

U.S. Department of Health and Human Services
Office of the National Coordinator for Health IT

**Closing the Gap between Standards
Development and Implementation**

**Program Guidance
Funding Opportunity Announcement
Fiscal Year 2015**

Application Due Date: July 24, 2015
Anticipated Award Date: August 21, 2015

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OPPORTUNITY OVERVIEW

Funding Opportunity Announcement Title: Closing the Gap between Standards Development and Implementation

Federal Funding Agency: Office of the National Coordinator for Health Information Technology (ONC), U.S. Department of Health and Human Services (HHS)

Announcement Type: Cooperative Agreement

Funding Opportunity Number: NAP-AX-15-003

Catalog of Federal Domestic Assistance (CFDA) Number: 93.826

Statutory Authority: Consolidated and Further Continuing Appropriations Act, 2015", Pub. L. No. 113-235, Division G, Title II, and Title XXX, §§ 3001 (c)(2) and 3011 of the Public Health Service Act

Approximate Amount of Funding Available: \$400,000

Anticipated number of Awards: One (1) award

Approximate Range of funding per award: N/A

Period of Performance: Five (5) years

Key Dates and Submission Information:

The application review and funding process for this cooperative agreement will take place according to the table below. The applicant will need to submit an application that will undergo an objective review. A successful application will result in the award of a five (5) year cooperative agreement.

FOA Release	Date ¹	Section Reference
Application Due Date	July 24, 2015 by 11:59pm EST	Section IV – Application and Submission Information
Anticipated Award Date	August 21, 2015	VI.A – Award Administration Information
Anticipated Project Start Date	September 1, 2015	

¹ The announcements and start dates are approximate.

Executive Summary

This funding opportunity announcement (FOA) will provide funds in the form of a sole source, single award, through a cooperative agreement, between the Office of the National Coordinator for Health Information Technology (ONC) and Health Level 7 International (HL7). HL7 supports advancements in the technical standards necessary to achieve interoperability among health IT systems.

U.S. Department of Health and Human Services (HHS) activities support efforts to increase access to health care, protect those in greatest need, expand educational opportunities, and modernize the nation's infrastructure. Total funding available is \$400,000. This collaboration with HL7 will begin with a focus on advancing the implementation consistency of the current versions of the Consolidated Clinical Document Architecture (C-CDA) (Releases 1.1 and 2.0) and supporting the implementation and governance of the Fast Healthcare Interoperability Resource (FHIR) standard and its accompanying resources and profiles. This cooperative agreement is one way ONC seeks to reach the milestones identified in ONC's "Connecting Health and Care for the Nation: A Shared Nationwide Interoperability Roadmap Draft Version 1.0 (draft Roadmap) (available at <http://www.healthit.gov/sites/default/files/nationwide-interoperability-roadmap-draft-version-1.0.pdf>).

I. Funding Opportunity Description:

A. Purpose

The purpose of this FOA is to establish a mechanism for ongoing cooperation between ONC and HL7. It aims to provide specific dedicated support to HL7 for work on HL7-led standards development as well as corresponding implementation guidance and testing concepts of mutual interest to ONC and HL7. Additionally, given HL7's broad standards portfolio and the many other purposes for which interoperability will be necessary and for which HL7-developed standards would need to be implemented, it is anticipated that this ongoing cooperative relationship could include specific work aimed at a range of different technical standards developed and maintained by HL7.

The initial tasks expected to be completed as part of this engagement include collaboration with HL7 to advance the implementation consistency and readiness of the current versions of the Consolidated Clinical Document Architecture (C-CDA) (Releases 1.1 and 2.0) and supporting the implementation and governance of the Fast Healthcare Interoperability Resource (FHIR) standard and its accompanying resources and profiles.

B. Background

The consistent implementation of standards within health IT systems is necessary to achieve interoperability among health care providers and across many different cases. Standardized ways to format and structure data, as well as represent its meaning in an unambiguous and computable way is critical to enable health care providers to send, receive, find, and use patient data when and where it is needed. Founded in 1987, HL7, an American National Standards Institute (ANSI), standards development organization (SDO), has developed and maintained a standards and implementation guidance for the exchange, integration, sharing, and retrieval of electronic health information in support of clinical practice.

When a computer system receives electronic health information from another system, it needs to be able to process the information without time-consuming human intervention. This can only occur if the sending system has used a consistent data format that is known to – and expected by – the receiving system. Given the

vast number of systems that exchange electronic health information, expecting each to negotiate agreed-upon exchange formats with all other systems with which it interacts is impractical. To address this issue, stakeholders in the health IT ecosystem have organized themselves under the auspices of standards development organizations (SDOs) to develop standardized data formats pertaining to specific purposes. HL7 is one such SDO.

The primary responsibility of SDOs are development and maintenance of the data formats as technical standards and any accompanying implementation specifications/profiles that provide additional implementation instructions to developers based on the particular purpose for which the standard is intended to be used.

HL7 and the health IT industry have worked diligently to update the C-CDA specification to release an updated version (Release 2.0), and are on a trajectory to publish the next version of the newer FHIR standard in 2015. The C-CDA has been included in ONC's health IT certification regulations since 2012, and is also referenced in ONC's recently published 2015 Interoperability Standards Advisory. FHIR and its data-focused approach is anticipated to be an important contributor to achieving several of the milestones identified in ONC's draft Roadmap, which was released for public comment in early 2015.

Despite the effort and commitment exhibited by HL7 volunteers, more work remains in order to refine these specific standards, close any gaps between the standards development and implementation, develop broad and more comprehensive testing infrastructures, and disseminate additional guidance back to the health IT developers and health care providers.

1. Consolidated Clinical Document Architecture (C-CDA)

The Consolidated Clinical Document Architecture (C-CDA) is an implementation guide that was created in 2012 to help simplify implementations and contains the commonly used HL7's Clinical Document Architecture (CDA) templates. CDA is the base standard which provides a common architecture for the creation of an electronic clinical document. Though much of the industry has implemented C-CDA, there remains significant variability in its implementation. This variability impacts interoperability overall and limits a receiving system's ability to fully process the information and properly integrate the information into a patient record. At the same time, health care providers have adopted, implemented, and are using health IT systems to send summary of care records formatted according to the C-CDA at a steadily increasing rate. Implementation experience and feedback from the field indicates that more guidance on how to consistently implement the C-CDA specification is needed in order to support interoperability among health IT systems.

2. Fast Healthcare Interoperability Resources (FHIR)

Over the long-term, FHIR is poised to fundamentally change aspects of interoperability in health care, allowing for more specific, tailored, data-centric ways of exchanging information. To achieve automated interoperability, individual data elements are exchanged (e.g. medication or allergies) rather than an entire C-CDA document. HL7's FHIR is emerging and exploring ways to accommodate new methods of exchanging information. Work is currently underway in HL7 to complete the development of a second draft standard for trial use. This next version's timely release is significant and necessary to continue to advance industry momentum surrounding its implementation and use. Additionally, it will also be necessary for the industry to plan additional infrastructure necessary to support the adoption of the FHIR standard, as well as thoughtful planning for the migration and transition from C-CDA to the FHIR standard for specific purposes.

C. Program Description

This potential cooperative agreement involves interoperability specifications and standards work specific to Standards Development Organizations (SDOs). In this instance, HL7 is uniquely positioned as the sole SDO that can work with ONC to develop and ballot additional implementation guidance for HL7 standards through its ANSI-accredited processes as well as serve as the authoritative source for implementation best practices and testing concepts associated with the standards it produces and maintains. HL7 will work with ONC and external stakeholders to provide the necessary steps to improve specific technical standards (such as C-CDA and FHIR) to achieve interoperability. Activities completed through this cooperative agreement will be made available for public use at an agreed upon timeframe post-award.

D. Project Approach and Structure

To close the gap between standards development and implementation, ONC will fund one award of \$400,000 through a cooperative agreement. The awardee will close any gaps between the standards development and implementation, develop broad and more comprehensive testing infrastructures, and disseminate additional guidance back to the health IT developers and health care providers. While ONC provides an expected outcome for each goal, ONC will provide more in depth clarity of the intent of the goals during their meetings in the implementation phase of this agreement. Furthermore, HL7 is expected to provide a detailed list of how it plans to accomplish each of the tasks for each of the goals. The goals and activities listed below are explicitly for C-CDA and FHIR. It should also be noted these goals are based on ONC's assessment of activities, and should be considered neither complete nor exhaustive.

- a. Improve consistency of C-CDA Release 1.1 and Release 2.0 Implementations across health IT developers

It is expected that an outcome of this cooperative agreement is that health IT systems will implement the C-CDA Releases 1.1 and 2.0 those specified by ONC in its regulations.

List of Activities:

- Task 1: *CDA Examples Task Force*² developed artifacts are used by HL7 to develop additional implementation guidance for single and consistent implementation of C-CDA Releases 1.1 and 2.0.
- Task 2: HL7 organizes connect-a-thon events, to identify real-world implementation inconsistencies with C-CDA Releases 1.1 and 2.0. And, based on the results, develops detailed guidance for developers and implementers on any identified barriers to interoperability as well as any implementation guidance or tools necessary to migrate from Release 1.1 to 2.0.

- b. Improve the use and consistency of semantic information in C-CDA

Another expected outcome of this cooperative agreement is to have e-health IT systems implement C-CDA with consistent semantic information and with greater semantic accuracy³.

² http://wiki.hl7.org/index.php?title=CDA_Example_Task_Force

³ "Are Meaningful Use Stage 2 certified EHRs ready for interoperability? Findings from the SMART C-CDA Collaborative" by John D. D'Amore et.al., <http://jamia.oxfordjournals.org/content/21/6/1060>

List of Activities:

- Task 1: HL7 develops quantitative measures and testing infrastructure for evaluating syntactic and semantic accuracy in C-CDA Release 1.1 and 2.0 using previous work from Substitutable Medical Apps and Reusable Technology (SMART) Program⁵.
- Task 2: HL7 develops additional guidance for use of terminology and vocabulary standards for specific sections and entries in C-CDA Releases 1.1 and 2.0 from large coding systems used in C-CDA, including but not limited to Systemized Nomenclature of Medicine-Clinical Terms (SNOMED-CT), RxNorm and Logical Observation Identifiers Names and Codes (LOINC).

c. Additional Support for developers implementing the C-CDA Specification

ONC expects HL7 to be able to respond accurately and promptly to developer questions on implementing C-CDA Release 1.1 and 2.0 specifications.

List of Activities:

- Task 1: HL7 publishes updated C-CDA Companion Guide⁴ for Releases 1.1 and 2.0 based on additional guidance developed through this cooperative agreement and other activities.
- Task 2: HL7 supports “Help Desk” for answering questions from developers that are implementing C-CDA Releases 1.1 and 2.0.
- Task 3: HL7 publishes Frequently Asked Questions (FAQs) on implementing and using C-CDA Releases 1.1 and 2.0.
- Task 4: HL7 organizes webinars periodically with developer community.

d. Publish the latest release of FHIR Standard⁵ as soon as possible

ONC will support HL7’s timely publication and release of the latest FHIR Draft Standard for Trial Use version 2 (DSTU2).

List of Activities:

- Task 1: HL7 monitors the FHIR DSTU2 ballot reconciliation activities and provides additional technical support as needed to HL7 working groups to complete the standard development process in timely manner.
- Task 2: HL7 provides administrative support for the publication of the balloted FHIR DSTU2 standard during 2015.

⁴ “HL7 Implementation Guide: S&I Framework Transitions of Care Companion Guide to Consolidated-CDA for Meaningful Use Stage 2, Release 1 – US Realm”,

http://www.hl7.org/implement/standards/product_brief.cfm?product_id=374

⁵ FHIR DSTU Release 2, <http://hl7.org/implement/standards/FHIR-Develop/>

- e. Comprehensive planning to ensure support for adoption of FHIR Standard

HL7 is expected to begin any necessary planning and infrastructure development for sustained adoption of FHIR standard.

List of Activities:

- Task 1: HL7 builds on its existing infrastructure to expand and organize the governance and tools needed to support development and the unambiguous maintenance of FHIR Profiles.
- Task 2: HL7 initiates the development of a testing platform to support testing of FHIR compliant systems.

E. Deliverable Table

The table below identifies specific milestones to support the execution of the cooperative agreement and the due date by which the milestones will be met. Deliverables No. 1, No. 2 and No. 3 in the table below, have been already specified. There is currently a placeholder in the deliverable table for deliverables associated with each goal described in “Project Goals” section. The specific deliverables for individual goals should be submitted by HL7 in their response to the cooperative agreement. ONC and HL7 will work together to set specific deliverables per the outlined goals identified in the Program Evaluation and Measurement Section.

No.	Deliverable	Due Date
1.	Detailed Implementation Plan from HL7 (includes specific list of activities and deliverables approved by ONC)	2 weeks after award date and monthly thereafter
2.	Monthly progress meetings with ONC	Monthly; additional meetings as requested by HL7 or ONC
3.	Progress Report on each Goal	Quarterly

F. Proposal Criteria

Applicant must address the following in their proposal:

- How the awardee will implement the C-CDA specification in a single and consistent manner;
- How semantic information will be improved to increase accuracy;
- How support for developers’ questions implementing C-CDA standards will be accomplished;
- The timeline between new standards development and release to the public; and
- How the awardee will plan for the adoption of the FHIR standard

G. General Funding Requirements

The application must address the following requirements:

- Improve the consistency of C-CDA implementations;

- Provide semantic information in a consistent manner;
- Have a support plan for developers;
- Publish updated standards releases within a timely manner; and
- Show a plan for adoption of the FHIR standard.

H. Project Evaluation and Measurement

This FOA provides applicants with flexibility to propose methods that continue to improve the consistency and readiness of the C-CDA specification and FHIR technical standard. ONC will measure the success of the awardee through project goals, including, but not limited to the following:

Project Goals:

1. Successfully improve the consistency of C-CDA implementations
 - a. The publication of a first suite of additional implementation guidance, best practices, and other such specific tools during 2015 and 2016 that provide for unambiguous methods for health IT developers to implement the C-CDA Release 1.1 and 2.0 specifications in a single and consistent manner.
2. Semantic information consistency
 - a. The publication of a first suite of additional implementation guidance, best practices, and other such specific tools during 2015 and 2016 that provide for unambiguous methods for health IT developers to implement the semantic requirements included in C-CDA Releases 1.1 and 2.0 with a high degree of accuracy and consistency.
3. Provide support for developers.
 - a. Have accurate and prompt responses to developer questions relating to implementation of C-CDA Release 1.1 and 2.0 specifications.
4. The successful publication of a FHIR DSTU2 release during 2015.
5. Ensure adoption support of the FHIR Standard.
 - a. The formation and iteration of the governance and tools needed to support development and the unambiguous maintenance of FHIR Profiles.

ONC requires that at a minimum, 75% of the funds be allocated for achieving Goals 1 through 3, and 25% of the funds be allocated for Goals 4 and 5.

I. Statutory Authority

Consolidated and Further Continuing Appropriations Act, 2015", Pub. L. No. 113-235, Division G, Title II, and Title XXX, §§ 3001(c)(2) and 3011 of the Public Health Service Act.

II. Award Information

Type of Award	Cooperative Agreement
Approximate Total Funding	\$400,000
Number of Awards	One
Anticipated Award Date	August 21, 2015

Project Period Length	5 years
Estimated Start Date	TBD

Throughout the project period, ONC's commitment to continuation of awards will be conditioned on the availability of funds, evidence of satisfactory progress by the recipient (as documented in required reports), and the determination that continued funding is in the best interest of the Federal Government.

A. Performance Evaluation

The Awardee's performance will be evaluated on a monthly basis by ONC to ensure that the project is meeting program objectives.

B. Award Type

The funding instrument used for this program will be the cooperative agreement, an award type in which substantial ONC programmatic involvement with the awardee is anticipated during the performance of the activities. Under the cooperative agreement, ONC's purpose is to support and stimulate an awardee's activities by involvement in and otherwise working jointly with the awardees in a partnership role; it is not to assume direction, prime responsibility, or a dominant role in the activities. Consistent with this concept, the dominant role and prime responsibility resides with the awardee for the project as a whole, although specific tasks and activities may be shared among the awardee and ONC as defined in this funding agreement.

C. Substantial Involvement in Cooperative Agreements

ONC will work closely with the awardee to plan and implement processes in a collaborative fashion. More particularly, ONC staff is substantially involved with the program activities, above and beyond routine grant monitoring. These activities include, but are not limited to: a) review and approval of the implementation plan and all other deliverables submitted to meet the goals of the project (identified in the Deliverable Table); b) providing tactical guidance and feedback during project execution; and c) engaging with leadership of the organization, as necessary, to ensure successful execution of the cooperative agreement.

III. Eligibility Information

A. Eligible Applicants

This is a non-competitive funding opportunity and is restricted to the organization designated below. Organizations not designated as such are not eligible to apply for this opportunity, and therefore should not submit an application. Applications submitted by organizations not designated below will not be considered.

Designated Organization: Health Level 7 International (HL7).

B. Sole Source Justification

Health Level 7 International (HL7) is the exclusive standards development organization (SDO) with the ability, authority, and intellectual property rights to develop and maintain the C-CDA specification and FHIR standard among other produced by HL7. As a result, it is the Office of the National Coordinator for Health IT (ONC)'s belief that HL7 is the only organization that can successfully deliver the goals articulated in this cooperative agreement. Additionally, HL7 members include organizations that are actively engaged in

implementing the C-CDA and FHIR standard in health IT systems, and hence can provide necessary feedback in timely manner through a well-established and ANSI-accredited process for consensus standards development. The goals and expected outcomes of this cooperative agreement can only be achieved accurately and in timely manner by HL7.

The primary responsibility of SDOs are the development and maintenance of health IT technical standards, as well as any accompanying implementation specifications that provide additional implementation instructions for developers. HL7 is the single organization responsible for the development and maintenance of the C-CDA specification and FHIR standard, and solely governs the process by these standards and accompanying implementation guidance are issued and updated. Attempting to complete these or any future tasks specific to HL7 standards with another SDO or organization would be time consuming, inefficient, and would still ultimately require HL7 engagement to ballot and publish a final product. Thus, HL7's involvement is both fundamental and always necessary to publish an HL7 standard or implementation guide. Furthermore, it is ONC's intent to broadly coordinate with health IT industry stakeholders to improve and advance the technical standards and specifications required for interoperability. Working directly with HL7 will enable this coordination to be more effective and efficient, and will enable broad industry consensus to be more rapidly when done through HL7's processes.

C. Cost Sharing or Matching

There is no cost sharing or match requirement for this award.

IV. How to Apply Information

A. Address to Request Application Package

Application materials will be available for download at <http://www.grants.gov>. ONC requires the applicant to submit application materials as a complete package. Such materials must be delivered through the electronic mail function at <http://www.grants.gov>.

APPLICATION WILL NOT BE ACCEPTED THROUGH ANY OTHER WEBSITE, AND WILL NOT BE ACCEPTED THROUGH PAPER MAIL, COURIER, OR DELIVERY SERVICE.

APPLICANT IS STRONGLY ENCOURAGED TO COMPLETE AND SUBMIT ITS APPLICATION AS FAR IN ADVANCE OF THE SUBMISSION DEADLINE AS POSSIBLE. THE APPLICATION INCLUDING ALL REQUIRED ATTACHMENTS AND INCLUDED FILES FOR POTENTIAL CONSIDERATION IN THE REVIEW PROCESS MUST BE RECEIVED BY 11:59 PM EASTERN TIME ON THE DATE SPECIFIED IN SECTION IV C, BELOW.

Applications Procedures:

- You must access the electronic application for this program via <http://www.grants.gov>. You must search the downloadable application page by the Funding Opportunity Number **NAP-AX-15-003** or CFDA number **(93.826)**.
- Applicant should have a Dun and Bradstreet (D&B) Data Universal Numbering System (DUNS) number and register in the System for Award Management (SAM). Allow a minimum of five days to complete the SAM registration. It is critical to know that SAM registration requires an annual renewal.

- Submit all documents electronically, including all information included on the SF-424 and all necessary assurances and certifications.
- Ensure that the application complies with any page limitation requirements described in this Program Guidance.
- After electronically submitting your application, an automatic email notification will be sent to confirm the email was received. This notification does not provide assurance that your application was complete, only that the email was received.
- After ONC reviews submission, a return receipt will be emailed to the applicant contact indicating the files that were received and able to be successfully opened and read. Organizations applying for federal grants need to be registered with SAM. You can register with the SAM online in a process that will take about 30 minutes (<http://www.sam.gov>). 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 at <http://www.sam.gov>.

B. Content and Form Submission

Project Abstract

Applicant shall include a one-page abstract (no more than 500 words) of the application. This abstract is often distributed to provide information 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
- Address
- Contact Name
- Contact Phone Numbers (Voice, Fax)
- E-Mail Address
- Web Site Address, if applicable

Budget Forms

The applicant is required to fill out the following budget forms to include the costs associated with the proposed project activities. These forms will be submitted through grants.gov as part of the application package and will include the following:

Application for Federal Assistance (SF-424)
 Budget Information for Non-Construction Programs (SF-424A)
 Assurances for Non-Construction Programs (SF-424B)
 Disclosure of Lobbying Activities (SF-LLL)

Please note that these forms do not replace program-specific guidance provided in this funding opportunity announcement. Additional instruction regarding budget forms can be found in Appendix A.

Project Narrative

The Project Narrative is the part of the application that will offer the most substantive information about the proposed project, and it will be used as the primary basis to determine whether or not the project meets the minimum requirements for awards. The Project Narrative should provide a clear and concise description of your project.

The Project Narrative must provide the reader with an understanding of how the applicant will:

- Improve consistency of C-CDA implementations across health IT developers;
- Improve the use and consistency of semantic information in C-CDA;
- Provide additional support to developers implementing the C-CDA specification;
- Publish the latest release of the FHIR standard as soon as it's available; and
- Begin comprehensive planning of adoption of the FHIR standard.

The Project Narrative must be double-spaced, formatted to 8 ½" x 11" (letter-size) pages with 1" or larger margins on top, bottom, and both sides, and a font size of not less than 11 point. The maximum length allowed for the Project Narrative is 10 pages. A full application with a Project Narrative that exceeds 10 pages will not be accepted. Resumes of Key Personnel are not counted as part of the Project Narrative for purposes of the 10-page limit.

(Note: a concise resource offering tips for writing proposals for HHS grants and cooperative agreements can be accessed via the Web at: <http://www.hrsa.gov/grants/apply/granttips.html>)

Budget Narrative

The applicant is required to outline proposed costs that support all project activities in the Budget Narrative/Justification. The application must include the allowable activities that will take place during the funding period and outline the estimated costs that will be used specifically in support of the program. Costs are not allowed to be expended until the start date listed in the Notice of Grant Award. Whether direct or indirect, all costs must be allowable, allocable, reasonable and necessary under the applicable Uniform Guidance: <http://www.ecfr.gov> (2 CFR 200 Subpart E) and based on the programmatic requirements for administering the program. The budget period will be equivalent to the project period.

C. Submission Dates and Times

The applicant will be required to submit an application that will undergo screening for completeness and responsiveness and, if indicated, an objective review process. The application must be submitted via grants.gov no later than 11:59 p.m. EST July 24, 2015. If the application fails to meet the application due date, it will not be reviewed and will receive no further consideration. Grants.gov will automatically send the applicant a tracking number and date of receipt verification electronically once the application has been successfully received and validated. After the Office of Grants Management retrieves the application form from grants.gov, a return receipt will be emailed to the applicant contact. This will be in addition to the validation number provided by grants.gov.

FOA Released	Letters of Intent Due	Applications Due	Cooperative Agreements Awarded	Anticipated Start Date
April 24, 2015	NA	July 24, 2015	August 21, 2015	September 1, 2015

D. Application Screening Criteria

If the application fails to meet the following screening criteria described below, it will not be reviewed and will receive no further consideration.

In order for an application to be reviewed, it must meet the following screening requirements:

- The application must be submitted electronically via <http://www.grants.gov> by 11:59 p.m., Eastern Time, July 24, 2014.
- The Project Narrative section of the application must be double-spaced, on 8 ½" x 11" plain white paper with 1" margins on both sides, and a font size of not less than 11.
- The Project Narrative must not exceed 10 pages. Any pages over the limit will not be reviewed.
NOTE: Letters of Commitment and Resumes of Key Project Personnel are not counted as part of the Project Narrative for purposes of the 10-page limit.

E. Application Responsiveness Criteria

If the application does not meet the following responsiveness criteria, it will be administratively eliminated and will not be sent forward for merit review:

The application clearly addresses the project theme.

The applicant meets the eligibility criteria as required by Section III.A, Eligible Applicants.

The application is complete and includes the required components stated in Section I.B, including all elements of the program narrative needed to forward it for merit review.

F. Application Completeness Criteria

ONC will screen the application to identify those that do not meet criteria outlined below. The application screening criteria are:

- The application is received by the deadline required under Section IV.C, Submission Dates and Times.
- The application meets the formatting and length requirements found in Section IV.B, Content and Form of Application Submission.
- Appendices and attachments are not used as a mechanism to exceed page limits in Project Narrative.

G. Grants.gov Registration

Registration with Grants.gov can take several days. The applicant is strongly encouraged to locate and test current logins and passwords for this system well in advance of the deadline date. For assistance with

www.grants.gov, please contact them at support@Grants.gov or 1-800-518-4726 24 hours a day/7 days a week.

H. Applying Electronically through Grants.gov

All information needed to submit the application electronically through this site can be found at Grants.gov. Additionally, there are a variety of requirements that are critical to know and comply with in order to meet the application deadline and submission requirements:

- The applicant will be able to download a copy of the application packet, complete it off-line, and then upload and submit the application via the website.
- The applicant can access the electronic application for this program on Grants.gov. Applicants must search the downloadable application page by the Funding Opportunity **NAP-AX-15-003** or CFDA number 93.826.
- ONC strongly recommends that applicant not wait until the application due date to begin the application process through Grants.gov.
- To complete an application in Grants.gov, applicant must have a Dun and Bradstreet (D&B) Data Universal Numbering System (DUNS) number and be registered in the System for Award Management (SAM). Applicant should allow a minimum of five days to complete the SAM registration. It is critical to know that SAM registration requires an annual renewal. As a result, ONC strongly encourages applicant to ensure that their registrations are current or to renew their registration well in advance of the application deadline. For more information or to check or renew registration, go to <http://www.sam.gov>.
- The applicant must submit all documents electronically, including all information included on the SF424 and all necessary assurances and certifications.
- Prior to application submission, if Microsoft Vista and Office 2007 are used, applicant should review the Grants.gov compatibility information and submission instructions provided at Grants.gov (click on “Vista and Microsoft Office 2007 Compatibility Information”).
- If the application fails to meet the application due date, it will not be reviewed and will receive no further consideration.
- After application is submitted electronically, applicant will receive an automatic acknowledgement from Grants.gov that contains a Grants.gov tracking number.
- After ONC reviews the submission, a return receipt will be emailed to the awardee contact indicating the files that were received and able to be successfully opened and read.
- Application must be submitted via <http://www.grants.gov> no later than 11:59p.m. EST on July 24, 2015.

Key Contact for Applications:

Inquiries should be addressed to:

Matthew Rahn

U.S. Department of Health and Human Services

Office of the National Coordinator for Health Information Technology

Email: SDOFOA@hhs.gov

I. Proof of the Applicant’s Status as a Non-Profit Entity

If the applicant is a US-based non-profit entity it must provide documentation of its 501C status or IRS determination letter, IRS tax exemption certificate, or letter from state taxing body verifying tax-exempt status.

J. Intergovernmental Review of Applications

The application for this cooperative agreement is not subject to review by states under Executive Order 12372, “Intergovernmental Review of Federal Programs” (45 CFR 100). Please check box “C” on item 19 of the SF 424 (Application for Federal Assistance).

K.. Funding Restrictions

Funds under this announcement cannot be used for the following purposes:

- To supplant or replace current public or private funding.
- To supplant on-going 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.
- Indirect costs should not exceed 8% of direct costs.

If you are requesting indirect costs in your budget, you must include a copy of your indirect cost rate agreement. If your indirect cost rate is a provisional rate, the agreement should be less than 12 months of age. Guidance for completing your budget can be found in [Appendix A](#).

V. Application Review Information

A. Criteria

A panel that may include both expert peer reviewers and Federal staff will review the application to ensure that it meets the responsiveness and screening criteria outlined in this section. The purpose of this review is to determine if the approach and strategy are aligned with grant requirements. The detailed results of this review will be shared with the applicant upon request. The application will be scored according to the following point system:

1. Discussion and Understanding of the Project – 25 points maximum

The applicant demonstrates knowledge and understanding of the implementation challenges of the technical standards specified in the cooperative agreement. The applicant provides guidance that specifies solutions to overcome these challenges and leads to consistent implementation and adoption of technical standards.

2. Technical Approach – 25 points maximum

The applicant’s approach is succinct and logical in format and demonstrates methods consistent with the tasks to be accomplished. The applicant must propose a clear and detailed actionable plan which includes specific list of activities and deliverables to achieve the goals specified in the cooperative agreement.

3. Personnel Qualification and Past Performance – 30 points maximum

The applicant must demonstrate and provide evidence of technical experience for identifying, assessing and determining improvements to be made to technical standards and specifications listed in the cooperative agreement. The technical experts to perform tasks on this Funding Opportunity Announcement (FOA) must have the expertise to be able to successfully complete the tasks. The applicant must demonstrate ability to successfully manage projects of similar size and ability to engage with health IT industry stakeholders. All evidence of their past work must be provided in the personnel resumes in the appendix of the applicant's proposal.

4. Management Plan – 15 points maximum

The applicant must provide a project plan that includes a detailed implementation plan to carry out each of the activities proposed in the response, monthly progress meetings, progress reports and a timeline for draft and final deliverables for each of the goals with specific dates identified.

5. Budget Plan – 5 points maximum

The applicant must provide a detailed breakdown on how they plan to spend the allotted resources to complete the tasks outlined in the cooperative agreement based on the guidance provided by ONC in the Purpose of the cooperative agreement.

MAXIMUM TECHNICAL SCORE = 100 POINTS

The application will be reviewed for completeness by the Office of Procurement and Grants, and for responsiveness by ONC. An incomplete application and application that is non-responsive to the eligibility criteria will not advance through the review process. The applicant will be notified that their application did not meet submission requirements.

- An objective review panel will evaluate your application according to the criteria listed in the Criteria section above.

Anticipated Announcement and Award Dates

Award Date: August 21, 2015.

VI. Award Administration Information

Type of Award:	Cooperative Agreement
Total Amount of Funding Available	\$400,000 (Estimated)
Number of Awards	1
Project Period and Budget End Date	5 years

A. Performance Evaluation

The awardee's performance will be evaluated on a monthly basis by ONC. The awardee will partner with ONC to establish monthly reporting mechanisms to track and monitor progress towards goals (quantitative and qualitative data). The awardee shall submit one Final Project Report related to the overall project performance. A specific Final Project Report format will be finalized by ONC following the award date.

B. Public Materials Use

Section 508-compliant materials developed through this funding will be made publicly available at the end of the project period, if not released over the course of the program period.

C. Intellectual Property/Copyrights

The Government reserves all rights granted by, and recipient agrees to be bound by, Administrative Requirements, Cost Principles, and audit requirements as codified in 2 CFR 200 regarding rights in intangible property, 2 C.F.R §200.315, which is specifically incorporated therein. Generally, the recipient may copyright any work that is subject to copyright and was developed, or for which ownership was purchased under this award. The Government 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. 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, non-exclusive, and irrevocable right to reproduce, publish, or otherwise use the work for Federal purposes, and authorize others to do so.

D. Notice of Award

The Notice of Grant Award (NGA) is signed by the ONC Grants Management Officer. The successful applicant's Authorized Representative will receive the NGA electronically from ONC. The NGA is considered the official authorizing award document.

The NGA will include amount of funds awarded, the terms and conditions of the cooperative agreement, the effective date of the award, the budget period for which support will be given, the total project period timeframe, and the total approved budget.

The NGA will provide pertinent instructions and information including, at a minimum, the following:

1. Legal name and address of performing organization or institution to whom ONC has issued an award under the terms of this request for applications;
2. Title of project;
3. Name(s) of institution(s) or Project Directors (PDs) chosen to direct and control approved activities;
4. Identifying award number assigned by ONC;
5. Project period, specifying the amount of time ONC intends to support the project without requiring re-competition of funds;
6. Total amount of financial assistance approved by ONC during the project period;
7. Legal authorities under which the award is issued;
8. Appropriate Catalog of Federal Domestic Assistance (CFDA) number;
9. Applicable award terms and conditions;

10. Approved budget plan for categorizing allocable project funds to accomplish the stated purpose of the award; and
11. Other information or provisions deemed necessary by ONC to carry out its respective awarding activities or to accomplish the purpose of a particular award.

In accepting an ONC award, the awardee 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. Failing to comply with these requirements may result in suspension or termination of the award and/or ONC's recovery of award funds.

VII. Other Terms

These special terms and conditions of the award are in addition to and not in lieu of otherwise applicable OMB administrative guidelines, HHS grant administration regulations in 2 CFR Part 200, Subparts B through D, and other HHS and ONC policy statements.

This cooperative agreement is for a period of five years. By accepting an award, the awardee is required to abide by 2CFR Part 200, Subparts B through D, and other HHS and ONC policy statements. Drawdown of funding for this cooperative agreement serves as official acceptance of this cooperative agreement. If you do not plan to accept the award, please send a letter of declination to the ONC Project Officer within 30 days of receipt of the Notice of Grant Award.

A. Administrative and National Policy Requirements

The award is subject to HHS Administrative Requirements, which can be found in 2 CFR 200, Subparts B through D and the Standard Terms and Conditions implemented through the HHS Grants Policy Statement (GPS) located at <http://www.hhs.gov/asfr/ogapa/aboutog/hhsggps107.pdf>.

B. Post-Award Reporting Requirements

All reporting requirements will be provided to the applicant of a successful application, adherence to which is a required condition of any award. In general, a successful applicant under this guidance must comply with the following reporting and review activities:

C. Audit Requirements

The awardee must comply with audit requirements of Office of Management and Budget (OMB) Uniform Guidance as codified in 2 CFR Part 200, Subpart F. Information on the scope, frequency, and other aspects of the audits can be found at <http://www.ecfr.gov/cgi-bin/text-idx?SID=ed90f54836feb6a994f657188eb05e33&node=2:1.1.2.2.1&rgn=div5>. The HHS Office of the Inspector General (OIG) maintains a toll-free number (1-800-HHS-TIPS [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 reports are treated as sensitive material and submitters may decline to give their names if they choose to remain anonymous.

D. HHS Grants Policy Statement

ONC awards are subject to the requirements of the HHS GPS that are applicable to the grant/cooperative agreement based on recipient type and purpose of award. This includes, as applicable, any requirements in Parts I and II of the HHS GPS that apply to the award, as well as any requirements of Part IV. The HHS GPS is available at <http://www.hhs.gov/asfr/ogapa/aboutog/hhsgps107.pdf>. The general terms and conditions in the HHS GPS will apply as indicated unless there are statutory, regulatory, or award-specific.

E. Record Retention

The awardee 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 three years from the date the final annual FFR is submitted. For awards where the FFR is submitted at the end of the competitive segment, the three-year retention period will be calculated from the date the FFR for the entire competitive segment is submitted. The awardee must retain the records pertinent to the entire competitive segment for three years from the date the FFR is submitted. See 2 CFR 200.333 for exceptions and qualifications to the three-year retention requirement (e.g., if any litigation, claim, financial management review, or audit is started before the expiration of the three-year period, the records must be retained until all litigation, claims, or audit findings involving the records have been resolved and final action taken). Those sections also specify the retention period for other types of grant-related records, including indirect cost proposals and property records. See 2 CFR 200.326 for record retention and access requirements for contracts under grants.

F. Reporting

All reporting requirements will be provided to applicant, adherence to which is a required condition of any award. In general, applicant must comply with the following reporting and review activities.

G. Financial Status and Cash Transaction Reports

Semi-annual expenditures must be submitted for each fiscal year during the period of performance (October 1 through September 30) using 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 is submitted via the Payment Management System (PMS) every calendar quarter for the life of the grant. The report must be submitted within 30 days after the end of the quarter (January 30, April 30, July 30, and October 30). The awardee is still required to complete the FFR Cash Transaction Report via the PMS each calendar quarter.

H. Performance Reports

The awardee's performance will be evaluated on a monthly basis by ONC. Awardee will partner with ONC to establish monthly reporting mechanisms to track and monitor progress towards goals (quantitative and qualitative data). The awardee shall submit one Final Project Report related to the overall project performance. A specific Final Project Report format will be finalized by ONC following the award date.

I. Non-Disclosure Requirements

Since this cooperative agreement may require a awardee to have access to information relating to any and all aspects of grants management operation that may be of a technical; legal; sensitive and/or confidential nature; and which may be of the sole property of the U.S. Government, each awardee must ensure that all its personnel (to include chief executives, directors, any consultants, sub-recipients, or any other personnel that are substantially involved in the performance of this cooperative agreement) who will be personally and substantially involved in the performance of this cooperative agreement:

- Execute and submit Non-Disclosure Agreements prior to the commencement of any work on the cooperative agreement; and
- Put in place appropriate procedures for the protection of such information, and must be liable to the Government for any misuse or unauthorized disclosure of such information by its personnel, as defined above.

J. Potential for Organizational and Personal Conflicts of Interest (COI)

The term “organizational conflict of interest” means that the applicant (to include its chief executives, directors, any consultants, sub-recipients, or any other personnel that are substantially involved in the performance of this cooperative agreement) has interests in which:

- i. May diminish its capacity to give impartial, technically sound, objective assistance and advice in performing these tasks;
- ii. May otherwise result in a biased work product under this cooperative agreement; or
- iii. May result in an unfair competitive advantage to itself or others.

In accordance with Section 200.112, the applicant and non-federal entities must disclose in writing any potential conflicts of interest (COI) that they have with the HHS awarding agency and/or any other pass-through entities. The applicant must notify the HHS awarding agency and their respective grants management officer (GMO) when they believe a COI may exist. If after award, the awardee discovers a COI, with respect to this cooperative agreement, must make an immediate and full disclosure in writing to the GMO. The disclosure must include identification of the conflict, the manner in which it arose, and description of the action the awardee has taken or proposed to take to avoid, eliminate, or neutralize the conflict.

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

The rights and remedies of the Government provided in this clause must not be exclusive and are in addition to any other rights and remedies of the Government provided by law or under this cooperative agreement.

K. Cooperative Agreement Terms and Conditions of Award

The following special terms of award are in addition to, and not in lieu of, otherwise applicable OMB administrative guidelines, HHS grant administration regulations at 2 CFR Part 200, Subpart B through D, and other HHS and ONC grant administration policies.

The administrative and funding instrument used for this program will be the cooperative agreement, an “assistance” mechanism, in which substantial ONC programmatic involvement with each awardee is anticipated during the performance of the activities. Under the cooperative agreement, the ONC purpose is to support and stimulate the awardee’s activities by involvement in and otherwise working jointly with each award awardee in a partnership role; it is not to assume direction, prime responsibility, or a dominant role in the activities. Consistent with this concept, the dominant role and prime responsibility resides with the awardee for the project as a whole, although specific tasks and activities may be shared among the awardee and ONC as defined below.

To facilitate appropriate involvement, during the period of this cooperative agreement, ONC and the awardee will be in contact monthly and more frequently, when appropriate. Requests to modify or amend the cooperative agreement may be made by ONC or the awardee at any time. 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, 2 CFR Part 200, Subpart B through D, or other applicable regulation or statute to make unilateral amendments.

Cooperative Agreement Roles and Responsibilities

The Office of the National Coordinator for Health Information Technology (ONC) will have substantial involvement in program awards as outlined below:

- Technical Assistance – This includes, but is not limited to: federal guidance on C-CDA and FHIR requirements, and other criteria established by the Secretary through the rulemaking process.
- ONC will also assist in meeting the strategic goals of this initiative and overall program on a national level through ongoing support made available through other ONC/HHS funded programs.
- Collaboration – to facilitate compliance with the terms of the cooperative agreement and to more effectively support the awardee, ONC will actively coordinate with critical stakeholders, such as:
 - Medicaid and Medicare Administrators
 - State Designated Entities
 - State Government HIT Leads
 - Relevant Federal Agencies
- Project Officers – ONC will assign a specific Project Officer to this cooperative agreement award to support and monitor the awardee throughout the period of performance.
- Release of Funds Approval – the ONC Project Officer will be responsible for requesting authorization of the release of funds this project.
- Monitoring – ONC Project Officers in conjunction with the Grants Division will monitor the progress of the awardee on a regular basis. This monitoring may be by phone, document review, on-site visit, other meeting, and by other appropriate means, such as reviewing program progress reports and Federal Financial Reports (FFR 425). This monitoring will be to determine compliance with programmatic and financial requirements.

Standard Terms and Conditions - Awardee

The Awardee and assigned point of contact retain the primary responsibility and dominant role for planning, directing, and executing the proposed project as outlined in the terms and conditions of the cooperative agreement with substantial ONC involvement. Responsibilities include:

- Requirements – The awardee must comply with all current and future requirements of the project, including meaningful use requirements, certification criteria, and standards (including privacy and security) specified and approved by the Secretary of HHS.
- Awardee is required to collaborate with the state, local, and federal stakeholders described in their application and the ONC team, including the assigned Project Officer.
- Reporting – Awardee is required to comply with all reporting requirements outlined in this Funding Opportunity Announcement and the terms and conditions of the cooperative agreement to ensure the timely release of funds.

Standard Terms and Conditions – ONC Grants

The awardee and any sub-recipient must comply with the most recent version of the HHS Grants Policy Statement. In addition, awardee must comply with the Administrative Requirements, Cost Principles, and Audit Requirements as codified in 2 CFR Part 200, Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards, Subparts B-F.

The awardee agrees that all allocations and use of funds under this award will be in accordance with the Funding Opportunity Announcement specific to this program.

The awardee understands and agrees to comply with 31 U.S.C. 1352, “Limitation on use of the appropriated funds to influence certain Federal contracting and financial transactions,” and will not use any Federal funds, either directly or indirectly, in support of the enactment, repeal, modification, or adoption of any law, regulation, or policy at any level of government.

This award is subject to the requirements of Section 106 (g) of the Trafficking Victims Protection Act of 2000, as amended (22 U.S.C. 7104). For the full text of the award term, go to <http://www.hrsa.gov/grants/trafficking.htm>. If you are unable to access this link, please contact Division of Grants at ONCGrants@hhs.gov.

Green Procurement: To mitigate the environmental impacts of acquisition of IT and other products/equipment, awardee is encouraged to:

- (1) Participate in “Green procurement” based on the HHS Affirmative Procurement Plan (http://www.hhs.gov/asfr/ogapa/acquisition/10-2010_hhs_affirmative_procurement_plan.doc) and similar guidance from the Environmental Protection Agency (EPA) and the President’s Council on Environmental Quality (CEQ);
- (2) Use electronic products that are Energy Star® compliant and Electronic Product Environmental Assessment Tool (EPEAT) Silver registered or higher, when available;
- (3) Activate Energy Star® features on all equipment, when available; and
- (4) Use environmentally sound end-of-life management practices, including reuse, donation, sale, and recycling of all electronic products.

Requirements for the System for Award Management (SAM) and Data Universal Numbering System (DUNS) numbers: Unless your entity is exempt from SAM requirement under 2 CFR 25.110, it is incumbent upon you, as the awardee, to maintain the accuracy/currency of your information in the SAM until the end of the project. Additionally, this term requires your entity to review and update the information at least annually after the initial registration, and more frequently if required by changes in your information or another award term.

If your entity is authorized to make sub-awards under this award, you: 1) must notify potential direct sub-recipients that no entity may receive a sub-award from you unless the entity has provided its DUNS number to you; and 2) may not make a sub-award to an entity unless the entity has provided its DUNS number to you.

Semi-annual expenditures must be submitted for each fiscal year during the period of performance (October 1 through September 30) using 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 awardee indicates acceptance of the terms and conditions of the award, and agrees to perform in accordance with the requirements of the award by requesting funds from the designated grant payment system.

Funding of future non-competing continuation awards is conditioned on the availability of funds, satisfactory progress by each awardee, and an awarding office determination that continued funding of the award is in the best interest of the Government.

VIII. Agency Contacts

Matthew Rahn

Office of the National Coordinator for Health Information Technology

Email: SDOFOA@hhs.gov

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:

- i) the communication is purely logistical;
- ii) the communication is made at a widely attended gathering;
- iii) the communication is to or from a Federal agency official and another Federal Government employee;
- iv) 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; or
- v) the communication is initiated by the Federal agency official.

For additional information see: www.ecfr.gov

IX. Tips for Writing a Strong Application

Include DUNS Number. You must include a DUNS Number to have your application reviewed. Applications will not be reviewed without a DUNS number. 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 program requirements and expectations are complete and clearly written. Do not assume that reviewers are familiar with the lead awardee organization. Keep the review criteria in mind when writing the application.

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 awardee 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.

X. Appendices

Appendix A. Instructions for completing the SF-424, Budget (SF 424A)

Budget Narrative/Justification, and Other Required Forms

This section provides step-by-step instructions for completing the four (4) standard Federal forms required as part of your grant application, including special instructions for completing Standard Budget Forms 424 and 424A. Standard Forms 424 and 424A are 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, please use the instructions below in lieu of the standard instructions attached to SF-424 and 424A to complete these forms.

a. Standard Form 424

- 1. Type of Submission:** (Required): Select one type of submission in accordance with agency instructions.
 - Pre-application • Application • Changed/Corrected Application – If requested, check if this submission is to change or correct a previously submitted application.
- 2. Type of Application:** (Required) Select one type of application in accordance with agency instructions.
 - New • Continuation • Revision
- 3. Date Received:** Leave this field blank.
- 4. Applicant Identifier:** Leave this field blank
- 5a. Federal Entity Identifier:** Leave this field blank
- 5b. Federal Award Identifier:** For new applications leave blank. For a continuation or revision to an existing award, enter the previously assigned Federal award (grant) number.
- 6. Date Received by State:** Leave this field blank.
 - 1. State Application Identifier:** Leave this field blank.
 - 2. Applicant Information:** Enter the following in accordance with agency instructions:
 - a. Legal Name:** (Required): Enter the name that the organization has registered with the Central Contractor Registry. Information on registering with SAM may be obtained by visiting the Grants.gov website.
 - b. Employer/Taxpayer Number (EIN/TIN):** (Required): Enter the Employer or Taxpayer Identification Number (EIN or TIN) as assigned by the Internal Revenue Service.
 - c. Organizational DUNS:** (Required) Enter the organization's DUNS or DUNS+4 numbers received from Dun and Bradstreet. Information on obtaining a DUNS number may be obtained by visiting the Grants.gov website.

- d. **Address:** (Required) Enter the complete address including the county.
 - e. **Organizational Unit:** Enter the name of the primary organizational unit (and department or division, if applicable) that will undertake the project.
 - f. **Name and contact information of person to be contacted on matters involving this application:** Enter the name (First and last name required), organizational affiliation (if affiliated with an organization other than the applicant organization), telephone number (Required), fax number, and email address (Required) of the person to contact on matters related to this application.
- 9. Type of Applicant:** (Required) Select the applicant organization “type” from the following drop down list.
- 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 Authority M. Nonprofit with 501C3 IRS Status (Other than Institution of Higher Education) N. Nonprofit without 501C3 IRS Status (Other than Institution of Higher Education) O. Private Institution of Higher Education P. Individual Q. For-Profit Organization (Other than Small Business) R. Small Business S. Hispanic-serving Institution T. Historically Black Colleges and Universities (HBCUs) U. Tribally Controlled Colleges and Universities (TCCUs) V. Alaska Native and Native Hawaiian Serving Institutions W. Non-domestic (non-US) Entity X. Other (specify)
- 10. Name of Federal Agency:** (Required) Enter Office of the National Coordinator
- 11. Catalog of Federal Domestic Assistance Number/Title:** The CFDA number can be found on page one of the Program Announcement.
- 12. Funding Opportunity Number/Title:** (Required) The Funding Opportunity Number and title of the opportunity can be found on page one of the Program Announcement.
- 13. Competition Identification Number/Title:** Leave this field blank.
- 14. Areas Affected By Project:** List the largest political entity affected (cities, counties, state etc.).
- 15. Descriptive Title of Applicant’s Project:** (Required) Enter a brief descriptive title of the project.
- 16. Congressional Districts Of:** (Required) 16a. Enter the applicant’s Congressional District, and 16b. 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 12th district, and NC-103 for North Carolina’s 103rd 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.

17. Proposed Project Start and End Dates: (Required) Enter the proposed start date and final end date of the project. Therefore, if you are applying for a multi-year grant, such as a 3 year grant project, the final project end date will be 3 years after the proposed start date.

18. Estimated Funding: (Required) Enter the amount requested or to be contributed during the first funding/budget period by each contributor. Value of in-kind contributions should be included on appropriate lines, as applicable. If the 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.

NOTE: Applicants should review cost sharing or matching principles contained in 2 CFR 200.306(b) before completing Item 18 and the Budget Information Sections A, B and C noted below.

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 1/3rd of the amount of Federal funds being requested (the amount in 18a). For a full explanation of ONC's match requirements, see the information in the box below. For sub-item 18f, enter only the amount, if any, which is going to be used as part of the required match.

There are two types of match: 1) non-Federal cash and 2) non-Federal in-kind. In general, costs borne by the applicant and cash contributions of any and all third parties involved in the project, including sub-awardees, contractors and consultants, are considered matching funds. Generally, most contributions from sub-contractors or sub-awardees (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 includes budgetary funds provided from the applicant agency's budget for costs associated with the project.

NOTE: 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 DHHS 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-awardees are requesting indirect costs, copies of their indirect cost agreements must also be included with the application.**

19. Is Application Subject to Review by State Under Executive Order 12372 Process? Check
c. Program is not covered by E.O. 12372

20. Is the Applicant Delinquent on any Federal Debt? (Required) This question applies to the applicant organization, not the person who signs as the authorized representative. If yes, include an explanation on the continuation sheet.

21. Authorized Representative: (Required) To be signed and dated by the authorized representative of the applicant organization. Enter the name (First and last name required) title (Required), telephone number (Required), fax number, and email address (Required) of the person authorized to sign for the applicant. 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.)

Standard Form 424A

NOTE: 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 one year budget.

Section A - Budget Summary

Line 5: Leave columns (c) and (d) blank. Enter TOTAL Federal costs in column (e) and total non-Federal costs (including third party in-kind contributions and any program income to be used as part of the awardee 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 contractual, detailed Budget Narratives/Justifications must be provided for each sub-contractor or sub-awardee.

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.

For your use in developing and presenting your Budget Narrative/Justification, a sample format with examples and a blank sample template have been included in these Attachments. 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-awardee (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/awardee staff. Do not include the costs 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.

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 break-down of amounts and percentages that comprise fringe benefit costs, such as health insurance, FICA, retirement insurance, etc.

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, 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 awardees, "equipment" is non-expendable tangible personal property having a useful life of more than one year and an acquisition cost of \$5,000 or more per unit or as indicated in negotiated IDC agreement with cognizant federal agency. 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-awardees. The justification also must contain plans for the use or disposal of the equipment after the project ends.

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.

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/awardee intends to delegate more than 33% of a project's total budget to the contractual line item, the applicant/awardee must provide a completed copy of Section B of the SF-424A Budget Categories for each sub-contractor or sub-awardee, and separate Budget Narrative/Justification for each sub-contractor or sub-awardee for each year of potential grant funding.**

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

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

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 DHHS 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-awardees 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 program, 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

Line 12: Enter the amounts of non-Federal resources that will be used in carrying out the proposed project, by source (Applicant; State; Other) and enter the total amount in Column (e). Keep in mind that if the match requirement is not met, Federal dollars may be reduced.

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.

b. Standard Form 424B - Assurances

This form contains assurances required of applicants under the discretionary funds programs administered by the Assistant Secretary for Preparedness and Response. Please note that a duly authorized representative of the applicant organization must certify that the organization is in compliance with these assurances.

c. Certification Regarding Lobbying

This form contains certifications that are required of the applicant organization regarding lobbying. Please note that a duly authorized representative of the applicant organization must attest to the applicant's compliance with these certifications.

d. Other Application Components

Survey on Ensuring Equal Opportunity for Applicants

The Office of Management and Budget (OMB) has approved an HHS form to collect information on the number of faith-based groups applying for a HHS grant. Non-profit organizations, excluding private universities, are asked to include a completed survey with their grant application packet. Attached you will find the OMB approved HHS "Survey on Ensuring Equal Opportunity for Applicants" form (Attachment F). Your help in this data collection process is greatly appreciated.

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

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.

Appendix B. Budget Narrative/Justification, Page 1 – Sample Format with EXAMPLES

NOTE: These are sample costs as to how they should be reflected in the template, and are suggested to offer guidelines when applicants are completing their budget justifications.

Object Class Category	Federal Funds	Non-Federal Cash	Non-Federal In-Kind	TOTAL	Justification
Personnel	\$40,000	\$5,000		\$45,000	Project Administrator (name) = .3FTE @ \$50,000/yr = ... \$15,000 (\$10,000 = Federal; \$5,000 = Non-Federal cash) Project Director (name) = 1FTE @ \$30,000 = ... \$30,000 (Federal) TOTAL:\$45,000
Fringe Benefits	\$12,600	0	0	\$12,600	Fringes on Project Staff @ 28% of salary. (Federal) FICA (7.65%)= \$ 3,442 Health (12%) = ... \$ 5,400 Dental (5%) = ... \$ 2,250 Life (2%) = ... \$ 900 Workers Comp Insurance (.75%) = ... \$ 338 Unemployment Insurance (.6%) = ... \$ 270 TOTAL:\$12,600

Object Class Category	Federal Funds	Non-Federal Cash	Non-Federal In-Kind	TOTAL	Justification
Travel	\$4,120	\$1,547		\$5,667	Travel to 2 Annual Awardee Meetings: (Federal) Airfare: 1 RT x 2 people x \$750/RT x 2 = ... \$3,000 Lodging: 2 nights x 2 people x \$100/night x 2 = ... \$ 800 Per Diem: 2 days x 2 people x \$40/day x 2 = ... \$ 320 TOTAL: \$4,120 Out-of-Town Project Site Visits (Non-Federal cash) Car mileage: 3 trips x 2 people x 350 miles/trip x \$.365/mile = ... \$ 767 Lodging: 3 trips x 2 people x 1 night/ trip x \$50/night = ... \$ 300 Per Diem: 3 trips x 2 people x 2days/trip x \$40/day = ... \$ 480 TOTAL:..... \$1,547
Equipment	0	0	0	0	No equipment requested
Supplies	\$1,340	\$2,160		\$3,500	Laptop computer for use in client intakes = ... \$1,340 (Federal) Consumable supplies (paper, pens, etc.) \$100/mo x 12 months = ... \$1,200 (Non-Federal cash) Copying \$80/mo x 12 months = ... \$ 960 (Non-Federal cash) TOTAL: \$3,500
Contractual	\$150,000		\$50,000	\$200,000	Contracts to A,B,C direct service providers (name providers) contractor A = ... \$75,000 (Federal) contractor B = ... \$75,000 (Federal) contractor C = ... \$50,000 (Non-Federal In-Kind) TOTAL:..... \$200,000

Object Class Category	Federal Funds	Non-Federal Cash	Non-Federal In-Kind	TOTAL	Justification
Other	\$1,250	\$2,000		\$3,250	Local conf registration fee (provide conference name = ... \$ 200 (Non-Fed cash) Printing brochures (25,000 @ \$0.05 ea) = ... \$ 1,250 (Federal) Postage: \$150/mo x 12 months = ... \$ 1,800 (Non-Fed cash) TOTAL..... \$3,250
TOTAL	\$209,310	\$10,707	\$50,000	\$270,017	

Appendix C. Budget Narrative/Justification — Sample Template

Object Class Category	Federal Funds	Non- Federal Cash	Non- Federal In- Kind	TOTAL	Justification
Personnel					
Fringe Benefits					
Travel					
Equipment					
Supplies					
Contractual					
Other					
Indirect Charges					
TOTAL					

Appendix D. Project Work Plan, Page 1 – Sample Template

Goal:
Measurable Outcome(s):

Major Objectives	Key Tasks	Lead Person	Timeframe (Start/End Dates by Month in Project Cycle)											
			1	2	3	4	5	6	7	8	9	10	11	12
1.														
2.														

Appendix E. Project Work Plan, Page 2 – Sample Format

Major Objectives	Key Tasks	Lead Person	Timeframe (Start/End Dates by Month in Project Cycle)											
			1	2	3	4	5	6	7	8	9	10	11	12
3.														
4.														