

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**

Application Due Date: [08/17/2018]

Anticipated Award Date: [09/19/2018]

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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 inhibiting the development, use, and/or advancement of well-designed, interoperable health IT, which is scalable across the health care industry. Solutions are expected to further a new generation of health IT research and inform the development, implementation, and refinement of standards, methods, and techniques for overcoming major barriers and challenges in an innovative fashion as they are identified. It is critical that the field of health care innovate and leverage the latest technological advancements and breakthroughs far quicker than it currently does to optimize real-time solutions, especially in areas which are ripe for acceleration.

This funding opportunity is specifically interested in innovative solutions and breakthrough advances in the following areas of interest:

- Expanding the scope, scale, and utility of population-level data-focused application programming interfaces (APIs); and
- Advancing clinical knowledge at the point of care.

ONC anticipates issuing one award per area of interest (for a total of 2 recipients), up to \$1 Million per recipient (for a total of up to \$2 Million in funding in fiscal year 2018). These awards will have a 2-year project and budget period at initial award. However, applicants are encouraged to submit their responses based on a 5-year project and budget period. Additional funding for out years 3-5 may be provided; contingent on availability of funds and meaningful progress.

This funding opportunity will have a 3-year open application period. ONC may issue future awards under this NOFO to other eligible applicants for future priority areas of interest. This is contingent on the availability of funds and ONC priorities.

A. Funding Opportunity Description

1. Background

The Office of the National Coordinator for Health Information Technology (ONC) is the principal federal entity charged with coordination of nationwide efforts to implement and use the most advanced health IT and the electronic exchange of health information. Created in 2004 through Executive Order 13335¹ and statutorily authorized by the Health Information Technology for Economic and Clinical Health (HITECH) Act of 2009, ONC is at the forefront of the federal government's health IT efforts and is a resource to the entire health system to support the adoption of health IT and the promotion of nationwide health information exchange to improve health care.

In 2010, through the HITECH Act, ONC created the Strategic Health Information Technology Advanced Research Projects (SHARP) cooperative agreement program² to close the gap between the promise of health IT and its realized benefits. Specifically, SHARP funded projects to create a more robust research infrastructure, achieve breakthrough advances needed to address well-documented problems that have impeded the adoption of health IT, and accelerate progress towards achieving nationwide use of health IT in support of a high-performing health care system.

Since then, the health care ecosystem and technology supporting it have rapidly evolved. More providers than ever have implemented electronic health record (EHR) systems³ 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 7 International (HL7®)'s Fast Healthcare Interoperability Resources (FHIR®)⁴ and APIs are making it easier for consumers to seamlessly access and share their health data with providers and for health systems to integrate disparate data sources.

Passage of the 21st Century Cures Act⁵ (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 of using EHRs.

While working to implement Cures Act provisions, ONC has identified gaps with respect to leveraging EHR data to support population-level analyses and services as well as integrating clinical knowledge into routine clinical practice.⁶ The reasons for these gaps range from data standards and interoperability, and digitization, integration, and presentation of new evidence into clinical workflows in safe, useful, and useable ways. These challenges could compound as we move into the era of precision medicine - defined by an ever-growing corpus of data and findings.

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 health care delivery system by:

- Exploring and defining fundamental research questions within an identified set of high-priority

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 Stat. 130 (December 13, 2016).

⁶ https://www.healthit.gov/sites/default/files/jsr-17-task-002_aiforhealthandhealthcare12122017.pdf

areas; answers to these research questions will address barriers to the nationwide electronic exchange and use of health information in a secure, private, and accurate manner;

- Providing opportunities for relevant academic and industrial researchers, health IT developers and implementers, health care providers and delivery system researchers, and other stakeholders to cooperate for the purpose of stimulating innovation and incorporating the results of research into health IT products;
- Creating breakthrough approaches, prototype(s), and/or enhancements, which may be applied in health IT in the near- and long-term, and which address identified challenges and opportunities relevant to the use of health IT;
- Identifying a range of approaches that serve as motivating and unifying forces to drive fundamental research in health IT; and
- Encouraging effective use of health IT through rapid dissemination of findings on innovations to developers and purchasers of health IT.

Taken together, these activities will significantly enhance the performance of health IT solutions to support care and research.

2. Purpose

Through the proliferation of new methods and advanced solution that are scalable across the health care industry, this funding opportunity will address well-documented and fast emerging challenges which inhibit the development, use, and/or advancement of well-designed, interoperable health IT.

New approaches are expected to further a new generation of health IT development and inform the implementation and refinement of standards, methods, and techniques for overcoming major barriers and challenges in an innovative fashion as they are identified. It is critical that the field of health care innovate and leverage the latest technological advancements and breakthroughs far quicker than it currently does to optimize real-time solutions, especially in areas which are ripe for acceleration.

This funding opportunity is specifically interested in innovative solutions and breakthrough advances in the following areas of interest:

- Expanding the scope, scale, and utility of population-level data-focused APIs; and
- Advancing clinical knowledge at the point of care.

ONC anticipates issuing one award per area of interest (for a total of 2 recipients), up to \$1Million per recipient (for a total of up to \$2Million in funding in fiscal year 2018). These awards will have a 2-year project and budget period at initial award. However, applicants are encouraged to submit their responses based on a 5-year project and budget period. Additional funding for out years 3-5 may be provided; contingent on availability of funds and meaningful progress.

This funding opportunity will have a 3-year open application period. ONC may issue future awards under this NOFO to other eligible applicants for future priority areas of interest. This will be contingent on the availability of funds and ONC priorities.

3. Approach

ONC expects to award two cooperative agreements to support establishment of LEAP in Health IT, each

for a project period of 2 years. Each recipient will 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. Each recipient will implement a cooperative, inter-disciplinary research project addressing one of the specific areas of interest listed below.

Areas of Interest

The two areas of interest identified below will be addressed by this NOFO. The areas 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 were identified as critical areas of investigation, presenting both short-term and long-term opportunities for study and innovation.

Area 1. Expanding the scope, scale, and utility of population-level data-focused APIs

The rapid adoption of EHRs over the past several years has resulted in an ever-expanding amount of digitally available data on patients. Yet at the same time, the ease of getting data out of EHRs to inform population-level analyses (such as quality measurement by providers for their own use and assessments by payors and registries) has proven difficult. As such, there is a growing interest in the health IT community to use standardized, FHIR-based APIs to support the availability of and access to defined groups of patient data.⁷

More specifically, the goal of this area of interest is for the recipient to discover and document the limitations of existing FHIR, data format, and associated security specifications designed to support population-level services; propose enhancements to such specifications in consultation with relevant standards development organizations; and test the feasibility of such enhancements by developing of one or more working prototypes. After receiving ONC's approval, these prototypes will be made publically accessible by the recipient upon completion at no cost to the general public. Further, the recipient will also need to assess the expected legal and policy landscapes in which these population services would be deployed and determine whether any such legal and policy limits would need be factored into the technology capabilities to make it easier for future users to configure/tailor their technology to applicable compliance requirements. In so doing, the recipient is expected to focus on specific objectives:

1. Reducing provider burdens associated with reporting through this technology;
2. Investigating and assessing trade-offs associated with various big data formats; and
3. Technical and legal/policy challenges to the scope and scale of FHIR-based APIs for these purposes.

Objective One envisions a future where health care providers can simply use their health IT for clinical care without the need to proactively “report” to any organization or program. Instead, via population-level API services, health care providers would be empowered to enable entities to connect their health IT to query the applicable data that would have otherwise been reported. Thus, the recipient will focus on how to fundamentally transform the current “provider reports to...” paradigm. The recipient will demonstrate through one or more working prototypes that this could be accomplished and how the applicable scope(s) of data for different requestors can be limited/compartimentalized. Ultimately, this kind of “reporting” could prove to be a valuable option in the future to help providers avoid having to invest resources to specially develop reports for the myriad of external entities to whom they must report. Examples of such reporting include, but are not limited to, federal government programs, state programs, health insurers, and accreditors.

⁷ <https://www.healthit.gov/topic/interoperability/population-level-data-export-meeting-report>

For Objectives Two and Three, the recipient will need to research and evaluate what an ideal state and functionality set would entail in the health care setting. The current state of population health APIs (as described in more detail below) has evolved in conjunction with the development of APIs that apply to single patients. However, an entirely new approach untethered from the needs of single-patient data has been identified only to a limited extent, and would provide a new, more appropriate target state. Further, the scope, scale, speed, and practical and engineering limits of FHIR-based APIs handling massive data sets has not yet been fully explored. Thus, the recipient will investigate various approaches to the population-level services FHIR APIs that explores how current and future FHIR-based APIs could lead to the ideal state identified in objective one as well as the legal/policy paradigms that could impact the scope of data that is accessible.

Before tackling the stated three primary objectives, the recipient will familiarize itself with the current state of the larger landscape of population health APIs. However, considering the resources cited within this NOFO, a full environmental scan is unnecessary. Instead, the recipient will assess the current limitations of existing technology and the pros and cons of the current alternatives.

Population health API – current state

While FHIR-based APIs allow access to data from multiple patients at a time, most of the implementations are constrained to single-patient access and typically require human-mediated login.

Providers and organizations accountable for managing the health of large numbers of patients often need to efficiently access large amounts of information on a group of patients in order to calculate, for example, quality measures for reporting to payer organizations. This is often done as a custom software solution for each type of data access need, which perpetuates inefficiencies for health IT developers and yields substantial costs to health care providers and inefficiencies.

The health IT stakeholder community recognized the need to provide a more efficient population-level API service based on the FHIR standard and has developed a draft specification, the FHIR Bulk Data Export API Proposal,⁸ to support access and transfer of large amounts of data on groups of individuals in a scalable and secure manner. The draft specification is currently being piloted in environments using test data.

The draft specification currently supports asynchronous generation of data files for all patients or groups of patients contained in the FHIR server. The specification also contains APIs for only accessing data updated after a certain period and limiting the types of data that are primarily designed to make the APIs run efficiently and reduce infrastructure load. However, there have not been large scale efforts carried out to test that the APIs would work as designed in a production setting.

The use of the ndjson⁹ data format, which separates data into multiple files based on FHIR resources, is also an area for potential enhancement. While these changes were geared towards use of modern computational techniques such as parallel computing and the MapReduce¹⁰ programming model, more analysis is needed to ensure that the data formats and file structures would indeed provide sufficient efficiencies for big data analytics.

⁸ <https://github.com/smart-on-fhir/fhir-bulk-data-docs>

⁹ <http://ndjson.org/>

¹⁰ <https://en.wikipedia.org/wiki/MapReduce>

Finally, the security model that has been developed for the use of the population-level API is based on a profile of OAuth2, called “SMART Backend Services: Authorization Guide”.¹¹ It uses public key infrastructure (PKI) and JSON Web Tokens (JWT)¹² as a means of providing access to the API. While the underlying security model is based on a robust industry standards, the security technologies have not undergone sufficient testing to support large scale adoption.

Area 2. Advancing clinical knowledge at the point of care

The volume and rate at which new clinical evidence is produced is difficult for clinicians to stay abreast of and implement into clinical practice to deliver effective care.¹³ The expectation that this will increase in size and complexity with the advent of precision medicine only intensifies the need for new, innovative health IT solutions and approaches for integrating evidence in an easy to use and useful way to deliver clinical knowledge at the point of care. The goal of this area of interest is to advance clinical knowledge into the health care setting via innovative health IT tools and approaches. More specifically:

- Researching and identifying new methods to create resources or tools that will, through their incorporation into deployed technology(ies), enhance delivery of new evidence into practice, while understanding: end-user needs, workflows, data integration, and data-visualization and cognitive support. In doing so, the recipient under this area of interest will, in critical areas, close the gap between the promise of data-driven infrastructure supporting clinical knowledge precision medicine, and health IT, and its realized benefits.
- Supporting a data-driven infrastructure for improving optimal patient-specific models for improving diagnoses, interventions and outcomes that are accurate, objective, and reliable.
- Implementing new techniques and methods to incorporate and synthesize disparate but relevant data streams and evidence to advance clinical knowledge at the point of care that are accurate, objective, and reliable.

This area of interest has the following four objectives:

1. Emerging Innovations in Clinical Medicine

Investigate new and emerging methods to create data-driven resources or tools necessary to advance evidence delivery to inform clinical knowledge at the point of care. Explore the gaps and barriers inhibiting innovative approaches from advancing evidence via data-driven resources and tools to support clinical knowledge at the point of care.

Investigate clinicians from diverse care settings and backgrounds to learn what would legitimately improve their point of care decision-making using data driven tools and approaches, while considering workflows and end-user design.

2. Data-driven Medicine Infrastructure

Investigate approaches to create high quality training data sets that enable advanced analytics—clinical data combined with other data types, which are contextually relevant

¹¹ <https://github.com/smart-on-fhir/fhir-bulk-data-docs/blob/master/authorization.md>

¹² <https://tools.ietf.org/html/rfc7523>

¹³ Bastian H, Glasziou P, Chalmers I. Seventy-five trials and eleven systematic reviews a day: how will we ever keep up? PLoS Med2010;7:e1000326

and are accurate, objective, and reliable.

- Investigate testing and validation approaches for advanced data science algorithms to evaluate performance of the algorithms under conditions that differ from the training set.
- Consider approaches to ensure privacy and transparency of data use.
- Support research to characterize the tradeoffs between data quality, information content (complexity and diversity) and sample size, with the goal of enabling quantitative prediction of the quantity and quality of data needed to support a given application.

Investigate and develop data infrastructures and standards necessary to extrapolate clinical and/or contextually relevant data to be leveraged by health IT tools and capabilities:

- Clinically relevant data can include but are not limited to:
 - Electronic health record data
 - Laboratory results
 - Genomic information
 - Medical images
 - Prescription information
 - Claims data
- Contextual relevant data derived from the patient can include but are not limited to:
 - Data from wearables, medical devices, smart devices, or sensors
 - Patient reported outcomes

Investigate protocols and IT capabilities to collect and integrate diverse data sets.

Investigate, develop, adopt, and demonstrate transparent processes and policies to ensure reproducibility for large-scale computational models.

Investigate and develop data infrastructures to capture and integrate data generated from smart devices, such as wearables and support advanced data science applications.

3. Integrating Knowledge at Point of Care

Utilize innovative tools and methods to rapidly synthesize disparate but relevant data and evidence into the point of care that is innovative and usable, while taking into account the needs of end-users, workflows, cognitive support, data-integration barriers, and enhanced data visualization requirements;

- Clinically relevant data can include but are not limited to:
 - Electronic health record data
 - Laboratory results
 - Genomic information
 - Medical images
 - Prescription information

- Claims data
- Contextual relevant data derived from the patient can include but are not limited to:
 - Data from wearables, medical devices, smart devices, or sensors
 - Patient reported outcomes

4. *Legal and Policy Implications for Innovative Approaches*

Assess the expected legal and policy landscapes in which these approaches would be deployed and determine whether any such legal and policy limits would need to be factored into the technology capabilities.

4. Project Activities

Within each area of interest, each project will carry out at least the following set of activities:

- Initially define and subsequently update or redefine on a yearly basis, the key issues and challenges within their respective area of interest. The issues and challenges identified will be those that significantly address barriers and solutions to the use of health IT. Projects to address the identified issues and challenges will be mapped via their project plan to either a short-term (2 year) and/or long-term (3-5 year) timeframe if out years are proposed. Because this is a cooperative agreement, recipients will plan and allow for collaboration with ONC and other federal staff with relevant expertise – as identified or approved by ONC – in establishing and updating the definition of key issues and challenges in the project’s area of interest;
- Conduct ambitious research addressing these key issues and challenges. This work will draw on the scientific methods and expertise of researchers and practitioners in diverse fields;
- Collect specific, uniform data about the project activities and track progress toward milestones;
- Facilitate practical and efficient processes that enable translation of project outputs into health care, facilitating the transition of multidisciplinary research outcomes into new health care products and services both the short- and long-term;
- Publish and otherwise disseminate these project findings to maximize the accessibility of this knowledge to the entire health IT community; and
- Select desired, measurable outcomes specific to the chosen research issues and challenges for attaining results.

In addition, applicants will provide a draft project plan, as an appendix to the application, with corresponding table of key dates and milestones to ensure objectives are met within the self-contained 2-year period. Recipients will also conduct virtual mid-point demonstrations/update of any proposed approaches, prototype(s), and/or enhancements to illustrate their progress on the selected area of interest.

Deliverable Table

For each area of interest, applicants will provide a table that consists of expected deliverables which will be produced in support of execution of the cooperative agreement and the due date by which they s will be delivered to ONC.

No.	Deliverable	Due Date
1	Draft Project Plan and Timeline <i>The recipient will submit a detailed draft project plan, that should include (but is not limited to), key milestones, identified risks and risk mitigation strategies, stakeholder</i>	NLT 1 month after award date

No.	Deliverable	Due Date
1 cont.	<i>coordination (as applicable), and timeline.</i>	
2	Mid-point demonstration/update of proposed approach, prototype(s), and/or enhancements <i>The recipient will provide ONC with a live, virtual demonstration of their project progress to-date</i>	NLT 13 months after award date
3	Mid-point specification revisions revised project plan and timeline (as applicable) <i>Based on milestone and project progress up to the mid-point, in addition to feedback from ONC from the mid-point demonstration, the recipient will submit a revised project plan and timeline and initiate any specification revisions as applicable.</i>	NLT 1 month after completion of deliverable 2
4	Draft legal and policy landscape assessment <i>The recipient will submit a draft assessment that addresses the impact of legal and policy factors on project goals</i>	NLT 20 months after award date
5	Final legal and policy landscape assessment <i>The recipient will submit a final assessment that addresses impact of legal and policy factors on project goals</i>	NLT 22 months after award date
6	Submission of final approach and if applicable, prototype(s) (i.e., computer software, including all associated code and tools), and/or enhancements, as well as making prototypes publically accessible for approval by ONC.	NLT 23 months after award date

5. Performance Goals and Milestones

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

ONC's evaluations will assess project performance and progress towards the key milestones specified below.

Potential questions for each area of interest might include, but will not be limited to, the following:

- To what extent do the project issues being pursued relate to challenges along pathway towards innovative use?
- How effective are the methods used to accelerate translation of research into health care?
- To what extent has the project identified the salient, potentially breakthrough challenges?
- What problems have been encountered in implementing all of the required features of the project?
- What relationships, as appropriate, has the project established with industry to facilitate the translation of the research?

The key project milestones include:

- Developing an initial 2-year project plan, delineating components that will complete in 2 years, as well as longer term components if proposed;
- Establishing a technical expert panel to review research methods, results, and provide guidance;
- Implementing the plan to translate project outcomes into broader uptake;
- Scheduling and conducting (as appropriate) and participating in expert panel meetings, team meetings and stakeholder meetings;
- Conducting and managing project to conclusion in 2 years;
- Conducting and managing the long-term projects to significant, demonstrable progress in out years, if awarded; and
- Communicating findings through appropriate mechanisms and making available as they are generated.

Area 1: Expanding the scope, scale, and utility of population-level data-focused APIs

ONC is seeking innovative solutions and enhancements to the currently specified population-level FHIR API approach. Such solutions will need to address ways to reduce provider reporting burden and the use of population-level FHIR-based API services at scale. Recipient's demonstrated and communicated progress through detailed quarterly reports and monthly check-ins will determine fund drawdowns. Recipients will work towards all three objectives identified above for this area.

Area 2: Advancing Clinical Knowledge at the Point of Care

ONC is seeking innovative health IT approaches to advance clinical knowledge into the health care setting. Recipient's demonstrated and communicated progress through detailed quarterly reports and monthly check-ins will determine fund drawdowns. Recipients will work towards all four objectives identified above for this area.

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* - A cooperative agreement is a support mechanism used when there will be substantial Federal Involvement.

Application Type: *New*

Funding Opportunity Number: *NAP-AX-18-003*

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 health care 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 must 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, 2018, Pub. L. 115-141, Division H, Title II

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

Anticipated Number of Awards: Two (*one per area of interest*)

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

Project Period: *09/19/2018 to 09/18/2023*

Budget Period(s):

09/19/2018 to 09/18/2020

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 3-year open application period, where 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 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.

Cost-Sharing Requirements: There are no cost sharing requirements associated with this award.

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 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 project, 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. If program income is generated, ONC recipients must use the additive method.

Costs paid by program income generally are subject to the applicable cost principles and other Federal requirements and must be disbursed for project 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 must be returned to ONC.

Intergovernmental Review: This project is *excluded* from Executive Order 12372

Key Dates

Milestone	Date
NOFO Released	06/29/2018
Informational Session	07/12/2018
Letter of Intent Due	07/19/2018
Applications Due	08/17/2018
Anticipated Award Date	09/19/2018
Anticipated Project Start Date	09/19/2018

Roles and Responsibilities Under a Cooperative Agreement

The funding instrument used for this funding opportunity 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 work cooperatively with each recipient; 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.

Specific tasks and activities may be shared between the recipient and ONC include, but not limited to:

- ◆ *participating in the selection of key personnel*
- ◆ *releasing funds based on achievement of performance goals/project milestones*
- ◆ *agency review and approval of substantive provisions of proposed subawards or contracts*

- ◆ *reviewing deliverables or other grant products*
- ◆ *selecting technical expert panel members*
- ◆ *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*

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
- 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://www.healthit.gov/topic/onc-funding-opportunities/leading-edge-acceleration-projects-leap-notice-funding-opportunity>

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 no later than 3 days prior to the call.

Letter of Intent

Although not required, applicants are strongly encouraged to submit a non-binding e-mail notice of intent to apply for this funding opportunity. This letter of intent will assist ONC in planning for the application review process. When submitting your letter of intent, please identify which area of interest your organization plans to apply for.

The letter of Intent is requested by 11:59 P.M. Eastern Standard Time on **July 17, 2018**, and should be sent to ONC-LEAP@hhs.gov. The letter 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.

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
- 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 must 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 must 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 provides the most substantive information regarding the proposed project in a clear and concise manner. To that end, the project narrative should address the elements articulated in the Funding Opportunity Description section of this NOFO. The project narrative should also align with the Performance Goals and Milestones, and Merit Review Evaluation criteria presented in this NOFO.

The Project Narrative must 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. 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, if requested, are not counted as part of the Project Narrative and are not included in the 35-page limit. Pages must be numbered.

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

1. Area of Interest, Vision Statement, and Key Challenges (2-3 pages)
2. Proposed Approach (10-14 pages)
3. Project Team (2-3 pages, exclusive of biosketches)
4. Plan for Disseminating and Transitioning Appropriate Research Results into Practice (2-3 pages)
5. Stakeholder Coordination (2-3 pages)
6. Project Management (3-5 pages, exclusive of project timeline and organizational chart)
7. Organizational Capability (2-4pages)

- 1. Area of Interest, Vision Statement, and Key Challenges.** This section should offer the applicant's conceptualization of the selected area of interest. This should also 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 self-contained project period (2 years) and challenges requiring longer (3-5 years). Applicants must clearly state which area of interest of interest the proposed project will address. (2-3 pages).
- 2. Proposed Approach.** 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 in the area of interest and how to advance the field via proposed activities to meet the objectives of the of that specific area of interest. This section should be organized so that the relationship of each element of the plan to each of the areas objectives and associated activities are completely clear. The development or employing of novel concepts, approaches, methodologies, tools, or technologies; or combination of common research elements in an innovative fashion should be described and how it will generate much-needed insight to 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 objective being addressed should be described as a discrete activity, and each activity should have a separately itemized budget as described below. Each activity must be clearly identified as having a self-contained aim (2 year) and as appropriate long-term (3-5 year) aims delineated for each objective. While the applicant institution and sub-recipients may undertake activities that exclusively involve personnel at their own institutions, the integration and cohesiveness of the project will be enhanced by activities on which personnel from multiple projects directly collaborate.

The approach should include as much detail as possible given the page limitation. Notwithstanding, the plan for each activity, at a minimum, **must 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 area of interest being addressed; 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” section described below.

Applications should justify their arguments through reliance on 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, the narrative might state the number of citations that support the assertion and then include in the citation list only the most important exemplars.

All key personnel mentioned in this section must have biosketches (<https://grants.nih.gov/grants/forms/biosketch-blankformat.docx>) provided in a separate section of the application. (10-14 pages)

3. Project Team

- 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 scientist, human factors professionals, and health informatics. 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 grant. If less time is allocated, an explicit justification of the lower level of effort must be included.
- At least one person on the proposed research team must possess health IT expertise.
- For Area of Interest 1: Expanding the scope, scale, and utility of population-level data- focused APIs.
 - Does the proposed research team have expertise in the following areas:
 - Data standards development and balloting expertise
 - API development and EHR integration expertise
- For Area of Interest 2: Advancing clinical knowledge at the point of care
 - Does the proposed research team have expertise in the following areas:
 - User-Centered Design
 - Data Visualization
 - Cognitive Support
- Multidisciplinary research teams are strongly encouraged, as appropriate, to conduct the project and associated activities.
- The application should include a biosketch, utilizing the template found here: <https://grants.nih.gov/grants/forms/biosketch-blankformat.docx> for key project personnel, including all key personnel who will participate in the project’s work.
 - Project team members must describe their proposed role and why their experience and qualifications make them well-suited for this role in the “Personal Statement” section of their biographical sketch. Include only relevant or similar past and current projects as it relates to the area of interest.

- Biosketch for each should not exceed 5 pages in length. These will not count towards the page limit.
- For proposed research team members for whom biosketches are not required, NOFO applications must describe their proposed role and why their experience and qualifications make them well-suited for this role in the in the Budget Justification. (2-3 pages)

- 4. Plan for Disseminating and Transitioning Appropriate Research Results into Practice.** This section should describe a plan for engaging health IT stakeholders and interested groups in promoting the dissemination and transition of appropriate research activities and results into data standards, data infrastructures, health IT products, tools, and best practices. The plan should be specific in proposing activities that will disseminate and transition the results of the proposed self-contained (2 year) projects in products and best practices. Collaborative arrangements with industry and other groups outside the applicant institution should be accompanied by appropriate letters of support. (2-3 pages)

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 publically available and acceptable domain at no cost to the general public.

- 5. 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)
- 6. 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 sub-recipients with contractual relationships, plans for coordinating research activities across multiple organizations should be described. This section should specify who would have day-to-day responsibility for key tasks such as: leadership of project; monitoring the project's on-going progress, preparation of reports; communications with other collaborating organizations, and ONC. Recipients will be required to maintain information relevant to achieving proposed milestones 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 milestones. The application should include a detailed project timeline as an appendix that incorporates those milestones. The project timeline will not count towards the narrative page limit. It 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)
- 7. Organizational Capability Statement.** For the area of interest being addressed the application should include an organizational capability statement.

The statement should outline the established research project relevant to the area of interest and highlight established collaborative relationships with health care stakeholders including, but not limited to, other academic and research institutions, health care providers, payors, consumers and end-users, local/state governments, and health IT developers and innovators within the health care industry, standards development organizations, and new emerging and innovative fields intersecting with health care. Note that the definition of IT products, vendors and organizations should be considered in the broadest possible sense and does not exclude those related to technologies

developed in non-commercial settings or those meant to be distributed as part of an open-source technology platform. Applicants are strongly encouraged to propose development of technology using open-source approaches and release the outcomes of their research into open-source communities.

The statement should highlight potential strategies the organization may employ in an effort to sustain research efforts beyond the scope of the project timeframe.

Include the relevant organizational resources available to perform the proposed project (e.g., facilities, equipment, and other resources). The statement should also highlight capabilities of the applicant not included in the project narrative, such as any current or previous relevant experience and/or the record of the project team in preparing cogent and useful reports, publications, research studies and other products. Also 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 must also provide letters of commitment from them. The letters of commitment shall be included with the appendices and will not count towards the 35-page limit. (2-4 pages)

Letters of Commitment from Key Participating Organizations and Agencies

Include confirmation of the commitments to the project (should it be funded) made by key collaborating organizations and agencies in this part of the application. Any organization that is specifically named to have a significant role in carrying out the project should be considered an essential collaborator. Signed letters of commitment should be scanned and included as attachments. In your transmission, be sure to include the funding opportunity number and your organization's name.

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 or all of 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 must be allowable, allocable, reasonable and necessary.

Form SF-424B, Assurances for Non-Construction Programs

This form contains laws and other assurances applicants must 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 must 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 must 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 must 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 must 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 (If Applicable)

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 must 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 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 must 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 must 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 must also be included with the application.

Application Submission Instructions

- 1) You must access the electronic application for this project via <http://www.grants.gov>. You can search the downloadable application page by the Notice of Funding Opportunity Number [NAP-AX-18-003](#)
- 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 must have a Dun and Bradstreet (D&B) Data Universal Numbering System (DUNS) number. A DUNS number can be obtained via <http://fedgov.dnb.com/webform> and typically takes 1 to 2 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 must be registered in the System for Award Management (SAM), at sam.gov, which requires having a DUNS number. The SAM registration process takes 7 to 10 business days so please plan accordingly. If you have already registered with 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 must 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 must 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 11:59 P.M. Eastern Standard Time on August 17, 2018. Applications that fail to meet the application deadline will not be reviewed and will receive no further consideration.

Restrictions on Oral Conversations

This funding announcement 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 or not the initiating party is a federally registered lobbyist.

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

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 applicant meets the eligibility criteria
- 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 must not exceed 35 pages. The Project Abstract and biosketches 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, of at least three individuals, will evaluate applications that meet the screening criteria identified above. These reviewers will be experts in their field from academic institutions, non-profit organizations, and local and Federal government agencies. Reviewers will review, evaluate, and score applications, in accordance with the criteria identified below:

Applications are scored by assigning a maximum of 100 points across four criteria:

- Understanding of Project Purpose - (10 points)
- Approach and Activities - (40 points)
- Applicant Capabilities - (30 points)
- Budget, Level of Effort, and Justification - (20 points)

Understanding of Project Purpose (10 points)

- How well does the application address the purpose and objectives of this NOFO and identify a specific area of interest? To what extent is the proposed project and activities parallel with NOFO goals and objectives associated with one of the two identified areas of interest?
- The extent to which the applicant has identified an important, coherent, and parsimonious set of challenges and associated research questions within one of the two identified areas of interest that are—or, if not addressed, will be—clear barriers to advancing interoperability and/or advancing clinical knowledge at the point of care.
- The extent to which the applicant describes how the project and expected outcomes and results will inform the field and future health IT development, research, and implementation, as appropriate.

Approach and Activities (40 points)

- The extent to which the proposed research methods promise to address the challenges with breakthrough findings on a proposed timeline within the parameters of a self-contained 2-year project period and potentially longer project period, if funded. (20 points)
Specifically:
 - Extent to which the theoretical framework, design, methods, and analyses are specifically stated, adequately developed, well-integrated, well-reasoned, and appropriate to the goals/objectives of the area of interest.
 - Extent to which proposed activities for achieving the research objectives are clear, feasible, and inform downstream work activities and challenges as appropriate.
 - Extent to which development or employment of novel concepts, approaches, methodologies, tools, or technologies; or combination of common elements in an innovative fashion are described and how it will generate much-needed insight to inform future health IT research activities or inform the field of health IT.
 - Extent to which an adequate understanding of the factors related to design, implementation, and use of health IT that may impact its effectiveness and user understanding of it are incorporated.
- The extent to which the applicant proposes a clear and detailed transition/dissemination plan. The extent to which the plan to transition/disseminate results to products and best practices is complete and feasible; and envisions the release of the outcomes of their research into open-source communities maximizing scalability. (15 points)
- The extent to which the plan describes a project management approach for ensuring project success within and across collaborators. (5 points)

Applicant Capabilities (30 points)

- Strength of evidence that the project brings an appropriate level of research and technical knowledge and expertise, for the chosen area of interest and strength of evidence that the project will integrate the efforts of those team members. (20 points).
 - Specifically:
 - Are the PD/PI, collaborators, and other project team members appropriately trained and well-suited to carry out this work?
 - Do the PD/PI and project team bring complementary and integrated expertise to the project?
 - Is there adequate PD/PI support allocated throughout the research period or a well-justified reallocation of leadership during the course of the research project when the PD/PI's effort is less than the suggested 20% annual level?
 - Does the research team include at least one team member with health IT expertise?
 - For Area of Interest 1: Expanding the scope, scale, and utility of population-level data- focused APIs.
 - Does the proposed research team demonstrate expertise in the

following areas:

- Data standards development and balloting expertise
- API development and EHR integration expertise
- For Area of Interest 2: Advancing clinical knowledge at the point of care.
 - Does the proposed research team demonstrate expertise in the following areas:
 - User-Centered Design
 - Workflow Design
 - Data Visualization
 - Cognitive Support
 - Does the grant application include a multidisciplinary project team drawing from diverse fields? Is needed expertise or are relevant disciplines adequately represented across the project team?
 - Does the grant application demonstrate the investigators' aptitude to identify and address weaknesses encountered during the conduct of the research project?
 - Does the grant application demonstrate that the project team will have adequate administrative structure and processes in place to oversee the successful conduct of the proposed study?
 - Did project team members describe and justify their proposed role and why their experience and qualifications make them well-suited for this role in the "Personal Statement" section of their biosketch?
 - Did research team members for whom biosketches are not required, describe their proposed role and why their experience and qualifications make them well-suited for this role in the Budget Justification?
- Extent to which the proposed activities bring all the resources necessary to perform the proposed work and the identification of proposed strategies to complete activities within a two year time frame and sustain research efforts beyond the project time-frame (5 points)
- 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)

Budget, Level of Effort, and Justification (20 points)

- Is the use of consultants and/or sub-recipients appropriate and adequate to advance the project in accordance with the timelines? (10 points)
- Extent to which the budget is justified with respect to the adequacy and reasonableness of resources requested, and the amount of the budget allocated to administration is minimized while still allowing coherent management of an integrated project. (10 points)

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 take into account 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, such as the

Excluded Parties List System, 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 Part 75.205.)

F. Federal Award Administration Information

Award Decisions

The final award decision will be made by the National Coordinator for Health Information Technology 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; and the likelihood that the proposed project will result in the benefits expected. All applicants will receive a summary of the objective review panel's assessment of the application's strengths, weaknesses, and score.

Notice of Grant Award

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 Grant Award (NGA). The NGA 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, milestones, 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 NGA 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

Incorporated by Reference

The NGA is subject to, by reference, the terms and conditions incorporated in the following documents:

- 45 CFR, Part 75—Uniform Administrative Requirements, Cost Principles, and Audit Requirements For HHS Awards
<http://www.ecfr.gov/cgi-bin/text-idx?SID=06a0b0411d1520fae5e2799030e64ebf&node=pt45.1.75&rgn=div5>
- HHS Grants Policy Statement
<https://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf>

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

Performance Reporting

- 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 establish points of contacts, expectations, and set-up regular check-in calls.
- A monthly check-in meeting to be scheduled with your ONC Project Officer to discuss:
 - implementation trajectory, accomplishments, next steps, challenges, barriers, and recommendations to address challenges and barriers
- ONC Progress Reports are due quarterly. The progress report 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 and format of the PPR before the reports are due.

- A draft of the final report must 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
- Report Components
 - 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 must 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 will 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 publically available at no cost to the general public.

Financial Reporting

Expenditures must 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 Online Data Collection (OLDC) system. ONC will not accept reports sent directly to the ONC Grants mailbox.

The FFR Cash Transaction Report, a subset of the SF-425, Federal Financial Report, is submitted via the Payment Management System (PMS) every calendar quarter for the life of the award. The report must be submitted within 30 days after the end of the quarter (January 31, April 30, July 31, and October 31).

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.fsr.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 new mandatory disclosure requirements. Recipients that have Federal contracts, grants, and cooperative agreement awards with a cumulative total value greater than \$10,000,000 must disclose in FAPIIS, semiannually, any information about criminal, civil, and administrative proceedings for 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. All information posted in FAPIIS on or after April 15, 2011, except past performance reviews required for Federal procurement contracts, will be publicly available.

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

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 advice 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 Section 75.112 of Uniform Administrative Requirements, Cost Principles, and Audit Requirements for HHS Awards, all applicants and non-federal entities must 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 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 Section 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 must 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.

Intangible Property and Copyrights (45 CFR Part 75)

Intangible property 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 §75.2 Intangible property) acquired under a Federal award vests upon acquisition in the non-Federal entity. The non-Federal entity must use that property for the originally-authorized purpose, and must 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 must occur in accordance with the provisions in §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 must request, and the non-Federal entity must 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 must retain financial and programmatic records, supporting documents, statistical records, and all other records that are required by the terms of a grant, or may reasonably be considered pertinent to a grant, for a period of 3 years from the date the final FFR is submitted. For awards where

the FFR is submitted at the end of the competitive segment, the 3-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 3-year retention requirement. For example, if any litigation, claim, financial management review, or audit is started before the expiration of the 3-year period, the records must be retained until all litigation, claims, or audit findings involving the records have been resolved and final action taken. This section also specifies the retention period for other types of grant-related records, including indirect cost proposals and property records. See 45 CFR 75.335 for record retention and access requirements for contracts under grants.

Modifications

Modifications and/or amendments to the cooperative agreement must 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 must have a single or project-specific audit. Subpart F provides further guidance including the manner in which expenditures are determined, the distinction between a single audit and a project-specific audit, frequency of audits, and roles and responsibilities in the conduct of audits.

Steven's Amendment

Statutory Requirement: Division H, Title V, Section 505 of Public Law 114-113, of the Consolidated Appropriations Act of 2016

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.

G. Points of Contact

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ONC E-Mail Address

In addition, a separate ONC e-mail address has been established for this cooperative agreement to which all comments and inquiries can be directed. The e-mail address is ONC-LEAP@hhs.gov.

DUN and Bradstreet

<http://www.dnb.com/>
800.234.3867

System for Award Management (SAM) Customer Support

<https://www.sam.gov>
Federal Service Desk -- www.fsd.gov
866-606-8220

Grants.Gov Customer Support

Questions regarding Grants.gov registration and submission, downloading or navigating forms

Contact Center Phone: 800-518-4726

Email: support@grants.gov

HHS Office of the Inspector General

The HHS Office of the Inspector General (OIG) maintains a toll-free number (1-800-HHS-TIPS or 1-800-447-8477) for receiving information concerning fraud, waste, or abuse under grants and cooperative agreements. Information also may be submitted by e-mail to hhstips@oig.hhs.gov or by mail to Office of the Inspector General, Department of Health and Human Services, Attn: HOTLINE, 330 Independence Ave., SW, Washington, DC 20201. Such information is treated as sensitive and complainants may decline to give their names if they choose to remain anonymous.

Tips for Writing a Strong Application

Include DUNS Number. You must include a DUNS Number to have your application reviewed. To obtain a DUNS number, access <http://www.dunandbradstreet.com> or call 1-866-705-5711. Please include the DUNS number in item 8c on the application face page.

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 project 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.

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. <ul style="list-style-type: none"> • 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. <ul style="list-style-type: none"> • 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. <ul style="list-style-type: none"> 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.
6.	Date Received by State:	Leave this field blank. This date will be assigned by the state, if applicable.

Item	Field Name	Information
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:
8a.	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 .
8b.	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.
8c.	Organizational DUNS:	(Required) Enter the organization's DUNS or DUNS+4 number received from Dun and Bradstreet. Information on obtaining a DUNS number may be obtained by visiting www.Grants.gov .
8d.	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).
8e.	Organizational Unit:	Enter the name of the primary organizational unit, department or division that will undertake the assistance activity.
8f.	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) 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

Item	Field Name	Information
10.	Name Of Federal Agency:	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:	
<p>(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 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.</p>		
<p>Applicants should review matching principles contained in 2 CFR 200.306 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 must total at least <i>[cite percentage or fraction]</i> 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.</p>		
<p>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,</p>		

Item	Field Name	Information
<p>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.</p>		
<p><i>ONC's Match Requirement – (Sample Language)</i> <i>Under this project, 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 must 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:</i></p>		
<p><i><u>Federal Funds Request/3 = Minimum Match Requirement</u></i></p>		
<p><i>For example, if you request \$100,000 in Federal funds, then your <u>minimum</u> 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.</i></p>		
<p>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 must be included with the application. Further, if any sub-contractors or sub-recipients are requesting indirect costs, copies of their indirect cost agreements must also be included with the application.</p>		
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 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 must be on file in the applicant's office. (Certain federal agencies may require that this authorization be submitted as part of the application.)

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 must 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 must 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/Justifications 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 must 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.

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 must be justified as necessary for the conduct of the project. The equipment must be used for project-related functions; the equipment, or a reasonable facsimile, must not be otherwise available to the applicant or its sub recipients. The justification also must 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?
 - Office
 - Training
 - Research
 - 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 are 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 must 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
 - Is an hourly, daily or weekly base rate given?
 - Are rates allowable, justified, reasonable and comparable to market?
- ◆ Is the total amount for any contract in excess of \$150,000?
 - Is procurement method described?
 - If the contract is not competitively bid, has a sole source justification been provided?

Note: The competitive process must 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, goals 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 project.

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 must 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 must 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 project, the authorized representative of the applicant organization must 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 must 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.

Budget Narrative/Justification Template (with SAMPLE information)

Object Class Category	Federal Funds	Non-Federal Cash	Non-Federal In-Kind	TOTAL	Justification
Personnel Salary	\$40,000	\$5,000		\$45,000	◆ Project Administrator Jane Doe = .3FTE @ \$50,000/year = \$15,000 \$10,000 = Federal funds and \$5,000 = non-federal cash
					◆ Project Director John Smith = 1FTE @ \$30,000/year = \$30,000 Federal funds
					TOTAL: \$45,000
Fringe Benefits	\$12,600	0	0	\$12,600	<p>Fringes benefit rate is 28% of salary as follows. All Federal Funds</p> <p>FICA (7.65%)= \$3,442 Health Insurance (12%) = \$5,400 Dental Insurance (5%) = \$2,250 Life Insurance (2%) = \$900 Workers Comp Insurance (.75%) = \$338 Unemployment Insurance (.6%) = \$270</p> <p>TOTAL: \$12,600 (\$45,000 * 28%)</p>

Object Class Category	Federal Funds	Non-Federal Cash	Non-Federal In-Kind	TOTAL	Justification
Travel	\$4,120	\$1,547		\$5,667	<p>◆ Travel to two annual recipient meetings: All Federal funds.</p> <p>Airfare: 2 people x 2 trips \$750/per round trip = \$3,000</p> <p>Lodging: 2 nights per trip x 2 people x \$100/night x 2 trips = \$800</p> <p>Per Diem: 2 days per trip x 2 people x \$40/day x 2 trips = \$320</p> <p>Subtotal: \$4,120</p> <p>◆ Out-of-town site visits. Non-federal cash.</p> <p>Car mileage: 3 trips x 2 people x 350 miles/trip x \$.365/mile = \$767</p> <p>Lodging: 3 trips x 2 people x 1 night/trip x \$50/night = \$300</p> <p>Per Diem: 3 trips x 2 people x 2days/trip x \$40/day = \$480</p> <p>Subtotal: \$1,547</p> <p>TOTAL: \$5,667</p>
Equipment	0	0	0	0	No equipment requested
Supplies	\$1,340	\$2,160		\$3,500	<p>◆ Laptop computer for use in client intakes – Federal Funds = \$1,340</p> <p>◆ Consumable supplies (paper, pens, etc.) – Non-federal cash \$100/mo x 12 months = \$1,200</p> <p>◆ Copying – Non-federal cash \$80/mo x 12 months = \$960</p> <p>TOTAL: \$3,500</p>
Contractual	\$150,000		\$50,000	\$200,000	<p>Contracts to A,B,C</p> <p>Contractor A to deliver supplies – Federal funds = \$75,000</p> <p>Contractor B to print materials – Federal funds= \$75,000</p> <p>Contractor C for logistical support– Non-Federal = \$50,000</p> <p>TOTAL: \$200,000</p>

Object Class Category	Federal Funds	Non-Federal Cash	Non-Federal In-Kind	TOTAL	Justification
Other	\$11,250	\$2,000		\$13,250	♦ Subaward to ABC to conduct training – Federal funds = \$10,000 ♦ Printing brochures – Federal funds (25,000 @ \$0.05 each) = \$1,250 ♦ Registration fee for annual ABC conference – Non-federal cash = \$200 ♦ Postage – Non-Federal Cash (\$150/mo x 12 months) = \$1,800 TOTAL \$3,250
Indirect Costs	\$12,000	\$1,000	\$1,000	\$14,000	♦ Rent – Federal funds (\$1,000/mos. x 12 months) = \$12,000 ♦ Utilities – Non-federal cash = \$1,000 ♦ Administrative Support – Non-Federal In-Kind 100 hours x \$10/hour = \$1,000 TOTAL \$14,000
TOTALS	\$231,310	\$11,707	\$51,000	\$294,017	

Letter of Commitment Template

Donald Rucker, MD
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 Dr. Rucker,
(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