Notice of Funding Opportunity
Accelerating and Expanding LOINC® Development to Support Public Health Needs

Application Due Date: 09/11/2020
Anticipated Award Date: 09/30/2020
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Executive Summary

Logical Observations Identifiers Names and Codes (LOINC®)¹ is an open source, universal code system for identifying laboratory and clinical observations produced and copyrighted by the Regenstrief Institute (Regenstrief). LOINC® is used in conjunction with many other standards published by standards development organizations (SDOs), such as Health Level 7 International (HL7®)², Integrating the Healthcare Enterprise (IHE)³, SNOMED International (SNOMED®)⁴, and Radiological Society of North America (RSNA®)⁵. LOINC® provides for semantic interoperability and has been identified by HL7® as the preferred code set for laboratory test names in transactions between health care facilities, laboratories, laboratory testing devices, and public health authorities. LOINC® has also been adopted by the U.S. Department of Health and Human Services (HHS) and incorporated by reference as part of the Office of the National Coordinator for Health Information Technology (ONC)’s 2015 Edition certification criteria⁶ (see 45 CFR 170.299(o)). LOINC® is also referenced in the annual ONC Interoperability Standards Advisory (ISA)⁷.

The LOINC® team at Regenstrief maintains the LOINC® database and supporting documentation, processes submissions and edits to the content, develops and curates accessory content (descriptions, hierarchies, other attributes, etc.), develops the Regenstrief LOINC® Mapping Assistant (RELMA®) mapping program (a software that helps users map their local terms or lab tests to universal LOINC® codes), and coordinates LOINC® releases. In addition, Regenstrief continues to cultivate and support the LOINC® community worldwide by increasing and updating the standardized list of LOINC® codes available for the most commonly ordered laboratory tests in ambulatory care settings, the Universal Common Order Codes Value Set (Common Lab Orders).

Laboratories play an essential role in the ability to test and diagnosis patients for the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) virus, using LOINC® codes in the in vitro diagnostics (IVD) SARS-CoV-2 test kits that identify the presence of the SARS-CoV-2 virus (the virus, in the Coronavirus disease 2019 [COVID-19]) in patients suspected of having COVID-19. Since the beginning of the COVID-19 outbreak⁸, Regenstrief, as the sole owners and stewards of LOINC®, has experienced an overwhelming increase in requests for LOINC® codes to support the lab test kits being used to test and identify patients experiencing symptoms of the virus. As of May 22, 2020, Regenstrief has developed 1,073 new LOINC® “Special Use” codes, codes that are developing in response to an urgent or emergent situation, resulting in substantial resource constraints and need to divert staff from other priorities.

The purpose of this Notice of Funding Opportunity (NOFO) is to provide time sensitive additional support to increase the development and pre-release of LOINC® Special Use codes⁹, and updating of their technical infrastructure in order to support the search ability and rapid dissemination of the codes to IVD manufacturers, laboratories, and other entities both nationally and internationally. This funding opportunity is in the form of a cooperative agreement and is for the purposes of accelerating and expanding LOINC® development to support public health needs as authorized under the Coronavirus Aid, Relief, and Economic Security (CARES) Act (CARES Act) (Pub. L. No. 116-136, March 27, 2020), as well as Section 3011 of the Public Service Health Act (PHSA) Through this funding

¹ https://loinc.org/
² http://www.hl7.org/index.cfm
³ https://www.ihe.net/
⁴ http://www.snomed.org/
⁵ https://www.rsna.org/
⁷ https://www.healthit.gov/isa/
⁸ https://www.who.int/emergencies/diseases/novel-coronavirus-2019
⁹ https://loinc.org/prerelease/
opportunity, ONC will award a sole source cooperative agreement in support of the rapid development of LOINC® Special Use codes and the deployment of corresponding technical and educational resources to ensure all affected stakeholders can adequately respond to the COVID-19 pandemic.

Under this sole source cooperative agreement, Regenstrief should work collaboratively with ONC to develop LOINC® codes in coordination with other federal agencies such as the Centers for Disease Control and Prevention (CDC)10, and the Food and Drug Administration (FDA)11, infrastructure upgrades that provide mapping services and corresponding technical support, such as drafting and publishing of content for its partners, external stakeholders, and end users. Regenstrief should collaborate with ONC to ensure efforts align with recommendations made by HHS specific to COVID-19, and also support expansion of interoperability objectives such as those define in the 21st Century Cures Act (Cures Act) Final Rule.12

The expected outcomes of this cooperative agreement are to 1) support the rapid development of SARS-CoV-2 LOINC® codes and associated mapping services; 2) upgrade technical infrastructure necessary to support IVD manufacturers, laboratories, and other entities in testing efforts; and 3) to standardize the terminology for test order and lab results. Combined, we anticipate these efforts will streamline communication and processes, provide timely support to the LOINC® community, and reduce the number of unnecessary lab orders and erroneous results delivery that is currently being reported.

10 https://www.cdc.gov/
11 https://www.fda.gov/
A. Program Description/Purpose

In 2018, ONC issued a sole source cooperative agreement, “Enhancing the Logical Observation Identifiers Names and Codes (LOINC®) Standard to Support U.S. Interoperability,” with the Regenstrief Institute (Regenstrief). The goal of this cooperative agreement was to upgrade their underlying technical infrastructure in order to update existing, and develop new LOINC® codes to advance interoperable health IT, and position LOINC® to support the continued evolution of the U.S. Core Data for Interoperability (USCDI)\(^\text{13}\).

Through this cooperative agreement, Regenstrief has been able to update their servers; convert, test, and publically deploy their legacy Access-based Multiaxial Hierarchy process to a new set SQLServer stored procedure; upgrade and deploy LHC-Forms\(^\text{14}\) and LOINC® panel content\(^\text{15}\), deploy LOINC® Release versions 2.65 and 2.66; and develop tools to support the creation and management of Health Level 7 International’s (HL7®) Fast Healthcare Interoperability Resources (FHIR®) ValueSets\(^\text{16}\).

The outbreak of the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) virus has increased the number of requests for new LOINC® codes, which are being released in real-time as “Special Use” codes; codes that are developing in response to an urgent or emergent situation. The rapid creation of Special Use codes supporting the coronavirus disease (COVID-19) pandemic has resulted in 1,073 new LOINC® codes as of May 22, 2020.

To objectives under this cooperative agreement award are:

1) To support the rapid development of SARS-CoV-2 LOINC® codes and associated mapping services;
2) Upgrade technical infrastructure necessary to support IVD manufacturers, laboratories, and other entities in testing efforts; and
3) Terminology standardization.

Structure and Approach

The recipient is encouraged objectives to submit a plan to ONC that outlines the methodological approach it intends to take to meet the purpose of the cooperative agreement and collaborate with ONC when developing this plan.

The plan and methodological approach may include, but are not limited to, the following components:

- Term Creation and Mapping Services for SARS-CoV-2 Testing and Other Public Health Needs;
- Technical Infrastructure Upgrades to Support SARS-CoV-2 and Other Public Health Content and Interoperability Development; and
- Standardization of terminology to reduce errors and the need for unnecessary tests, both which help to decrease costs within health care.

Roles and Responsibilities Under a Cooperative Agreement

\(^{13}\) https://www.healthit.gov/isa/united-states-core-data-interoperability-uscdi
\(^{14}\) https://loinc.org/lhc-forms/
\(^{15}\) https://loinc.org/panels-and-forms/
\(^{16}\) https://loinc.org/fhir/
The funding instrument used for this program will be the cooperative agreement, an assistance mechanism in which substantial ONC programmatic involvement is anticipated during the project period-of-performance. Under the cooperative agreement, the ONC purpose is to support and stimulate the recipient’s activities by involvement in, and otherwise working jointly with, the recipient in a partnership role; it is not to assume direction, prime responsibility, or a dominant role in the activities. Consistent with this premise, the dominant role and prime responsibility resides with the recipient for the project as a whole. To facilitate appropriate involvement, during the cooperative agreement period-of-performance, ONC and the recipient will be in contact monthly, at minimum, and more frequently when appropriate.

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

♦ Providing substantive input and policy direction as appropriate, and collaborate with the recipient to identify and prioritize the types and numbers of underlying technical infrastructure upgrades needed, as well as the timeline in which these upgrades must be completed

♦ Working with the recipient to set the priorities and implementation direction that will be detailed in the Project Implementation Plan and all other deliverables submitted to meet the goals of the project (identified in Deliverable Table)

♦ Providing tactical guidance and feedback during project execution

♦ Collaborate with the recipient and other federal agencies to ensure programmatic and policy alignment, awareness, and use of SARS-CoV-2 test orders and results.

♦ Collaborate with the recipient to identify and prioritize the types and numbers of underlying technical infrastructure upgrades needed, as well as the timeline by which these upgrades must be completed.

♦ Provide substantive input in the development of the terminology standardization pilot projects, including pilot partners and pilot sites.

♦ Conduct, on an annual basis reassessments of the state of public health needs, and in collaboration, update the Project Implementation Plan and any other related activities and priorities. The Project Implementation Plan and any other related activities and priorities may also be reassessed and adjusted at any time if deemed necessary by ONC and/or the recipient.

♦ Participating in the selection of key personnel, as deemed necessary.

♦ Releasing funds based on achievement of performance goals/project milestones.

♦ Agency review and approval of substantive provisions of proposed sub-awards or contracts.

♦ Agency review, assessment, and final approval of priorities and deliverables as identified by the recipient.

♦ 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.
Performance Goals/Program Milestones
ONC will measure the success of the projects through applicant reporting of progress on milestones and metrics and how well they advance one of both of the following ONC objectives: advancing the development and use of health IT capabilities, and establishing transparent expectations for data sharing. The applicant will develop an audit-appropriate process for validating milestone achievement and a measurement process and tools for recording metrics. Applicants must provide baseline measurements and propose performance metrics to demonstrate successful support for the rapid development of Special Use LOINC® codes for SARS-CoV-2. For each milestone and metric, ONC will work with the applicant to determine the appropriate targets and reporting requirements.

The performance goals/program milestones associated with each are of interest in this NOFO, and ensuing award, are as follows:

Objective 1: Prioritize Term Creation and Mapping Services for SARS-CoV-2 Testing and Other Public Health Needs
The recipient is able to respond to incoming requests for SARS-CoV-2-related LOINC® codes for test kits and rapidly deploy Special Use codes as they complete development, in addition to mapping services for In Vitro Diagnostics (IVD) manufacturers, laboratories, and other entities with limited impact to the development of non-SARS-CoV-2-related LOINC® codes.

Objective 2: Technical Infrastructure Upgrades to Support SARS-CoV-2 and Other Public Health Content and Interoperability Development
The recipient, deploys technical infrastructure improvements that support the new SARS-CoV-2/COVID-19 related content development, and improve the availability of other public health resources for future interoperability needs.

Objective 3: Terminology Standardization
The recipient increases the implementation and use of standardized terminology for SARS-CoV-2/COVID-19 test ordering and results delivery naming.

Performance Goals shall be tracked and measured by the recipient in order to assess overall programmatic results over the entirety of the cooperative agreement’s period-of-performance and the project’s impact in supporting their response to SARS-CoV-2/COVID-19 and the advancement of public health needs across the health care continuum. Specific objectives, approach, measurement metrics, performance targets, and data source shall be proposed by the recipient within 4-weeks of award date, for discussion with and for approval by ONC. A sample table for measuring progress of specific objective is given below for reference.

<table>
<thead>
<tr>
<th>Objectives and Goal(s)</th>
<th>Approach</th>
<th>Metric/Measure</th>
<th>Type of Measure</th>
<th>Performance Target</th>
<th>Data Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>New SARS-CoV-2 LOINC Codes</td>
<td>How do we plan to achieve this goal?</td>
<td>How can we demonstrate that we have achieved the stated goal?</td>
<td>Input, Output, Outcome</td>
<td>What is the performance target for the measure and by the end of the 5-year period of performance?</td>
<td>How will you capture data to measure performance?</td>
</tr>
</tbody>
</table>
Objectives and Goal(s)  
What are we trying to achieve with this project?

Approach  
How do we plan to achieve this goal?

Metric/Measure  
How can we demonstrate that we have achieved the stated goal?

Type of Measure  
Input, Output, Outcome

Performance Target  
What is the performance target for the measure and by the end of the 5-year period of performance?

Data Source  
How will you capture data to measure performance?

Adoption Level

Stakeholder/SDO Outreach and Engagement

Sample Measurement Table:

<table>
<thead>
<tr>
<th>New SARS-CoV-2 LOINC Codes</th>
<th>Y1 Q1 Actual</th>
<th>Y1 Q2 Actual</th>
<th>Y1 Q3 Actual</th>
<th>Y1 Q4 Actual</th>
</tr>
</thead>
<tbody>
<tr>
<td>Year 1</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Q1 Target</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Q2 Target</td>
<td>-</td>
<td>-</td>
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</tr>
<tr>
<td>Q3 Target</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Q4 Target</td>
<td>-</td>
<td>-</td>
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<td>-</td>
</tr>
</tbody>
</table>

B. Funding Opportunity Award Information

Key Award Parameters

Title: Accelerating and Expanding LOINC® Development to Support Interoperable Public Health Reporting

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

Announcement Type: Cooperative Agreement

Application Type: New

Funding Opportunity Number: COVID-C3-20-004

Catalog of Federal Domestic Assistance (CFDA) Number: 93.346
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: Regenstrief Institute

1. Sole Source Justification

Regenstrief Institute (Regenstrief) is a non-profit medical research organization, associated with Indiana University, and is the exclusive standards development organization (SDO) with the ability, authority, and intellectual property rights to develop and maintain the Logical Observation Identifiers Names and Codes (LOINC®), an open source common terminology for laboratory and clinical observations. As a result, Regenstrief is the only organization that can successfully deliver the goals articulated in this funding opportunity. Moreover, Regenstrief members include organizations that are actively engaged in implementing LOINC® codes in health IT systems and standards, and hence can provide necessary feedback in a timely manner through a well-established process for consensus standards development. As the field of medicine continues to evolve, there is an ongoing need for Regenstrief to provide new codes in a timely manner. The goals and expected outcomes of this funding opportunity can only be achieved accurately and in a timely manner by Regenstrief, given its authoritative role as the steward for LOINC®. Thus, Regenstrief’s involvement is both fundamental and always necessary to publish an update to LOINC® codes and associated LOINC® infrastructure components. As such, this funding opportunity announcement seeks to establish a formal collaboration with Regenstrief through a sole source cooperative agreement in order to accelerate the development of new LOINC® codes to support SARS-CoV-2 testing, including code development, mapping services, and technical infrastructure upgrades. This project would assist to coordinate with the health care industry to rapidly respond to incoming SARS-CoV-2/COVID-19 related requests, standardize terminology, and improve and advance the technical standards and specifications required for public health interoperability. Working directly with Regenstrief will enable this coordination to be more effective and efficient and will enable broad industry consensus to be more rapidly achieved when done through Regenstrief’s processes.

This NOFO is a new, sole source, 5-year cooperative agreement for a maximum award of $1,500,000. (Funding Opportunity Number COVID-C3-20-004; Catalog of Federal Domestic Assistance Number 93.346). The eligible applicant must submit an application by 93.346. Subsequent years of funding for this cooperative agreement is contingent on meaningful progress and availability of funds.

HHS grants policy requires that the grant recipient perform a substantive role in the conduct of the planned project or program 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 grantee and what substantive role the applicant organization will play.

An incomplete and/or non-responsive application not following instructions given in this NOFO will not be reviewed. Only the review criteria described below will be considered in the review process.

Legislative Authority: Coronavirus Aid, Relief, and Economic Security (CARES) Act (CARES Act) (Pub. L. No. 116-136, March 27, 2020), as well as Section 3011 of the Public Health Service Act (PHSA)
Approximate Amount of Available Funding (inclusive of direct and indirect costs): $1,500,000.00

Anticipated Number of Awards: 1

Approximately Amount of Each Award: $1,500,000

Project Period: TBD

Budget Period(s): TBD

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 project/program costs to determine the net allowable costs on which the Federal share of costs is based; 2) add it to funds otherwise available for the 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.

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 program is excluded from Executive Order 12372

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### Key Dates

<table>
<thead>
<tr>
<th>Milestone</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOFO Released</td>
<td>08/12/2020</td>
</tr>
<tr>
<td>Applications Due</td>
<td>09/11/2020</td>
</tr>
<tr>
<td>Anticipated Award Date</td>
<td>09/30/2020</td>
</tr>
<tr>
<td>Anticipated Project Start Date</td>
<td>09/30/2020</td>
</tr>
</tbody>
</table>

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**Roles and Responsibilities Under a Cooperative Agreement**

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

Specific activities may be shared between Regenstrief and ONC include, but are not limited to:

- Providing substantive input and policy direction as appropriate, and collaborate with Regenstrief to identify and prioritize the types and numbers of underlying technical infrastructure upgrades needed, as well as the timeline in which these upgrades must be completed

- Working with Regenstrief to set the priorities and implementation direction that will be detailed in the Project Implementation Plan and all other deliverables submitted to meet the goals of the project (identified in Deliverable Table)
Providing tactical guidance and feedback during project execution

Collaborate with Regenstrief and other federal agencies to ensure programmatic and policy alignment, awareness, and use of SARS-CoV-2 test orders and results.

Collaborate with Regenstrief to identify and prioritize the types and numbers of underlying technical infrastructure upgrades needed, as well as the timeline by which these upgrades must be completed.

Provide substantive input in the development of the terminology standardization pilot projects, including pilot partners and pilot sites.

Conduct, on an annual basis reassessments of the state of public health needs, and in collaboration, update the Project Implementation Plan and any other related activities and priorities. The Project Implementation Plan and any other related activities and priorities may also be reassessed and adjusted at any time if deemed necessary by ONC and/or Regenstrief.

Participating in the selection of key personnel, as deemed necessary.

Releasing funds based on achievement of performance goals/project milestones.

Agency review and approval of substantive provisions of proposed subawards or contracts.

Agency review, assessment, and final approval of priorities and deliverables as identified by Regenstrief.

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
An Informational Session will not be conducted.

Letter of Intent
A notice of intent is not required for this award.

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 is 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 Program Description/Purpose and Structure and Approach sections of this NOFO. The project narrative should also align with the Performance Goals/Program Milestones and Merit Review Evaluation criteria presented in this NOFO (e.g. organizational experience, past performance etc.).

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 30 pages. A Project Narrative that exceeds the 30 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 30 page limit.

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

1. Understanding the Requirements (20 Points)
2. Proposed Approach (40 Points)
3. Project Team and Staffing Qualifications (15 Points)
4. Project Management (15 Points)
5. Reasonableness of the Budget Narrative (10 Points)

1. Understanding the Requirements (20 Points)

The applicant demonstrates knowledge and understanding of the need to rapidly deploy a dedicated team focused on SARS-CoV-2 LOINC® requests, upgrade their underlying technical infrastructure to successfully support the codes and support services to LOINC® implementers, and the need for standardized terminology for test ordering and results naming. (2-3 pages)

2. Proposed Approach (40 Points)

The applicant provides guidance that specifies solutions to overcome currently known gaps both in their underlying technical infrastructure and in LOINC® codes and other support services as detailed above in this NOFO, and their proposed strategy to efficiently and effectively implement these solutions. The applicant’s approach is succinct and logical in format and demonstrates methods consistent with the activities to be accomplished. The applicant must propose a clear and detailed actionable plan which includes specific list of activities to achieve the objectives and deliverables specified in the NOFO. (10-18 Pages)

3. Project Team and Staffing Qualifications (15 Points)

The applicant must demonstrate and provide evidence of the following:

a. Experience for identifying, assessing, determining and implementing improvements necessary to effectively and efficiently upgrade their underlying technical infrastructure.

b. Experienced and knowledgeable technical experts to develop new and/or update existing LOINC® codes.

c. Knowledgeable about HL7® FHIR® and the standards development process, as well as the ability to successfully engage with SDOs and other industry stakeholders for purposes of advancing interoperable health IT using LOINC®.

d. Experienced and knowledgeable technical experts to develop new and/or update existing FHIR-based terminology services.

e. The ability to successfully manage projects of similar size, on time, and within the proposed budget.
All evidence of their past work must be provided in the personnel resumes in the appendix of the applicant’s proposal. (2-3 Pages)

4. **Project Management (15 Points)**
   This section should include a clear delineation of the roles and responsibilities of the principal investigator (PI), project staff, and collaborating organizations, and how they will contribute to achieving the research objectives and outcomes. If the application includes sub-awards recipients with contractual relationships, plans for coordinating these activities across multiple organizations should be described. This section should specify who would have day-to-day responsibility for key activities 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 that incorporates those milestones. The project timeline will not count towards the narrative page limit. It should also include an organizational chart that reflects roles and responsibilities. The organizational chart will not count towards the narrative page limit. (2-3 Pages)

5. **Reasonableness of the Budget Narrative (10 Points)**
   The applicant must provide a detailed breakdown on how they plan to spend the allotted resources to complete the activities detailed in the NOFO. (2-3 Pages)

**Appendices**

Applicants may submit no more than 30 pages of appendix material. Appendix material should be used to provide additional materials (for example, key papers or reports or excerpts) that will be of assistance in evaluating the merit of the application. Do not use the Appendix to circumvent the page limitations of the Project Narrative component. Applications that use appendix material as a mechanism to exceed the page length limitations of the project narrative will not be considered for award.

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

**Form SF-424A, Budget Information for Non-Construction Programs**
Appendix C provides line-by-line instructions to complete the form. Please note that the SF-424A is used for a wide variety of Federal grant programs, and Federal agencies have the discretion to require some 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 program via http://www.grants.gov. You can search the downloadable application page by the Notice of Funding Opportunity Number COVID-C3-20-004 or CFDA number 93.346.

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.

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

b) 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, www.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.
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 30 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 five criteria:

1. Understanding the Requirements (20 Points)
2. Proposed Approach (40 Points)
3. Project Team and Staffing Qualifications (15 Points)
4. Project Management (15 Points)
5. Reasonableness of the Budget Narrative (10 Points)

Understanding the Requirements (20 points)

- How well does the application understand the current challenges and address the purpose and objectives of this NOFO? To what extent is the proposed project parallel NOFO goals?
- The extent to which the applicant describe how the project and expected outcomes and results will inform the field and future health IT development, public health and emergency preparedness, and semantic interoperability.

Proposed Approach (40 Points)

- The extent to which the proposed approach will address the challenges on a proposed timeline within the parameters of a self-contained five-year project period-of-performance.
- The extent to which the proposed approach specifies solutions to known gaps, in a reasonable, efficient, and timely manner.
- The extent to which the proposed approach plans to engage industry stakeholders. Specifically:
  - Reaching consensus on standardized terminology; and
  - Approach to pilot projects
- The extent to which the plan describes a project management approach for ensuring project success within and across collaborators
- Extent to which the proposed approach are specifically stated, adequately developed, well-integrated, well-reasoned, and appropriate to the goals/objectives of the project.
- The extent to which the applicant proposes a clear and detailed implementation plan with a specific list of activities and deliverables to achieve the objectives proposed.

Project Team and Staffing Qualifications (15 Points)

- Strength of evidence that the project brings an appropriate level of technical knowledge and expertise, for the project and strength of evidence that the project will integrate the efforts of those team members. Specifically:
  - Are the PD/PI, collaborators, and other key 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 project period-of-performance?
• Does the application demonstrate the investigators’ aptitude to identify and address weaknesses encountered during the conduct of the project?
• Does the application demonstrate that the project team will have adequate administrative structure and processes in place to oversee the successful conduct of the proposed study?
• Did project team members describe and justify their proposed role and why their experience and qualifications make them well-suited for this role?
• Did team members for whom biographical sketches 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 five-year time frame?

Project Management (15 Points)

• The extent to which the applicant describes a sound project management approach that adequately tracks project activities, project budget, project reporting, milestones and deliverables, and project outcomes.
• The extent to which the applicants describes their approach to managing and tracking standardized terminology pilot projects.

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

• Is the use of consultants and/or subrecipients, if applicable, appropriate and adequate to advance the project in accordance with the timelines?
• 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.

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](http://www.ecfr.gov/cgi-bin/text-idx?SID=06a0b0411d1520fae5e2799030e64ebf&node=pt45.1.75&rgn=div5)

- HHS Grants Policy Statement

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 monthly check-in meeting to be scheduled with your ONC Project Officer to discuss:
  - Project trajectory, accomplishments, next steps, challenges, barriers, and recommendations to address challenges and barriers

ONC Program Progress Reports (PPR) are due quarterly. The PPR will address, to the extent applicable:
- Degree to which performance goals were attained (actual performance versus targeted performance)
- Data source and validation method for performance measures
- Opportunities to address performance deficiencies
- Accomplishments
- Next steps
- Challenges
- Barriers
- Recommendations to address challenges and barriers

ONC will provide specific guidance regarding the content and format of the PPR before the reports are due.

As a part of the grant-closeout process, a final report to ONC is required. It is to be submitted in Microsoft Word and include the following elements:

Title Page

  Include the following:
  - Title of Project
  - Principal Investigator and Team Members
  - Organization
  - Inclusive Dates of Project
  - Federal Project Officer
  - Acknowledgment of Agency Support
  - Grant Award Number

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 Payment Management 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.fsrs.gov on all sub-awards over $25,000.
Federal Recipient Performance and Integrity Information System (FAPIIS)

As of January 1, 2016, recipients of Federal grants and cooperative agreements are subject to 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 advise in performing this activities;
- 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 ten (10) days of becoming aware of such conflict, the Government may terminate the assistance agreement and the recipient shall not be entitled to reimbursement of any costs incurred in performing the assistance agreement.

The rights and remedies of the Government, under this term and condition, shall not be exclusive and are in addition to any other rights and remedies provided to the Government under law, regulation, or any other available enforcement mechanism.
Non-Disclosure Requirements
The federal award may require the recipient to have access to information relating to any and all aspects of grants management operations that may be of a technical, legal, sensitive and/or confidential nature and which may be the sole property of the U.S. Government. To mitigate risks associated with such access, the recipient shall ensure that all its personnel, including chief executives, directors, consultants, sub recipients, or any other personnel substantially involved in the performance of this award sign a non-disclosure agreement prior to the commencement of any work on the award.

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

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

Mandatory Disclosures
In accordance with 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
Intangible property, as defined in OMB’s, Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards 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.

(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 three years from the date the final FFR is submitted. For awards where the FFR is submitted at the end of the competitive segment, the three-year retention period will be calculated from the date the final FFR, for the entire competitive segment, is submitted.

45 CFR Part 75.361 provides exceptions and qualifications to the three-year retention requirement. For example, if any litigation, claim, financial management review, or audit is started before the expiration of the three-year period, the records 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 program-specific audit. Subpart F provides further guidance including the manner in which expenditures are determined, the distinction between a single audit and a program-specific audit, frequency of audits, and roles and responsibilities in the conduct of audits.

The Uniform Administrative Requirements, Cost Principles, and Audit Requirements for HHS Awards, 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 program-specific audit. Subpart F provides further guidance including the manner in which expenditures are determined, the distinction between a single audit and a program-specific audit, frequency of audits, and roles and responsibilities in the conduct of audits.

**G. Points of Contact**

**ONC Grants Management Officer**

*Carmel Halloun*

330 C Street, S.W.

Washington, D.C. 20201

*ONCGrants@hhs.gov*

**ONC Project Officer**

*Tracy H. Okubo*

330 C Street, S.W.

Washington, D.C. 20201

*ONCOTECH-Programs@hhs.gov*
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 ONCOTECH-Programs@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 program requirements and expectations are complete and clearly written. Do not assume that reviewers are familiar with the lead recipient organization. Keep the review criteria in mind when writing the application.

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

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

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

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

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

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

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

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

**Instructions - SF-424, Application for Federal Assistance**

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

<table>
<thead>
<tr>
<th>Item</th>
<th>Field Name</th>
<th>Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Type of Submission:</td>
<td><em>(Required)</em> Select one type of submission in accordance with agency instructions.</td>
</tr>
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<td></td>
<td></td>
<td>• Pre-application</td>
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<td></td>
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<td>• Application</td>
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<td></td>
<td></td>
<td>• 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.</td>
</tr>
<tr>
<td>2.</td>
<td>Type of Application:</td>
<td><em>(Required)</em> Select one type of application in accordance with agency instructions.</td>
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<td></td>
<td></td>
<td>• New - An application that is being submitted to an agency for the first time.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Continuation - An extension for an additional funding/budget period for a project with a projected completion date. This can include renewals.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• 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 &quot;Other&quot; is selected, please specify in text box provided.</td>
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<tr>
<td></td>
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<td>A. Increase Award</td>
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<td>B. Decrease Award</td>
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<td>C. Increase Duration</td>
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<td>D. Decrease Duration</td>
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<td></td>
<td>E. Other (specify)</td>
</tr>
<tr>
<td>3.</td>
<td>Date Received:</td>
<td>Leave this field blank. This date will be assigned by the Federal agency.</td>
</tr>
<tr>
<td>4.</td>
<td>Applicant Identifier:</td>
<td>Enter the entity identifier assigned by the Federal agency, if any, or the applicant's control number if applicable.</td>
</tr>
<tr>
<td>5a.</td>
<td>Federal Entity Identifier:</td>
<td>Enter the number assigned to your organization by the federal agency, if any.</td>
</tr>
<tr>
<td>5b.</td>
<td>Federal Award Identifier:</td>
<td>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.</td>
</tr>
<tr>
<td>6.</td>
<td>Date Received by State:</td>
<td>Leave this field blank. This date will be assigned by the state, if applicable.</td>
</tr>
<tr>
<td>Item</td>
<td>Field Name</td>
<td>Information</td>
</tr>
<tr>
<td>------</td>
<td>----------------------------------</td>
<td>--------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>7</td>
<td>State Application Identifier:</td>
<td>Leave this field blank. This identifier will be assigned by the state, if applicable.</td>
</tr>
<tr>
<td>8</td>
<td>Applicant Information:</td>
<td>Enter the following in accordance with agency instructions:</td>
</tr>
<tr>
<td>a</td>
<td>Legal Name:</td>
<td>(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 <a href="http://www.Grants.gov">www.Grants.gov</a>.</td>
</tr>
<tr>
<td>b</td>
<td>Employer/Taxpayer Number (EIN/TIN):</td>
<td>(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.</td>
</tr>
<tr>
<td>c</td>
<td>Organizational DUNS:</td>
<td>(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 <a href="http://www.Grants.gov">www.Grants.gov</a>.</td>
</tr>
<tr>
<td>d</td>
<td>Address:</td>
<td>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).</td>
</tr>
<tr>
<td>e</td>
<td>Organizational Unit:</td>
<td>Enter the name of the primary organizational unit, department or division that will undertake the assistance activity.</td>
</tr>
<tr>
<td>f</td>
<td>Name and contact information of person to be contacted on matters involving this application:</td>
<td>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.</td>
</tr>
</tbody>
</table>
| 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) |
<table>
<thead>
<tr>
<th>Item</th>
<th>Field Name</th>
<th>Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>10.</td>
<td>Name Of Federal Agency:</td>
<td>(Required) Enter the name of the federal agency from which assistance is being requested with this application.</td>
</tr>
<tr>
<td>11.</td>
<td>Catalog Of Federal Domestic Assistance Number/Title:</td>
<td>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.</td>
</tr>
<tr>
<td>12.</td>
<td>Funding Opportunity Number/Title:</td>
<td>(Required) Enter the Funding Opportunity Number and title of the opportunity under which assistance is requested, as found in the program announcement.</td>
</tr>
<tr>
<td>13.</td>
<td>Competition Identification Number/Title:</td>
<td>Enter the competition identification number and title of the competition under which assistance is requested, if applicable.</td>
</tr>
<tr>
<td>14.</td>
<td>Areas Affected By Project:</td>
<td>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.</td>
</tr>
<tr>
<td>15.</td>
<td>Descriptive Title of Applicant's Project:</td>
<td>(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.</td>
</tr>
<tr>
<td>16.</td>
<td>Congressional Districts Of:</td>
<td>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 &quot;all&quot; 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.</td>
</tr>
<tr>
<td>17.</td>
<td>Proposed Project Start and End Dates:</td>
<td>(Required) Enter the proposed start date and end date of the project.</td>
</tr>
<tr>
<td>18.</td>
<td>Estimated Funding:</td>
<td>(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. 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 recommended match amount outlined in NOFO as applicable, 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.</td>
</tr>
</tbody>
</table>
There are two types of match: 1) non-federal cash and 2) non-federal in-kind. In general, costs borne by the applicant and cash contributions of any and all third parties involved in the project, including sub-recipients, contractors and consultants, are considered matching funds. Generally, most contributions from sub-contractors or sub-recipients (third parties) will be non-federal in-kind matching funds. Volunteered time and use of facilities to hold meetings or conduct project activities may be considered in-kind (third party) donations. Examples of non-federal cash match include budgetary funds provided from the applicant agency’s budget for costs associated with the project.

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.

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.)
Appendix C

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

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

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

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

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

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

Separate Budget Narrative/Justification Requirement

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

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

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

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

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

Budget Narrative/Justification: State governments should enter the amount of indirect costs determined in accordance with HHS requirements. An applicant that will charge indirect costs to the grant 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 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** - 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)

<table>
<thead>
<tr>
<th>Object Class Category</th>
<th>Federal Funds</th>
<th>Non-Federal Cash</th>
<th>Non-Federal In-Kind</th>
<th>TOTAL</th>
<th>Justification</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Personnel Salary</strong></td>
<td>$40,000</td>
<td>$5,000</td>
<td></td>
<td>$45,000</td>
<td>♦ Project Administrator Jane Doe = .3FTE @ $50,000/year = $15,000; $10,000 = Federal funds and $5,000 = non-federal cash</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>♦ Project Director John Smith = 1FTE @ $30,000/year = $30,000; Federal funds</td>
</tr>
<tr>
<td><strong>Fringe Benefits</strong></td>
<td>$12,600</td>
<td>0</td>
<td>0</td>
<td>$12,600</td>
<td>Fringes benefit rate is 28% of salary as follows. All Federal Funds</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>FICA (7.65%) = $3,442</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Health Insurance (12%) = $5,400</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Dental Insurance (5%) = $2,250</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Life Insurance (2%) = $900</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Workers Comp Insurance (.75%) = $338</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Unemployment Insurance (.6%) = $270</td>
</tr>
<tr>
<td><strong>TOTAL:</strong></td>
<td></td>
<td></td>
<td></td>
<td><strong>$45,000</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td><strong>TOTAL:</strong> <strong>$12,600</strong> ($45,000 * 28%)</td>
</tr>
<tr>
<td>Object Class Category</td>
<td>Federal Funds</td>
<td>Non-Federal Cash</td>
<td>Non-Federal In-Kind</td>
<td>TOTAL</td>
<td>Justification</td>
</tr>
<tr>
<td>-----------------------</td>
<td>---------------</td>
<td>------------------</td>
<td>---------------------</td>
<td>-------</td>
<td>---------------</td>
</tr>
<tr>
<td>Travel</td>
<td>$4,120</td>
<td>$1,547</td>
<td></td>
<td>$5,667</td>
<td>Travel to two annual recipient meetings: All Federal funds. Airfare: 2 people x 2 trips $750/per round trip = $3,000 Lodging: 2 nights per trip x 2 people x $100/night x 2 trips = $800 Per Diem: 2 days per trip x 2 people x $40/day x 2 trips = $320 Subtotal: $4,120</td>
</tr>
<tr>
<td>Out-of-town 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 Subtotal: $1,547 TOTAL: $5,667</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Equipment</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>No equipment requested</td>
</tr>
<tr>
<td>Supplies</td>
<td>$1,340</td>
<td>$2,160</td>
<td></td>
<td>$3,500</td>
<td>Laptop computer for use in client intakes – Federal Funds = $1,340 Consumable supplies (paper, pens, etc.) – Non-federal cash $100/mo x 12 months = $1,200 Copying – Non-federal cash $80/mo x 12 months = $960 TOTAL: $3,500</td>
</tr>
<tr>
<td>Contractual</td>
<td>$150,000</td>
<td>$50,000</td>
<td></td>
<td>$200,000</td>
<td>Contracts to A,B,C Contractor A to deliver supplies – Federal funds = $75,000 Contractor B to print materials – Federal funds= $75,000 Contractor C for logistical support– Non-Federal = $50,000 TOTAL: $200,000</td>
</tr>
<tr>
<td>Object Class Category</td>
<td>Federal Funds</td>
<td>Non-Federal Cash</td>
<td>Non-Federal In-Kind</td>
<td>TOTAL</td>
<td>Justification</td>
</tr>
<tr>
<td>-----------------------</td>
<td>---------------</td>
<td>------------------</td>
<td>--------------------</td>
<td>-------</td>
<td>---------------</td>
</tr>
<tr>
<td>Other</td>
<td>$11,250</td>
<td>$2,000</td>
<td></td>
<td>$13,250</td>
<td>♦ Subaward to ABC to conduct training – Federal funds = $10,000</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>♦ Printing brochures – Federal funds (25,000 @ $0.05 each) = $1,250</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>♦ Registration fee for annual ABC conference – Non-federal cash = $200</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>♦ Postage – Non-Federal Cash ($150/mo x 12 months) = $1,800</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>TOTAL $3,250</td>
</tr>
<tr>
<td>Indirect Costs</td>
<td>$12,000</td>
<td>$1,000</td>
<td>$1,000</td>
<td>$14,000</td>
<td>♦ Rent – Federal funds ($1,000/mos. x 12 months) = $12,000</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>♦ Utilities – Non-federal cash = $1,000</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>♦ Administrative Support – Non-Federal In-Kind 100 hours x $10/hour = $1,000</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>TOTAL $14,000</td>
</tr>
<tr>
<td>TOTALS</td>
<td>$231,310</td>
<td>$11,707</td>
<td>$51,000</td>
<td>$294,017</td>
<td></td>
</tr>
</tbody>
</table>
Letter of Commitment Template

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

Date

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

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

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

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

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

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

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

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