U.S. Department of Health and Human Services

Office of the National Coordinator for Health Information Technology

Notice of Funding Opportunity (NOFO)

Public Health Emergency Response Related HL7® Standards,
Solutions and Future Pandemics

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

Table of Contents

Executive Summary

The coronavirus disease 2019 (COVID-19) pandemic has had a widespread impact around the world, and is reshaping ways of life, the economy, and health care delivery across our country. The virulence and transmissibility of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), the strain of coronavirus that causes COVID-19, are striking. But crucially there remains a paucity of relevant clinical information to drive an adequate response. Even in an information technology (IT) dominated era, fundamental measurements to guide a standardized public health response remains unclear. Knowledge lags on incidence, prevalence, case-fatality rates, and clinical predictors of outcomes. While some of the knowledge gaps relate to the need for further laboratory testing, data that should be widely available in electronic health records (EHRs) have not yet been effectively shared across clinical sites, public health agencies, or with policy makers. Standards Development Organizations (SDOs), who develop standardized data formats and exchange methods to support common use cases and business transactions, are working with stakeholders to address knowledge gaps and identify opportunities arising from the pandemic. SDOs are primarily responsible for developing and maintaining the technical standards and accompanying implementation specifications/profiles that provide instructions to implementers.

Health Level 7 International (HL7®) is the exclusive SDO with the ability, authority, and intellectual property rights to develop and maintain many technical standards of significance to health information exchange and interoperability across health IT systems, such as public health and Fast Healthcare Interoperability Resources (FHIR®) specifications, and their accompanying Implementation Guides (IGs). HL7® standards are developed through a public, transparent, and collaborative process and made available for use in the public domain.

Leveraging current work done by the Office of the National Coordinator for Health Information Technology (ONC), such as the 21st Century Cures Act (Cures Act) Final Rule[1], as well as the Center for Disease Control and Prevention (CDC)'s implementation guidance for the use of HL7® messaging standards for public health reporting[2], and the HL7® BRIDG[3] standard that the National Cancer Institute (NCI) and Food and Drug Administration (FDA) have helped develop, ONC has identified five key gap and opportunity areas that could be accelerated to support the advanced nationwide interoperability towards the diagnoses and treatment of patients of COVID-19 and future public health emergencies.

Through this Notice of Funding Opportunity (NOFO), a single source cooperative agreement will be awarded to HL7® to prioritize and expedite the accelerated development and deployment of five (5) gap and opportunity areas specifically identified by ONC that advances the diagnoses, treatment, and care of patients of COVID-19 and other public health emergencies. Specifically, these five areas are:
1) Expanding the clinical domains supported by HL7® Standards
2) Privacy, Security, and Consent
3) Application Programming Interface (API) for Population Level Services
4) Social Determinants of Health (SDOH) Standards
5) Advancing Public Health Standards

This NOFO is a new, sole source, 4-year cooperative agreement for a maximum award of $2,000,000. (Funding Opportunity Number COVID-C3-20-003; Catalog of Federal Domestic Assistance Number 93.826), as authorized

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[1] https://www.federalregister.gov/documents/2020/05/01/2020-07419/21st-century-cures-act-interoperability-information-blocking-and-the-onc-health-it-certification
[2] https://www.cdc.gov/vaccines/programs/iis/technical-guidance/hl7.html
[3] https://www.cdisc.org/standards/domain-information-module/bridg

under the Coronavirus Aid, Relief, and Economic Security Act (CARES Act) (Pub. L. No. 116-136, March 27, 2020) and Section 3011, Public Service Health Act (PHSA). The eligible applicant must submit an application by XXX. Subsequent years of funding for this cooperative agreement is contingent on meaningful progress and availability of funds.

A.   Program Description/Purpose

Background Information

The objective of this cooperative agreement is to close the gaps and leverage current opportunities in our current health IT environment that support the diagnoses, treatment, and care of patients of COVID-19 and other public health emergencies in the following areas:

Expanding the Clinical Domains Supported by HL7® Standards
COVID-19 has provided a live example for the importance of real time, up-to-date clinical health data. The development of technical standards that enhance the ability to exchange these data would be valuable next steps for the United States Health Information Technology (U.S. health IT) platform. This work will be done through the development of new HL7® standards and components in new and emerging clinical domains, prioritizing those highlighted by the current pandemic.

Privacy, Security, and Consent
Privacy and security protection in health information technology will become increasingly challenging due to need for the health information including patients' laboratory testing results to be accessible to public health organization, state and federal agencies, and to employers in a secure and privacy enabled manner. Federal funding will accelerate the development of privacy and security standards, and will provide guidance and tools that can help organizations improve the privacy and security of health information overall.

API for Population Services
Since the World Health Organization (WHO) declared COVID-19 a pandemic[4] on March 11, 2020, the need for fundamental measurements to guide public health response has become more urgent. This led to an immediate need for a durable national surveillance system with relevant standards-based API technologies. Enhancing surveillance and management of COVID-19 patients will be crucial in the coming months and beyond. It will require a widely deployed standardized solution and approach. The Bulk Data Access API allows large amounts of medical records for multiple patients to be moved between systems during a single transaction which supports public health and medical research use cases where large amounts of data need to be obtained and analyzed. Currently, most APIs only allow a single individual's medical records to be moved one at time.

Developing, Advancing and Harmonizing Social Determinants of Health (SDOH) Standards
 COVID-19 has highlighted the gaps and inequalities in our society. The social needs of the most vulnerable populations have been magnified which makes the documentation and integration of social risk data in clinical care a priority. More providers are seeing the intersection of social determinants and health status daily. For example, someone may not be able to get tested if they have no access to safe transportation. Special populations, such as those with substance use disorders (SUD), are vulnerable to the effects of COVID-19, as they are more likely to experience homelessness, social isolation, and hopelessness, which is expected to increase during this pandemic. Currently, there are advancements in standards development in the SDOH domains of food, housing,

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[5] https://www.hl7.org/implement/standards/product_brief.cfm?product_id=7

and transportation for the purposes of screening, diagnosis, goal-setting, and interventions. However, gaps remain in other domains of SDOH and the areas of referrals and interventions. The advancement and harmonization of SDOH-related data standards, through the use of FHIR® and APIs, can enhance SDOH data exchange to give providers access to data that can be used to support the needs of their patient and change expected reversal effects of vulnerable populations during a pandemic.

Advancing Public Health Standards
COVID-19 has presented challenges for reporting situational awareness across local jurisdictions and the federal level as it relates to bed and ventilator count, reporting of laboratory results, vaccine administration, and other medical counter measures such as morbidity and mortality. Other public health related issues include low-level adoption of Public Health IGs, lack of pre-hospital data, use of reusable concepts, and issues related to accurate real-time reporting. The public health goals that are outlined in this cooperative agreement are structured to address these challenges.

In summary, the pandemic has exposed numerous gaps in our current health IT infrastructure needed to address a nationwide, public health crisis. The important work that lies ahead for this country must begin now as we implement the various goals outlined in this cooperative agreement.

Structure and Approach

Key Goals, Activities, Deliverables, and Timeline

The goals and activities listed below outline HL7® standards development and implementation efforts to support the current COVID-19 pandemic, future pandemics, and other public health emergencies. Additional activities may be required to achieve the outlined goals. The recipient of the cooperative agreement is encouraged to work closely with programmatic support offices at ONC and other HHS components to accomplish these goals. The products of all standards development and implementation activities conducted under this cooperative agreement will be freely and publicly available on the HL7 website.

Objective 1: Expanding the Clinical Domains Supported by HL7® Standards

Goal: Support the development of HL7® standards and implementation specifications in new and emerging clinical domains.

HL7 standards, including FHIR®, Clinical Document Architecture (CDA®)[5], V3 and V2 support a broad set of clinical domains at varied levels of maturity. Recipient should identify the clinical domains that are of most importance to the industry and facilitate the development of new standards and additional implementation guidance to support interoperability of the health information.

The recipient is encouraged to prioritize clinical domains that have been highlighted by the current pandemic. While current FHIR® Resources, for example, capture clinical information at the patient level, new data elements could capture more detail. Additionally, new IGs could provide an out-of-the-box specialty packages for working

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[5] https://www.hl7.org/implement/standards/product_brief.cfm?product_id=7

with this data. Disease-specific IGs could also incorporate bulk data capabilities that enhance disease modeling and predictive analytics, in addition to use beyond the current pandemic.

Objective 2: Privacy, Security, and Consent

Goal: Improve the privacy and security of health information.

Recipient should accelerate the development and deployment of standards, guidance, and tools that can help health care organizations protect the privacy and security of health information, including identity management, authentication, authorization and consent management. Activities that may improve privacy and security of health information include but are not limited to:

- Development and publication of standards and IGs related to privacy and security.
- Development of educational materials, guidance, and tooling to support privacy and consent management.
- Enabling patients to express their privacy preferences in a computable manner.

Objective 3: Application Programming Interface (API) for Population Level Services

Goal: Advance the use of HL7® FHIR Bulk Data Access Implementation Guide[6] standard ("Bulk Access API") and other relevant API standards to improve surveillance capacity for future pandemics and other public health emergencies.

The "Bulk Access API" standard provides organizations and providers accountable for managing health of populations with an efficient way to access large volumes of information on groups of individuals.

Recipient is encouraged to further explore the use of the "Bulk Access API" standard to new use cases including, but not limited to public health surveillance and develop further guidance to expand the use of the "Bulk Access API" standard.

Objective 4: Developing, Advancing and Harmonizing Social Determinants of Health (SDOH) Standards

Goal: Develop, advance and harmonize SDOH Standards through the use of FHIR and APIs to enhance SDOH data exchange to give providers access to data that can be used to support the needs of their patients. ONC is interested in applying the three-part approach from the Cures Act to implement the strategies indicated in the Draft Federal Health IT Strategic Plan. This approach should include the following:
- Exploring the current state of federal (e.g., Advancing Standards for Precision Medicine) and non-federal stakeholder activities (e.g., Gravity Project,) and their future approaches.
- Identifying, recommending, and developing bidirectional mapping between non-health care data and relevant health IT standards for clinical care and nonclinical setting use (FHIR Resources, profiles).

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[6] https://build.fhir.org/ig/HL7/us-bulk-data/

Priority areas of interest include the following;
- Current standards in development related to food insecurity, transportation, and housing.
- Referral standards such as HL7®'s Bidirectional Services eReferrals (BsER).
- Standards that support the use of SDOH data for public/population health (e.g., Covid-19, opioid use) prediction, prevention, treatment, and planning.

Objective 5: Advancing Public Health Standards

Goal: Support the development of HL7® standards and implementation specifications to meet public health needs.

Recipient to support public health reporting requirements, including transmission to immunization registries, syndromic surveillance, electronic laboratory reporting, electronic case reporting, etc. Many of the standards need to be updated based on the experience of the recent pandemic, and also new standards need to be developed to support future needs.

Recipient is encouraged to evaluate the current HL7® standards used for public health related activities and facilitate the development of updated standards and new standards to support interoperability of the health information for public health.

Performance Goals/Program Milestones

To ensure the success of this cooperative agreement, the applicant will propose a performance metricf the projects through the progress on milestones and metrics. Applicants must provide baseline measurements and propose performance metrics to demonstrate successful support for the rapid development of the gap areas identified in this NOFO related to HL7® standards and solutions. For each milestone and metric, ONC, will work with the applicant to determine the appropriate targets and reporting requirements.

B.   Funding Opportunity Award Information

Key Award Parameters

Title: Public Health Emergency Response Related HL7® Standards, Solutions and Future Pandemics

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

Notice of Funding Opportunity Number: COVID-C3-20-003

 Catalog of Federal Domestic Assistance (CFDA) Number: 93.826

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

Designated Organization: Health Level 7 International (HL7®)

1.   Sole Source Justification

The primary responsibility of standards development organizations (SDOs) are the development and maintenance of health IT technical standards, as well as any accompanying implementation specifications that provide additional implementation instructions for developers. Health Level 7 International (HL7®) is the exclusive SDO with the ability, authority, and intellectual property rights to develop and maintain the v2, v3, CDA, and FHIR® standards. Additionally, HL7® solely governs the processes by which these standards and accompanying implementation guidance are issued and updated. Attempting to complete these or any future tasks specific to HL7® standards with another SDO or organization would require HL7® engagement to ballot and publish a final product. Thus, HL7®'s involvement is both fundamental and necessary to publish an HL7 standard or implementation guidance.

HL7® members include organizations that are actively engaged in implementing the v2, v3, CDA, and FHIR® standard in health IT systems, and hence can provide necessary feedback in timely manner through a well-established and American National Standards Institute (ANSI)-accredited process for consensus standards development. The goals and expected outcomes of this cooperative agreement can only be achieved accurately by HL7®.

Legislative Authority: Coronavirus Aid, Relief, and Economic Security Act (CARES Act) (Pub. L. No. 116-136, March 27, 2020) and Section 3011, Public Service Health Act (PHSA)

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

Anticipated Number of Awards: 1

Approximate Amount of Award: $2,000,000.00

Project Period: 09/30/3020 – 09/29/2024
Budget Period(s):   09/30/2020 - 09/29/2021

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.

Continued funding will be contingent on the recipient continuing to meet all the milestones and the availability of funds. Additional funding is also contingent on other HHS Components mission critical needs. In 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 incorporated into this award by reference. Failing to comply with these requirements may result in suspension or termination of the award and/or ONC's recovery of award funds.

Cost-Sharing Requirements: There are no matching or cost share requirements for this program.

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. **If program income is generated, the recipient must use the additive method.**

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

Key Dates

Milestone	Date
NOFO Released	08/12/2020
Applications Due	09/11/2020
Anticipated Award Date	09/30/2020
Anticipated Project Start Date	09/30/2020

Roles and Responsibilities Under a Cooperative Agreement

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

 Specific activities in which ONC may assume substantial involvement include, but are not limited to:

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

◆Reviewing and approving substantive provisions of proposed subawards or subcontracts.

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

◆Conduct, on an annual basis, reassessments of the state of public health needs, and in collaboration, update the Implementation Plan and any other related activities and priorities. The 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, 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.

◆Reviewing and accepting deliverables.

◆Providing tactical guidance and feedback during project execution.

◆Ending an activity if performance goals/project milestones are not met.

◆Meeting with recipient(s) monthly at a minimum, and more frequently as requested by the recipient(s) or ONC.

♦ Conduct regular meetings with HL7.

♦ Collaborate with HL7 to identify and prioritize the types and numbers of underlying technical infrastructure upgrades needed, as well as the timeline of which these upgrades must be completed by.

♦ Provide substantive input in the development of the Connect-a-thons and other in-person or virtual testing events.

♦ Conduct, on an annual basis, 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 HL7.

♦ Engage with HL7 leadership as necessary to ensure successful execution of the cooperative agreement.

Informational Session
An Informational Session will not be conducted.

Letter of Intent
A letter 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)

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

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

Project Abstract

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

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

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

Project Narrative

The project narrative provides the most substantive information regarding the proposed project in a clear and concise manner. To that end, the project narrative should address the elements articulated in the 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).

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. The specific sections that must be included in the Project Narrative are detailed below.

Project Implementation Plan

As a cooperative agreement between the recipient and ONC, administrative activities will be written out in the implementation plan completed by the recipient. Revisions may be conducted throughout the duration of the period-of-performance.

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

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. Cost allocation plans are not accepted.

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-C3-20-003 or CFDA number *93.826.*

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. <u>APPLICATIONS WILL NOT BE ACCEPTED THROUGH ANY OTHER WEBSITE, AND WILL NOT BE ACCEPTED THROUGH PAPER MAIL, COURIER, OR DELIVERY SERVICE.</u>

In order to upload applications into Grants.gov:
a) <u>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.</u>
b) <u> Please note that entities registering in SAM must submit a notarized letter appointing their authorized</u> Entity Administrator. This will not impact the registration approval process, but is required as part of your registration. For additional information, read SAM's updated FAQs to learn more about changes to the notarized letter review process and other system improvements.

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

c)   <u>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.</u>

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

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

The deadline for the submission of applications under this Notice of Funding Opportunity is 11:59 PM Eastern Standard Time on 09/11/2020. Applications that fail to meet the application deadline will not be reviewed and will receive no further consideration.

Restrictions on Oral Conversations

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

This restriction applies unless:
•   The communication is purely logistical.

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

E. Application Review Information

Screening Review
If the applicant does not meet the following screening criteria, the application 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).
- The application meets the formatting and length requirements. The Project Narrative must not exceed 30 pages. The Project Abstract and resumes do not count as part of the Project Narrative length limitation.
- Appendices and attachments are not used as a mechanism to exceed page limits of the Project Narrative.

Merit Review
An independent review consisting of at least one individual, will evaluate this application to ensure that it meets the screening criteria identified above. This reviewer will be an expert in their field from an academic institution, non-profit organization, and/or local and Federal government agencies. The reviewer will review, evaluate, and score the application, in accordance with the criteria identified below:

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

1. Understanding of the Project (20 Points)
2. Technical Approach (30 Points)
3. Project Team and Staffing Qualifications (20 Points)
4. Implementation Plan and Project Management (20 Points)
5. Reasonableness of the Budget Narrative (10 Points)

1. **Understanding of the Project – 20 points maximum**
   - How well does the applicant demonstrate their knowledge and understanding of the implementation challenges of the technical standards specified in the NOFO?
   - How well does the applicant provide guidance that specifies solutions to overcome these challenges and leads to consistent implementation and adoption of technical standards?
   - How well does the application understand the current challenges and addresses the purpose and objectives of this NOFO?
     - To what extent is the proposed project parallel NOFO goals?
   - To what extent does the applicant describe how the project and expected outcomes and results will inform the field and future health IT development, the use of FHIR®, public health, and emergency preparedness?

2. **Technical Approach – 30 points maximum**
   - 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.
   - 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's approach is succinct and logical and demonstrates methods consistent with the tasks to be accomplished.
     - Does the applicant propose a clear and actionable plan with a specific list of activities and deliverables to achieve the objectives proposed as specified in the NOFO?

3. **Personnel Qualification and Past Performance – 20 points maximum**
   - Does the applicant demonstrate and provide evidence of technical experience for identifying, assessing, and determining improvements to be made to technical standards and specifications listed in the NOFO?
   - To what extent does the applicant have the ability to engage with other health IT industry stakeholders?
   - Are the PD/PI, collaborators, and other key project team members appropriately trained and well-suited to carry out this work?
     - Is evidence of their past work supporting their suitability provided in their personnel resumes (as an appendix to the applicant's proposal)?
   - 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 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?

4. **Implementation Plan and Project Management – 20 points maximum**
   - The extent to which the applicant describes a draft implementation plan that includes a detailed plan to carry out each of the activities proposed in the response, monthly progress meetings, progress reports and a timeline for draft and final deliverables for each of the goals with specific dates identified.
   - The extent to which the plan describes a project management approach for ensuring project success within and across collaborators.

5. **Reasonableness of Budget Narrative –10 points maximum**
   - 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.

MAXIMUM TECHNICAL SCORE = 100 POINTS

Pre-Award Risk Assessment

ONC is required to conduct a risk assessment to assess the risk posed by a potential recipient, prior to issuing an award. In doing so, ONC will take into account the applicant's financial stability, quality of management systems, history of performance, reports and findings from audits, and the applicant's ability to effectively implement statutory, regulatory, or other requirements imposed on non-Federal entities. To facilitate this assessment, ONC may review information available in systems, such as the Excluded Parties List System, review documentation, such as previous audits, and/or desk reviews or site visits conducted from previous awards. ONC may elect not to fund applicants with management or financial instability that directly relates to the organization's ability to implement statutory, regulatory or other requirement s (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, program priorities; and the likelihood that the proposed project will result in the benefits expected. The applicant will receive a summary of the objective review panel's assessment of the application's strengths, weaknesses, and score.

Notice of Grant Award

The successful applicant 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, the successful applicant 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 Awardee accepts the award by drawing down funds. By accepting an ONC award, the awardee assumes legal, financial, administrative, and programmatic responsibility for administering the award in accordance with the terms and conditions of the award, as well as applicable laws, rules, regulations, and Executive Orders governing HHS assistance awards, all of which are to be incorporated into the award by reference. 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:

- 2 CFR, Part 200 - Uniform Administrative Requirements, Cost Principles, and Audit Requirements For Federal Awards
https://www.ecfr.gov/cgi-bin/text-idx?tpl=/ecfrbrowse/Title02/2cfr200_main_02.tpl

- 45 CFR, Part 75—Uniform Administrative Requirements, Cost Principles, and Audit Requirements For   HHS Awards - http://www.ecfr.gov/cgi-bin/text-idx?SID=06a0b0411d1520fae5e2799030e64ebf&node=pt45.1.75&rgn=div5

- HHS Grants Policy Statement - https://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf

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

Performance Reporting
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.

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 (PMS). 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 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 Awardee 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 tasks;
- 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 and Copyrights

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. (Please note, for the purpose of this funding opportunity "work" can be considered as: writings, films, sound recordings, pictorial reproductions, drawings, designs, or other graphic representations, procedural manuals, forms, diagrams, work flow charts, equipment descriptions, data files, data processing or computer programs (software), statistical records, and other technical research data.)**

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

(d) The Federal Government has the right to:

   (1) Obtain, reproduce, publish, or otherwise use the data produced under a Federal award; and

   (2) Authorize others to receive, reproduce, publish, or otherwise use such data for Federal purposes

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

(2) Published research findings means when:

(i)   Research findings are published in a peer-reviewed scientific or technical journal; or

(ii)   A Federal agency publicly and officially cites the research findings in support of an agency action that has the force and effect of law. "Used by the Federal Government in developing an agency action that has the force and effect of law" is defined as when an agency publicly and officially cites the research findings in support of an agency action that has the force and effect of law.

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

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

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

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

For any work owned by a third party that was licensed by the recipient under this award, the 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 (3) years from the date the final FFR is submitted. For awards where the FFR is submitted at the end of the competitive segment, the 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 (3) 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

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.

Enforcement Actions/Termination

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

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

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

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

Steven's Amendment

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

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

(1) The percentage of the total costs of the program or project which will be financed with Federal money;

(2) The dollar amount of Federal funds for the project or program; and

(3) Percentage and dollar amount of the total costs of the project or program that will be financed by non-governmental sources.

Recipients are required to use the following acknowledgement and disclaimer on all products produced by ONC grant funds:

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

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

508 Compliance

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

G. Points of Contact

ONC Grants Management Officer
Carmel Halloun
330 C Street, S.W.
Washington, D.C. 20201
ONCGrants@hhs.gov

ONC Project Officer
Wanda Govan-Jenkins
330 C Street, S.W.
Washington, D.C. 20201

ONCOTECH-Programs@hhs.gov

ONC E-Mail Address
Comments and inquiries can be directed to the e-mail address: ONCOTECH-Programs@hhs.gov, with the specific subject line: "Accelerating the Development and Implementation of Health Care Standards Supporting Interoperability"

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 1800-447-8477) 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 Dun & Bradstreet's website (http://www.dnb.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.

Instructions - SF-424, Application for Federal Assistance

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

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

Item	Field Name	Information
5b.	Federal Award Identifier:	For new applications leave blank. For a continuation or revision to an existing award, enter the previously assigned federal award identifier number. If a changed/corrected application, enter the federal identifier in accordance with agency instructions.
6.	Date Received by State:	Leave this field blank. This date will be assigned by the state, if applicable.
7.	State Application Identifier:	Leave this field blank. This identifier will be assigned by the state, if applicable.
8.	Applicant Information:	Enter the following in accordance with agency instructions:
8a.	a. Legal Name:	(Required) Enter the legal name of applicant that will undertake the assistance activity. This is the organization that has registered with the Central Contractor Registry (CCR). Information on registering with CCR may be obtained by visiting www.Grants.gov.
8b.	b. Employer/Taxpayer Number (EIN/TIN):	(Required) Enter the employer or taxpayer identification number (EIN or TIN) as assigned by the Internal Revenue Service. If your organization is not in the US, enter 44-4444444.
8c.	c. Organizational DUNS:	(Required) Enter the organization's DUNS or DUNS+4 number received from Dun and Bradstreet. Information on obtaining a DUNS number may be obtained by visiting www.Grants.gov.
8d.	d. Address:	Enter address: Street 1 (Required); city (Required); County/Parish, State (Required if country is US), Province, Country (Required), 9digit zip/postal code (Required if country US).
8e	e. Organizational Unit:	Enter the name of the primary organizational unit, department or division that will undertake the assistance activity.
8 f.	f. Name and contact information of person to be contacted on matters involving this application:	Enter the first and last name (Required); prefix, middle name, suffix, title. Enter organizational affiliation if affiliated with an organization other than that in 7.a. Telephone number and email (Required); fax number.

Item	Field Name	Information
9.	Type of Applicant: (Required) Select up to three applicant type(s) in accordance with agency instructions.	A. State Government B. County Government C. City or Township Government D. Special District Government E. Regional Organization F. U.S. Territory or Possession G. Independent School District H. Public/State Controlled Institution of Higher Education I. Indian/Native American Tribal Government (Federally Recognized) J. Indian/Native American Tribal Government (Other than Federally Recognized) K. Indian/Native American Tribally Designated Organization L. Public/Indian Housing M. Nonprofit N. Private Institution of Higher Education O. Individual P. For-Profit Organization (Other than Small Business) Q. Small Business R. Hispanic-serving Institution S. Historically Black Colleges and Universities (HBCUs) T. Tribally Controlled Colleges and Universities (TCCUs) U. Alaska Native and Native Hawaiian Serving Institutions V. Non-US Entity W. Other (specify)
10.	Name Of Federal Agency:	(Required) Enter the name of the federal agency from which assistance is being requested with this application.
11.	Catalog Of Federal Domestic Assistance Number/Title:	Enter the Catalog of Federal Domestic Assistance number and title of the program under which assistance is requested, as found in the program announcement, if applicable.
12.	Funding Opportunity Number/Title:	(Required) Enter the Funding Opportunity Number and title of the opportunity under which assistance is requested, as found in the program announcement.
13.	Competition Identification Number/Title:	Enter the competition identification number and title of the competition under which assistance is requested, if applicable.
14.	Areas Affected By Project:	This data element is intended for use only by programs for which the area(s) affected are likely to be different than the place(s) of performance reported on the SF-424 Project/Performance Site Location(s) Form. Add attachment to enter additional areas, if needed.

Item	Field Name	Information
15.	Descriptive Title of Applicant's Project:	(Required) Enter a brief descriptive title of the project. If appropriate, attach a map showing project location (e.g., construction or real property projects). For pre-applications, attach a summary description of the project.
16.	Congressional Districts Of:	15a. (Required) Enter the applicant's congressional district. 15b. Enter all district(s) affected by the program or project. Enter in the format: 2 characters state abbreviation - 3 characters district number, e.g., CA005 for California 5th district, CA-012 for California 12 district, NC103 for North Carolina's 103 district. If all congressional districts in a state are affected, enter "all" for the district number, e.g., MD-all for all congressional districts in Maryland. If nationwide, i.e. all districts within all states are affected, enter US-all. If the program/project is outside the US, enter 00-000. This optional data element is intended for use only by programs for which the area(s) affected are likely to be different than place(s) of performance reported on the SF-424 Project/Performance Site Location(s) Form. Attach an additional list of program/project congressional districts, if needed.
17.	Proposed Project Start and End Dates:	(Required) Enter the proposed start date and end date of the project.
18.	Estimated Funding:	

(As applicable) 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 45 CFR 75.306 before completing Item 18. All budget information entered under item 18 should cover the upcoming budget period. For sub-item 18a, enter the federal funds being requested. Sub-items 18b-18e is considered matching funds. The dollar amounts entered in sub-items 18b-18f must total at least *[cite percentage or fraction]* of the amount of federal funds being requested (the amount in 18a). For sub-item 18f, enter only the amount, if any, which is will be used as part of the required match.

There are two types of match: 1) non-federal cash and 2) non-federal in-kind. In general, costs borne by the applicant and cash contributions of any and all third parties involved in the project, including sub-recipients, contractors and consultants, are considered matching funds. Generally, most contributions from subcontractors 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

Item	Field Name	Information
	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.)

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 recipients 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 nonfederal 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, subcontractor 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 subrecipients. 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?
  o Office
  o Training
  o Research
  o Other types of supplies
♦How was cost determined?
♦Is the basis for the cost reasonable? (Monthly estimates are sufficient)
♦Are costs consistently treated?

Line 6f: Contractual: Enter the total costs of all contracts, including (1) procurement contracts (except those, which belong on other lines such as equipment, supplies, etc.). Also include any contracts with organizations for the provision of technical assistance. Do not include payments to individuals or consultants on this line. In the Budget Narrative/Justification attach a list of contractors indicating the name of the organization, the purpose of the contract, and the estimated dollar amount. If the name of the contractor, scope of work, and estimated costs 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
  o Is an hourly, daily or weekly base rate
    given?
  o Are rates allowable, justified, reasonable and comparable to market?
♦Is the total amount for any contract in excess of $150,000?
  o Is procurement method described?
  o If the contract is not competitively bid, has a sole source justification been provided?

Note: The competitive process 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.

<u>Line 6h: Other:</u> 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.

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

<u>Line 6j: Indirect Charges:</u> 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)

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

Object Class Category	Federal Funds	Non-Federal Cash	Non-Federal In-Kind	TOTAL	Justification

Travel	$4,120	$1,547		$5,667	♦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**
					
					♦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**

Equipment	0	0	0	0	No equipment requested

Supplies	$1,340	$2,160		$3,500	♦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**

Object Class Category	Federal Funds	Non-Federal Cash	Non-Federal In-Kind	TOTAL	Justification

Contractual	$150,000		$50,000	$200,000	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**

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

Letter of Commitment Template

Wanda Govan-Jenkins
Office of the National Coordinator for Health Information Technology
Department of Health and Human Services 330 C. Street, 7th Floor,
Office, S.W.
Washington, DC 20201

Date

Dear Dr. Govan-Jenkins,

[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).

(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