000 threshold, include it in your budget under Supplies, line 6e. In the justification: Equipment to be purchased with federal funds shall be justified as necessary for the conduct of the project. The equipment shall be used for project-related functions; the equipment, or a reasonable facsimile, shall not be otherwise available to the applicant or its sub recipients. The justification also shall contain plans for the use or disposal of the equipment after the project ends.

Some Points to Consider:

- ♦Are equipment items specified by unit and cost?
- ♦Is the request reasonable and allowable under the project?
- ♦Does the organization have a procurement policy in place?
- ♦Is a lease vs. purchase study necessary (vehicles, large items of equipment)?
- ♦Are purchases distinguishable from rentals?

Line 6e: Supplies: Enter the total costs of all tangible expendable personal property (supplies) other than those included on line 6d. In the justification: Provide general description of types of items included.

Some Points to Consider**:**

- ♦ Are supplies listed separately?
  - o Office
  - o Training
  - o Research
  - o Other types of supplies
- ♦ How was cost determined?
- ♦ Is the basis for the cost reasonable? Monthly estimates are sufficient
- ♦ Are costs consistently treated?

Line 6f: Contractual: Enter the total costs of all contracts, including (1) procurement contracts (except those, which belong on other lines such as equipment, supplies, etc.). Also include any contracts with organizations for the provision of technical assistance. Do not include payments to individuals or consultants on this line. In the budget narrative/justification attach a list of contractors indicating the name of the organization, the purpose of the contract, and the estimated dollar amount. If the name of the contractor, scope of work, and estimated costs is not available or have not been negotiated, indicate when this information will be available. Whenever the applicant/recipient intends to delegate more than 33% of a project's total budget to the contractual line item, the applicant/recipient shall provide a completed copy of Section B of the SF 424A Budget Categories for each sub-contractor or sub-recipient, and separate budget narrative/justification for each sub-contractor or sub-recipient for each year of potential grant funding.

Some Points to Consider:

- ♦ Is the type of each service to be rendered described?
- ♦ For Consultants/Individuals
  - o Is an hourly, daily or weekly base rate given?
  - o Are rates allowable, justified, reasonable and comparable to market?
- ♦ Is the total amount for any contract in excess of $150,000?
  - o Is procurement method described?

o If the contract is not competitively bid, has a sole source justification been provided?

Note: The competitive process shall be used if goods and services will be provided through a contract (e.g., vendor or consultant). All costs associated with contracts should be included in this category. Sub awards are made to entities carrying out part of the program effort, project, and objectives. Sub awards are to be listed individually in the "Other" cost category.

Line 6g: Construction: Leave blank since construction is not an allowable cost under this program.

Line 6h: Other: Enter the total of all other costs. Such costs, where applicable, may include, but are not limited to: insurance, medical and dental costs (i.e. for project volunteers this is different from personnel fringe benefits); non-contractual fees and travel paid directly to individual consultants; local transportation (all travel which does not require per diem is considered local travel); postage; space and equipment rentals/lease; printing and publication; computer use; training and staff development costs (i.e. registration fees). If a cost does not clearly fit under another category, and it qualifies as an allowable cost, then rest assured this is where it belongs. In the justification: Provide a reasonable

explanation for items in this category. For individual consultants, explain the nature of services provided and the relation to activities in the project. Describe the types of activities for staff development costs.

Some Points to Consider:

- ♦Are items listed by major type (space rental, printing, phone, maintenance, etc.)?
- ♦Are all costs justified, reasonable and allowable?
- ♦Is there a reasonable basis for costs?
- ♦List each sub award and amount of award
- ♦Provide description of activities to be performed
- ♦Describe method used to select the sub award and type of agreement to be awarded
- ♦Provide a separate budget and budget narrative for each sub award

Note: Costs for contractual arrangements (vendors, consultants) should be budgeted in the "Contractual" cost category.

Line 6i: Total Direct Charges: Show the totals of Lines 6a through 6h.

Line 6j: Indirect Charges: Enter the total amount of indirect charges (costs), if any. If no indirect costs are requested, enter "none." Indirect charges may be requested if: (1) the applicant has a current indirect cost rate agreement approved by the Department of Health and Human Services or another federal agency; or (2) the applicant is a state or local government agency.

Budget narrative/justification: State governments should enter the amount of indirect costs determined in accordance with HHS requirements. An applicant that will charge indirect costs to the grant shall enclose a copy of the current indirect cost rate agreement. If any sub-contractors or sub-recipients are requesting indirect costs, copies of their indirect cost agreements shall also be included with the application.

If the applicant organization is in the process of initially developing or renegotiating a rate, it should immediately upon notification that an award will be made, develop a tentative indirect cost rate proposal based on its most recently completed fiscal year in accordance with the principles set forth in the cognizant agency's guidelines for establishing indirect cost rates, and submit it to the cognizant agency. Applicants awaiting approval of their indirect cost proposals may also request indirect costs. It should be noted that when an indirect cost rate is requested, those costs included in the indirect cost pool should not also be charged as direct costs to the grant. Also, if the applicant is requesting a rate which is less than what is allowed under the program, the authorized representative of the applicant organization shall submit a signed acknowledgement that the applicant is accepting a lower rate than allowed.

Line 6k: Total: Enter the total amounts of Lines 6i and 6j.

Line 7: Program Income: As appropriate, include the estimated amount of income, if any, you expect to be generated from this project. Program income shall be used as additional program costs and cannot be used as match (non-federal resource).

Section C Non-Federal Resources **-** Not applicable.

Section D Forecasted Cash Needs **-** Not applicable.

Section E Budget Estimate of Federal Funds Needed for Balance of the Project
Line 20: Section E is relevant for multi-year grant applications, where the project period is 24 months or longer. This section does not apply to grant awards where the project period is less than 17 months.

Section F Other Budget Information
Line 22: Indirect Charges: Enter the type of indirect rate (provisional, predetermined, final or fixed) to be in effect during the funding period, the base to which the rate is applied, and the total indirect costs. Include a copy of your current Indirect Cost Rate Agreement.

Line 23: Remarks: Provide any other comments deemed necessary.

Appendix D

Budget and Narrative Justification Template

SAMPLE BUDGET AND NARRATIVE JUSTIFICATION
FOR COMPLETING SF 424A:

A. Personnel:
An employee of the applying agency whose work is tied to the application

TABLE 1: FEDERAL REQUEST

Position	Name	Annual Salary/Rate	Level of Effort	Cost
Program Director	John Doe	$164,890	10%	$6,489
Project Coordinator	To be selected	$46,276	100%	$46,276
			TOTAL	$52,765

NARRATIVE JUSTIFICATION: Enter a description of the Personnel funds requested and how their use will support the purpose and goals of this proposal. Be sure to describe the role, responsibilities and unique qualifications of each position.

FEDERAL REQUEST (enter in Section B column 1-line 6a of form SF424A): **$52,765**

B. Fringe Benefits:
Fringe benefits may include contributions for social security, employee insurance, pension plans, etc. Only those benefits not included in an organization's indirect cost pool may be shown as direct costs.

List all components of fringe benefits rate

TABLE 2: FEDERAL REQUEST

Component	Rate	Wage	Cost
FICA	7.65%	$52,765	$4,037
Workers Compensation	2.5%	$52,765	$1,319
Insurance	10.5%	$52,765	$5,540
		TOTAL	$10,896

NARRATIVE JUSTIFICATION: Enter a description of the Fringe funds requested, how the rate was determined, and how their use will support the purpose and goals of this proposal.

FEDERAL REQUEST (enter in Section B column 1-line 6b of form SF424A)**: $10,896**

C. Travel:

Explain need for all travel other than that required by this application. The lowest available commercial fares for coach or equivalent accommodations shall be used. Local travel policies prevail.

TABLE 3: FEDERAL REQUEST

Purpose of Travel	Location	Item	Rate	Cost
State HIE Leadership Training	Washington, DC	Airfare	$200/flight x 2 persons	$400
		Hotel	$200/night x 2 persons x 3 nights	$1200
		Per Diem (meals)	$64/day x 2 persons x 3 days	$384
State HIE Forum	Chicago, IL	Airfare	$200/flight x 2 persons	$400
		Hotel	$140/night x 2 persons x 3 nights	$840
		Per Diem (meals)	$49/day x 2 persons x 4 days	$392
Sate Travel		Airfare	$200/flight x 2 persons	$400
		Hotel	$200/night x 2 persons x 2 nights	$800
		Per Diem (meals)	$64/day x 2 persons x 3 days	$384
Local Travel		Mileage	3,000 miles@.38/mile	$1,140
			TOTAL	$6,340

NARRATIVE JUSTIFICATION: Describe the purpose of travel and how costs were determined.

The grant requires travel of two members to attend the two-day State HIE Leadership Training in Washington, DC. also required to send two members to Chicago, IL for a two-day State HIE Forum. In addition to the required trainings, funds for local travel are needed to attend local meetings, project activities, and training events. Local travel rate is based on agency's personally owned vehicle (POV) reimbursement rate at 50 cent a mile.

FEDERAL REQUEST (enter in Section B column 1-line 6c of form SF424A): **$6,340**

D. Equipment:
Permanent equipment is defined as nonexpendable personal property having a useful life of more than one year and an acquisition cost of $5,000 or more.

If applicant agency defines "equipment" at lower rate, then follow the applying agency's policy.

TABLE 4: FEDERAL REQUEST

Item(s)	Rate	Cost
None		0
	TOTAL	

NARRATIVE JUSTIFICATION: Enter a description of the Equipment and how its purchase will support the purpose and goals of this proposal.

FEDERAL REQUEST (enter in Section B column 1-line 6d of form SF424A): **$ 0**

E. Supplies: Materials costing less than $5,000 per unit and often having one-time use

TABLE 5: FEDERAL REQUEST

Item(s)	Rate	Cost
General office supplies	$50/mo. x 12 mo.	$600
Postage	$37/mo. x 8 mo.	$296
Laptop Computer	$900	$900
Printer	$300	$300
Projector	$900	$900
Copies	8000 copies x .10/copy	$800
Computer update (if needed)		$250
	TOTAL	$4,046

NARRATIVE JUSTIFICATION: Enter a description of the Supplies requested and how their purchase will support the purpose and goals of this proposal.

FEDERAL REQUEST (enter in Section B column 1-line 6e of form SF424A): **$4,046**

F. Contract:
The costs of project activities to be undertaken by a third-party contractor should be included in this category as a single line item charge. A complete itemization of the cost comprising the charge should be attached to the budget. If there is more than one contractor, each shall be budgeted separately and shall have an attached itemization.

A contract is generally the amount paid to non-employees for services or products. A consultant is a non-employee who provides advice and expertise in a specific program area.

TABLE 6: FEDERAL REQUEST

Name	Item	Cost
1. To be selected	Environmental Strategy Consultation Rate is $150/day for 35 days = $5,250 Travel 500 miles @ .38/mile = $190	$5,440
2. To be selected	Media 1.5-minute Public Service Announcement (PSA)	$3,000
3. To be selected	Evaluation Report	$4,500
4. To be selected	Training for Staff members Trainers: rate is $300/day for 4 days = $1,200 Materials: approx. $5/person X 25 people = $125 Room Rental = $75 Travel for Trainers = Flight $300/person X 2 people = $600 Per Diem - $46/day x 4 days x 2 people = $368	$2,368
5. To be selected	Data Analysis	$1,800

Name	Item	Cost
6. To be selected	Responsible Server Training Trainer: rate $500/day	$500
7. To be selected	Television advertising to run ads 5x/week x $50/ad X 52 wks.	$13,000
	TOTAL	$30,608

NARRATIVE JUSTIFICATION: Explain the need for each agreement and how their use will support the purpose and goals of this proposal. For those contracts already arranged, please provide the proposed categorical budgets. For those subcontracts that have not been arranged, please provide the expected Statement of Work, Period of Performance and how the proposed costs were estimated and the type of contract (bid, sole source…etc.)

FEDERAL REQUEST (enter in Section B column 1-line 6f of form SF424A): **$30,608**

G. Construction: NOT ALLOWED
On your SF424A, leave the following section blank: Section B, columns 1 & 2, line 6g

H. Other: Expenses not covered in any of the previous budget categories

TABLE 7: FEDERAL REQUEST

Item	Rate	Cost
1. Rent	$500/mo x 12 mo.	$6,000
2. Telephone	$100/mo. x 12 mo.	$1,200
3. Student Surveys	$1/survey x 2784	$2,784
4. Brochures	.89/brochure X 1500 brochures	$1,335
5. Web Service	$100/mo x 12 mo	$1,200
	TOTAL	$15,819

NARRATIVE JUSTIFICATION: Explain the need for each item and how their use will support the purpose and goals of this proposal. Be sure to break down costs into cost/unit: i.e. cost/square foot and explain the use of each item requested.

FEDERAL REQUEST (enter in Section B column 1, line 6h of form SF424A): **$15,819**

TOTAL DIRECT COSTS:
FEDERAL REQUEST (enter in Section B column 1, line 6i of form SF424A): **$120,474**

TOTAL INDIRECT COSTS:
FEDERAL REQUEST (enter in Section B column 1, line 6j of form SF424A): **$4,526**

TOTAL PROJECT COSTS: Sum of Total Direct Costs and Indirect Costs
FEDERAL REQUEST (enter in Section B column 1, line 6k of form SF424A): **$125,000**

TABLE 8: BUDGET SUMMARY

Category	Federal Request	Total
Personnel	$52,765	$52,765
Fringe	$10,896	$10,896
Travel	$6,340	$6,340
Equipment	0	0
Supplies	$4,046	$4,046
Contractual	$30,608	$30,608
Other	$15,819	$15,819
Total Direct Costs*	$120,474	$120,474
Indirect Costs	$4,526	$4,526
Total Project Costs	$125,000	$125,000

Appendix E

Letter of Commitment Template

Jane Jones
National Coordinator for Health Information Technology
Department of Health and Human Services
330 C. Street, 7th Floor, Office 7009A, S.W.
Washington, DC 20201

Date

Dear Ms. Jones,
(Name of organization/group submitting the letter) is very interested in addressing (insert the issue being addressed by the grant application) and (state why the issue is a concern).

(State knowledge of proposal, knowledge of agency submitting proposal, and encouragement of funding entity to provide resources to address issue identified above).

(State that the need to address the issue is significant and how other resources to address the need are insufficient to address or impact the need).

(Specifically state how your organization will support this project-through assistance with meeting matching requirements, board/commission participation, advocacy etc.).

(Describe your capacity and resources to produce required deliverables or services for the applicant)

(State how the organization will coordinate with appropriate partners to ensure efficient and effective use of grant funds).

(Conclude with general statement of confidence in and support for the organization seeking assistance, based on past experience with the applicant entity, reputation for effectiveness).

(Provide the following information for the point of contact in the supporting organization).
Name
Title
Agency
Division (if applicable)
State
Address
Phone
Fax Number
Email