

**U.S. Department of Health and Human Services**  
**Office of the National Coordinator for Health Information**  
**Technology**

**Funding Opportunity Announcement**  
**Certified Health IT Surveillance Capacity and Infrastructure**  
**Improvement Cooperative Agreement Program**

**Application Due Date: August 14, 2017**

**Anticipated Award Date: [September 18, 2017](#)**

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# Executive Summary

The Office of the National Coordinator for Health Information Technology (ONC) anticipates awarding one (1) to three (3) cooperative agreement awards to organizations to improve the surveillance capacity and infrastructure that exists for health information technology (health IT) certified under the ONC Health IT Certification Program (Program). The ONC Health IT Certification Program is a voluntary certification program established to provide for the certification of health IT standards, implementation specifications, and certification criteria adopted by the Secretary of Health and Human Services. In the 2015 Edition Health Information Technology (Health IT) Certification Criteria (2015 Edition), 2015 Edition Base Electronic Health Record (EHR) Definition, and ONC Health IT Certification Program Modifications Final Rule, 80 FR 62601 (October 16, 2015) (2015 Edition final rule), ONC included expanded surveillance requirements for ONC-Authorized Certification Bodies (ONC-ACBs). Subsequently, the 21<sup>st</sup> Century Cures Act (the Cures Act) was signed into law and expanded the scope and conditions on which certifications to health IT must be granted, including specific conditions of certification around information blocking, application programming interfaces, and “real world” testing. The Cures Act also included a provision that calls for the creation of an EHR reporting program with which the conditions of certification are related.

Recipients under this cooperative agreement program are expected to use awarded funds to improve and expand existing surveillance capacity and infrastructure beyond current requirements to provide greater confidence to the public, purchasers, and users that health IT certified under the Program continues to perform in-the-field/health care setting(s) consistent with the expectations of certification. Such work is expected to be accomplished with the current ONC Health IT Certification Program requirements and the Cures Act conditions of certification in mind and in ways that seek to prototype and test new methods of surveillance and real world testing that can minimize industry burden while also maximizing effectiveness and scale. In order to achieve the cooperative agreement objectives, desired impact, and outcomes, the cooperative agreement will be executed in two distinct phases. Each recipient’s award will include a planning phase (Phase 1) and an implementation phase (Phase 2) during which each will develop and implement Strategic and Operational Plans, and deliver a Final Surveillance Report that will be made publicly available. Successful implementation of the Strategic and Operational Plans should provide the general public valuable information about the long-term sustainability of a comprehensive certified health IT surveillance approach to support the Program, deployed strategies to improve surveillance of certified health IT, and successes and challenges evaluating whether certified health IT in the implementation setting (“in-the-field”/ “real world” setting) is consistent with its certification and intended purposes, as specified under ONC regulations.

# **A. Program Description/Purpose**

## **Background Information**

ONC is the principal federal entity charged with coordination of nationwide efforts to implement and use health IT and the electronic exchange of health information. Created in 2004 through Executive Order and legislatively mandated in the Health Information Technology for Economic and Clinical Health Act (HITECH Act) of 2009, ONC is at the forefront of the federal government's health IT efforts.

The ONC Health IT Certification Program, administered under section 3001(c)(5) of the Public Health Service Act, is a voluntary program that provides for the certification of health IT to standards, implementation specifications, and certification criteria adopted by the Secretary of Health and Human Services (HHS). In October 2015, ONC issued the 2015 Edition final rule, which included expanded surveillance requirements for ONC-ACBs. The 2015 Edition final rule also established specific performance expectations for the surveillance of certified health IT “in-the-field.” Additionally, the 21<sup>st</sup> Century Cures Act<sup>1</sup> (the Cures Act) was signed into law and expanded the scope and conditions on which certifications to health IT must be granted, including specific conditions of certification around information blocking, application programming interfaces, and “real world” testing. The Cures Act also included a provision that calls for the creation of an EHR reporting program with which the conditions of certification are related.

## **Purpose**

This Funding Opportunity Announcement (FOA) is aimed at improving the surveillance capacity and infrastructure that exists for health IT certified under the Program. Through this FOA, recipients are expected to improve and expand the in-the-field surveillance capacity and infrastructure for health IT certified under the Program, with a particular focus on capabilities that are directly related to interoperability<sup>2</sup> and, thus, have the greatest potential impact to the health IT consumers and individuals (e.g., providers, hospitals, individual users). Such work is expected to be accomplished with the current ONC Health IT Certification Program requirements and the Cures Act conditions of certification in mind and in ways that seek to prototype and test new methods of surveillance and real world testing that can minimize industry burden while also maximizing effectiveness and scale.

Recipients will develop and implement Strategic and Operational Plans and then deliver a Final Surveillance Report that will be made available to the public. By completing these steps, recipients will have identified and potentially established new ways to improve the surveillance capacity and infrastructure for certified health IT (i.e., the scale at which surveillance can be performed and the technology and techniques necessary to track surveillance enhancements and/or conduct new real-world testing, respectively). Enhanced surveillance capacity is intended to improve the scale and approaches by which surveillance can be performed in order to provide greater empirical evidence to users that certified health IT continues to perform as expected in the implementation/real-world setting. The Final Surveillance Report will include an analysis of findings as well as recommendations for future activities

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<sup>1</sup> See Section 4002(a) of the 21<sup>st</sup> Century Cures Act, P. L. 114-255, (Dec. 13, 2016), which amends Section 3001(c)(5) of the Public Health Service Act.

<sup>2</sup> Per the 21<sup>st</sup> Century Cures Act of 2016, the term ‘interoperability’, with respect to health information technology, means such health information technology that: (A) enables the secure exchange of electronic health information with, and use of electronic health information from, other health information technology without special effort on the part of the user; (B) allows for complete access, exchange, and use of all electronically accessible health information for authorized use under applicable State or Federal law; and (C) does not constitute information blocking as defined in section 3022(a).

that can be applied to inform all aforementioned interested parties, and boost consumer confidence in certified health IT products.

## **Scope of Services**

In order to achieve the cooperative agreement's objectives, desired impact, and outcomes, it will be executed in two distinct phases. Each recipient's award will include a planning phase (Phase 1) and an implementation phase (Phase 2). Phase 1 will be completed in the first 12 months of the award during which the recipients will develop draft and final versions of a Strategic Plan and an Operational Plan. After the plans are complete, each recipient will focus on the early stage implementation of its Strategic and Operational Plans developed in Phase 1 to improve "real world"/in-the-field surveillance of certified health IT.

Phase 2 will be completed during year 2. In Phase 2, each recipient will fully implement its Strategic and Operational Plans, including performing enhanced in-the-field surveillance/real-world testing of certified health IT. Such work is expected to be accomplished with the current ONC Health IT Certification Program requirements and the Cures Act conditions of certification in mind and in ways that seek to prototype and test new methods of surveillance and real world testing that can minimize industry burden while also maximizing effectiveness and scale. The actions taken to implement the Strategic and Operational Plans must achieve the milestone objectives identified in this FOA and meet all existing certification criteria and regulatory requirements<sup>3</sup>, as well as those found in any new regulations ONC publishes as a result of the Cures Act. Each recipient will also submit a Final Surveillance Report, which will be made public at the conclusion of Phase 2.

## **Structure and Approach**

### *Key Tasks, Deliverables, and Timeline*

As stated above, this cooperative agreement will be executed in two phases: Phase 1 – Planning and Phase 2 – Implementation.

### **Phase 1: Planning**

#### **Specific Requirements for the First Year**

The first year of this cooperative agreement is critical for certified health IT surveillance capacity building. As such, each recipient will complete a Strategic Plan and an Operational Plan to improve its surveillance capacity and infrastructure (i.e., the scale at which surveillance can be performed and the technology and techniques necessary to track surveillance enhancements and/conduct new real-world testing, respectively). Each recipient will submit its Draft Strategic (Task 1-1a) and Operational (Task 1-2a) Plans to ONC for review, subsequently incorporate any ONC feedback, and submit Final Strategic (Task 1-1b) and Operational (Task 1-2b) Plans. Each recipient will also begin to implement the technical infrastructure, business practices, and personnel needed to be successful during year 2/Phase 2 (Task 1-3). As such, funding available for drawdown in the first year will be based on meeting the required deliverables specified for Phase 1. The total amount of funds made available to each recipient under Phase 1 of this cooperative agreement is 65% of its total award. There will be future technical assistance and guidance regarding planning and implementation conducted during this phase.

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<sup>3</sup> <https://www.healthit.gov/policy-researchers-implementers/standards-and-certification-regulations>

In order to measure project success, each recipient should conduct a semi-annual review of its Strategic and Operational Plans. In consultation with ONC, updates should be made to the plans based upon findings from plan execution and any additional applicable ONC Health IT Certification Program requirements.

### **Strategic Plan – Task 1-1**

The Strategic Plan shall describe the overall strategic and business approaches for specific activities the recipients will complete to improve their surveillance capacity and infrastructure. Each recipient must establish a Strategic Plan that addresses the vision, goals, objectives, business, and technical strategies to improve and expand their surveillance capacity and infrastructure, specifically its ability to perform in-the-field surveillance/real-world testing of certified health IT. In addition to the vision, goals, objectives, business, and technical strategies, the recipient's Strategic Plan must address all four of the domains, further described below:

- Surveillance Capacity Strategy
- Business and Financial Operations
- Technical Approach and Infrastructure
- Personnel

#### *Surveillance Capacity Strategy*

Each recipient must address its expertise and knowledge of ONC Health IT Certification Program requirements, including, but not limited to, the health IT certification criteria and regulations<sup>4</sup> and knowledge of the health care industry in order to identify current gaps and challenges associated with the surveillance/real-world testing of certified health IT. Moreover, a recipient's surveillance capacity strategy should illustrate how to qualitatively and quantitatively improve surveillance activities/real-world testing of certified health IT with a focus on certified capabilities that directly support interoperability as those capabilities have the greatest potential impact to the health IT consumers and individuals (e.g., providers, hospitals, individual users).

Each recipient must also include proposals to address qualitative and quantitative enhancement of in-the-field surveillance/real-world testing activities, capabilities in certified health IT that are directly related to interoperability, and transparency provided by health IT developers to the public/users regarding information that may adversely impact the interoperability of certified health IT. For clarity, such proposals would need to remain scoped within the specific capabilities and technical outcomes expressed by adopted certification criteria and could not go beyond the conformance expectations of such criteria. Each recipient should provide baseline metrics of current surveillance activities, if applicable, and a proposed structure to measure their improvements of surveillance activities during the cooperative agreement period-of-performance. Each recipient is expected to include a long-term strategy in the Strategic Plan to sustain enhanced surveillance activities throughout the project period and beyond the performance period of the cooperative agreement. The creation of a long-term strategy will provide added value to the industry as whole due to the potential for greater predictability and consistency for how surveillance would be performed over time.

#### *Business and Financial Operations*

Each Recipient must assess its current business model and proposed expansion and enhancements to the surveillance of certified health IT. This section of the Strategic Plan should also address how a recipient plans to effectively generate funding and manage the resources necessary to implement the Strategic and Operational Plans during the full period-of-performance of the cooperative agreement as well as ways it intends to sustain its investments beyond the period-of-performance. This should include addressing

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<sup>4</sup> <https://www.healthit.gov/policy-researchers-implementers/standards-and-certification-regulations>

financial policies and implementing procedures to generate revenue, monitor spending, and overall fiscal responsibility so that investments made during the period-of-performance would be able to continue to be maintained after the cooperative agreement. Recipients will also address their strategy to establish a long-term strategic financial model that will consider that the costs of surveillance are distributed across health IT developers relative to their different types, sizes, technologies, past performance and market share.

#### *Technical Approach and Infrastructure*

Each recipient must describe its technical approach to develop, implement, and report/publicly list the results of their enhanced in-the-field surveillance, to include real-world testing, of certified health IT with a focus on evaluating end-user(s)/implementation setting(s) access to conformant certified health IT and improving widespread interoperability. A recipient may describe how it will leverage previous experience from existing efforts and resources to conduct in-the-field surveillance/real-world testing of certified health IT. This section of the Strategic Plan should describe the surveillance capacity and infrastructure that will be improved and expanded upon to conduct in-the-field surveillance/real-world testing of certified health IT in order to meet the purpose of this FOA and the strategic goals of the recipient's Surveillance Capacity Strategy section of the Strategic Plan. Each recipient should include proposals to implement creative mechanisms to conduct enhanced surveillance and real-world testing of certified health IT capabilities, with a particular focus on capabilities that are directly related to interoperability and, thus, have the greatest potential impact to the health IT consumers and individuals (e.g., providers, hospitals, individual users). This section of the Strategic Plan should include the recipient's plans to maintain ISO/IEC 17065 accreditation throughout the project period and beyond the performance period of the cooperative agreement. Finally, a recipient must address its strategy to include any yet-to-be-developed Conditions of Certification requirements developed by ONC as required by law (e.g., 21<sup>st</sup> Century Cures Act) in the implementation of its Strategic and Operational Plans.

#### *Personnel*

Each recipient must include a personnel strategy for ensuring the recipient has adequate resources available to implement their Strategic and Operational Plans. The personnel plans may include a Business Development Specialist, which will be considered as key personnel. The personnel plans must include a long-term and financial strategy for outreach and retention to meet the recipient's targeted personnel and operational goals.

#### **Operational Plan – Task 1-2**

The Operational Plan shall describe how the recipient will implement surveillance activities specifically focused on interoperability among users of certified health IT. The Operational Plan must contain specific details on how the Strategic Plan will be executed to enable the enhancement of a recipient's surveillance capacity and achieve the vision, objectives, and goals of the Strategic Plan. A recipient's plan must provide the specific actions and roles of various stakeholders in the development and implementation of the expanded and enhanced surveillance/in-the-field testing activities, to include reporting/public listing of the results of surveillance. In addition, the Operational Plan must include descriptions of any activities implemented, to date, with an explanation of how these prior activities inform and may be included into the recipient's future plans for enhanced and expanded surveillance. The Operational Plan must address all four of the domains, further described below:

- Surveillance Capacity Strategy
- Business and Financial Operations
- Technical Approach and Infrastructure
- Personnel

### *Surveillance Capacity Strategy*

Each recipient must include specific planned actions and project plans that will achieve the goals of the Surveillance Capacity Strategy section of the Strategic Plan. This should include actions to achieve qualitative and quantitative enhancement of in-the-field surveillance activities, focus on certified health IT that is directly related to interoperability, and transparency provided by health IT developers regarding information that may adversely impact the interoperability of certified health IT. For clarity, such proposals need to remain scoped within the specific capabilities and technical outcomes expressed by adopted certification criteria and could not go beyond the conformance expectations of such criteria. A recipient should describe its plans to implement mechanisms and gather data to measure improvements of surveillance activities during the cooperative agreement period-of-performance. The planned actions should also relate to the recipient's long-term sustainability to maintain surveillance activities throughout the project period and beyond the performance period of the cooperative agreement.

### *Business and Financial Operations*

Each recipient must include specific planned actions to improve/expand its business model relating to the enhanced surveillance/real-world testing of certified health IT. This should include specific actions the recipient will take to effectively generate and manage funding necessary to implement the recipient's Strategic Plan goals during the full period-of-performance. Recipients will also address their strategy to establish a long-term strategic financial model that will consider that the costs of surveillance are distributed across health IT developers relative to their different types, sizes, technologies, past performance and market share. The specific actions should relate to financial policies and procedures to generate revenue, monitor spending, and overall fiscal responsibility so that investments made during the period-of-performance would be able to continue to be maintained after the cooperative agreement. Recipients should include planned actions in Phase 1 of the period-of-performance to implement the necessary business and financial structure to be successful in Phase 2.

### *Technical Approach and Infrastructure*

Each recipient must include specific planned actions to implement the technical approach to develop or facilitate enhanced in-the-field surveillance and real-world testing of certified health IT, with focus and priority given to the assessment of certified health IT performance as implemented in a "production environment." The planned actions should show how the recipients will leverage previous experience from existing efforts and resources to conduct enhance and expanded in-the-field surveillance/real-world testing of certified health IT. This section of the Operational Plan should also describe the specific actions to be taken to implement the operational and surveillance administration infrastructure necessary to conduct in-the-field surveillance of certified health IT in meeting the strategic goals of the recipient's technical approach and infrastructure section of the Strategic Plan.. The project plans should address planned actions to implement creative mechanisms to conduct widespread conformance assessment and/or testing for certified health IT capabilities that are directly related to interoperability among users of certified health IT. This section should also address specific actions the recipient will take to maintain ISO/IEC 17065 accreditation throughout the project period and beyond the performance period of the cooperative agreement. Each recipient must also include specific actions to address any yet to-be-developed Conditions of Certification requirements developed by ONC as required by law (e.g., 21<sup>st</sup> Century Cures Act) are periodically incorporated into its Strategic and Operational Plans. A recipient should include planned actions in Phase 1 of the period-of-performance to implement the necessary technical approach and infrastructure to be successful in Phase 2.

### *Personnel*

Each recipient must include specific planned actions to implement the personnel strategy for demonstrating the recipient has adequate resources available to implement their Strategic and

Operational Plans. This may include hiring a Business Development Specialist, which will be considered as key personnel. The personnel plans must include actions to enable a long-term and financial strategy for outreach and retention to meet the recipient's targeted personnel goals. The recipient should plan to have the majority of their personnel plan filled by the end of Phase 1.

### **Phase 1 Implementation of Technical Infrastructure, Business Practices, and Personnel – Task 1-3**

Once ONC accepts the recipients' Final Strategic and Operational Plans, each recipient is expected to begin implementing key actions to establish the necessary business/financial structure, technical approach and infrastructure, and personnel resources in Phase 1 to ensure successful implementation and development of enhanced surveillance capacity in Phase 2. As described above, each recipient should include Phase 1 planned actions in these domains in its Operational Plan.

### **Phase 2: Implementation**

Phase 2, which is to occur during year 2 of this cooperative agreement, is focused on the implementation of the recipient's Strategic and Operational Plans. In addition, each recipient will deliver a public Final Surveillance Report that identifies ways to improve and expand the surveillance capacity and infrastructure related to certified health IT. The implementation of the recipient's aforementioned plans should demonstrate expansion and improvement of the surveillance of certified health IT and result in early identification and resolution of conformity issues in the implementation setting, as well as more effective and efficient surveillance/in-the-field testing approaches (e.g., 10% more certified health IT surveilled in the implementation setting; efficiencies gained via "connect-a-thon" testing). This expanded surveillance, early identification of issues and return to conformity will provide greater confidence to the public, health IT consumers, and individual users that health IT certified under the Program continues to perform in-the-field/health care setting(s) consistent with the expectations of certification. The total amount of funds made available to each recipient under Phase 2 of this cooperative agreement is 35% of the total award.

### **Successful Implementation of the Strategic Plan and Operational Plan – Task 2-1**

In order to qualify for the milestone payments, each recipient must meet the performance milestones as described below and detailed in their Final Strategic and Operational Plans accepted by ONC during Phase I. The recipients will work with ONC in identifying and further scoping its strategic and business approach, identification of current gaps and challenges in surveillance, and implementing approaches to qualitatively and quantitatively expand and enhance surveillance/real-world testing activities in the implementation environment with a focus on capabilities that are directly related to interoperability.

Moreover, the recipient's enhanced and expanded surveillance of certified health IT in the implementation setting should provide greater confidence to the public, health IT consumers, and individual users that health IT certified under the Program continues to perform in-the-field/health care setting(s) consistent with the expectations of certification.

Funds available for drawdown in Phase 2 for Task 2-1 will be allocated accordingly:

- (Task 2-1a) Successful implementation and appropriate documentation to ONC of the Strategic and Operational Plans in two of the four domains: *Surveillance Capacity Strategy*; *Business and Financial Operations*; *Technical Approach and Infrastructure*; or *Personnel* by the end of the fourth month of Phase 2; and
- (Task 2-1b) Successful implementation and appropriate documentation to ONC of the Strategic and Operational Plans in the two remaining domains by the end of the seventh month of Phase 2.

### **Final Surveillance Report – Task 2-2**

A critical component of this cooperative agreement is the Final Surveillance Report. It is anticipated that the recipients will create a Draft Final Surveillance Report (Task 2-2a) for ONC to review and provide feedback on the report. Furthermore, each recipient should incorporate the comments received from ONC and prepare the Final Surveillance Report (Task 2-2b). Final Surveillance Report should include a full evaluation of the cooperative agreement period-of-performance, analysis of findings from implementation of the Strategic and Operational Plans, metrics demonstrating enhanced surveillance capacity, and recommendations for future activities that can be applied to strengthen confidence in certified health IT. This Final Surveillance Report will be made public and may be used by ONC to inform future ONC Health IT Certification Program and/or 21<sup>st</sup> Century Cures Act-related regulations as well as other non-regulatory ONC programmatic investments and coordination opportunities with health IT stakeholders to improve certified health IT's ability to be assessed for conformance in real world settings as expected by certified health IT consumers and individuals (e.g., providers, hospitals, individual users).

### **Structure and Approach**

| <b>Task Number</b> | <b>Task</b>                                                                                                                                                                                                                                                          | <b>Deliverable</b>                                    | <b>Due Date</b>                 |
|--------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------|---------------------------------|
| <b>Task 1-0</b>    | Kick-Off Meeting with ONC                                                                                                                                                                                                                                            | Kick-Off Meeting with ONC and Key Recipient Personnel | Within 5 business days of award |
| <b>Task 1-1a</b>   | Draft Strategic Plan – A draft strategic plan that includes the requirements and domains as detailed above.                                                                                                                                                          | Draft Strategic Plan                                  | Within 2 months of award        |
| <b>Task 1-1b</b>   | Final Strategic Plan – A final strategic plan that includes the requirements and domains as detailed above and incorporating feedback from ONC.                                                                                                                      | Final Strategic Plan                                  | Within 4 months of award        |
| <b>Task 1-2a</b>   | Draft Operational Plan – A draft operational plan that includes the requirements and domains as detailed above, including project management plan and timeline for implementation of surveillance activities in Phases 1 and 2.                                      | Draft Operational Plan                                | Within 7 months of award        |
| <b>Task 1-2b</b>   | Final Operational Plan – A final operational plan that includes the requirements and domains as detailed above, including project management plan and timeline for implementation of surveillance activities in Phases 1 and 2, and incorporating feedback from ONC. | Final Operational Plan                                | Within 10 months of award       |

| <b>Task Number</b> | <b>Task</b>                                                                                                                   | <b>Deliverable</b>                                                                                                                                                                   | <b>Funds Available for Drawdown</b>                                         |
|--------------------|-------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| <b>Task 1-3</b>    | Phase 1 Implementation of Technical Approach and Infrastructure, Business Practices, and Personnel                            | Acceptance of the Final Strategic and Operational Plans and implementing key technical, business, and personnel actions to ensure successful implementation of the plans in Phase 2. | Within 12 months of award                                                   |
| <b>Task 2-0</b>    | Phase 2 Kick-Off Meeting with ONC                                                                                             | Kick-Off Meeting with ONC and Key Recipient Personnel                                                                                                                                | Within 5 business days of receiving approval from ONC to proceed to Phase 2 |
| <b>Task 2-1a</b>   | Successful Implementation of Strategic and Operational Plans.                                                                 | Implementation of two of the four milestones from the Final Strategic and Operational Plans.                                                                                         | Within 16 months of award                                                   |
| <b>Task 2-1b</b>   | Successful Implementation of Strategic and Operational Plans.                                                                 | Implementation of milestones from the Final Strategic and Operational Plans in the two remaining domains.                                                                            | Within 19 months of award                                                   |
| <b>Task 2-2a</b>   | Draft Final Surveillance Report – a draft final report that includes the requirements detailed above.                         | Draft Final Surveillance Report                                                                                                                                                      | Within 22 months of award                                                   |
| <b>Task 2-2b</b>   | Final Surveillance Report – a final report that includes the requirements detailed above and incorporating feedback from ONC. | Final Surveillance Report                                                                                                                                                            | Within 24 months of award                                                   |

## Performance Goals/Program Milestones

A performance goal/program milestone is a target level of performance expressed as a tangible, measurable objective, against which actual achievement can be compared. The performance goals/program milestones associated with this FOA, and ensuing award, are as follows:

| <b>Task Number</b> | <b>Task</b>                                                                                                 | <b>Deliverable</b>                                    | <b>Funds Available for Drawdown</b> |
|--------------------|-------------------------------------------------------------------------------------------------------------|-------------------------------------------------------|-------------------------------------|
| <b>Task 1-0</b>    | Kick-Off Meeting with ONC                                                                                   | Kick-Off Meeting with ONC and Key Recipient Personnel | 0% of total award                   |
| <b>Task 1-1a</b>   | Draft Strategic Plan – A draft strategic plan that includes the requirements and domains as detailed above. | Draft Strategic Plan                                  | 10% of total award                  |

| <b>Task Number</b> | <b>Task</b>                                                                                                                                                                                                                                                         | <b>Deliverable</b>                                                                                                                                                                                                                               | <b>Funds Available for Drawdown</b> |
|--------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|
| <b>Task 1-1b</b>   | Final Strategic Plan – A final strategic plan that includes the requirements and domains as detailed above and incorporating feedback from ONC.                                                                                                                     | Final Strategic Plan                                                                                                                                                                                                                             | 20% of total award                  |
| <b>Task 1-2a</b>   | Draft Operational Plan – A draft operational plan that includes the requirements and domains as detailed above, including project management plan and timeline for implementation of surveillance activities in Phases 1 and 2.                                     | Draft Operational Plan                                                                                                                                                                                                                           | 10% of total award                  |
| <b>Task 1-2b</b>   | Final Operational Plan – A final operational plan that includes the requirements and domains as detailed above, including project management plan and timeline for implementation of surveillance activities in Phases 1 and 2, and incorporating feedback from ONC | Final Operational Plan                                                                                                                                                                                                                           | 15% of total award                  |
| <b>Task 1-3</b>    | Phase 1 Implementation of Technical Infrastructure, Business Practices, and Personnel                                                                                                                                                                               | Documentation to ONC detailing successful implementation of Phase 1 milestones from the Final Strategic and Operational Plans for business/financial practices, technical infrastructure, and personnel needs needed to be successful in Phase 2 | 10% of total award                  |
| <b>Task 2-0</b>    | Phase 2 Kick-Off Meeting with ONC                                                                                                                                                                                                                                   | Kick-Off Meeting with ONC and Key Recipient Personnel                                                                                                                                                                                            | 0% of total award                   |

| <b>Task Number</b> | <b>Task</b>                                                                                                                                                                                                      | <b>Deliverable</b>                                                                                                                                                                                                                                                       | <b>Funds Available for Drawdown</b> |
|--------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|
| <b>Task 2-1a</b>   | Successful Implementation of Strategic and Operational Plans in two of the four domains; Surveillance Capacity Strategy; Business and Financial Operations; Technical Approach and Infrastructure; or Personnel. | Documentation to ONC detailing successful implementation of milestones from the Final Strategic and Operational Plans in two of the four domains; Surveillance Capacity Strategy; Business and Financial Operations; Technical Approach and Infrastructure; or Personnel | 15% of total award                  |
| <b>Task 2-1b</b>   | Successful Implementation of Strategic and Operational Plans in Two Remaining Domains                                                                                                                            | Documentation to ONC detailing successful implementation of milestones from the Final Strategic and Operational Plans in two remaining domains                                                                                                                           | 10% of total award                  |
| <b>Task 2-2a</b>   | Draft Final Surveillance Report – a draft final report that includes the requirements detailed above and incorporating feedback from ONC.                                                                        | Draft Final Surveillance Report                                                                                                                                                                                                                                          | 0% of total award                   |
| <b>Task 2-2b</b>   | Final Surveillance Report – a final report that includes the requirements detailed above and incorporating feedback from ONC.                                                                                    | Final Surveillance Report                                                                                                                                                                                                                                                | 10% of total award                  |

## B. Funding Opportunity Award Information

### Key Award Parameters

Title: **Certified Health IT Surveillance Capacity and Infrastructure Improvement Cooperative Agreement Program**

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

Announcement Type: **Cooperative Agreement.**

Application Type: **New**

Funding Opportunity Announcement Number: **NAP-AX-17-003**

Catalog of Federal Domestic Assistance (CFDA) Number: **93.355**

Eligible Applicants: **Specialized Groups and For Profit Organizations, who have ISO/IEC17065 Accreditation in good standing through the American National Standards Institute (ANSI).**

Legislative Authority:  
Consolidated Appropriations Act, 2017, Pub. L. No. 115-31, Division H, Title II

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

Anticipated Number of Awards: **1-3**

Approximately Amount of Each Award: **\$400,000 - \$1,250,000**

Project Period: **9/18/2017 to 9/17/2019**

Budget Period(s): **9/18/2017 to 9/17/2019**

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.

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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.

Intergovernmental Review: This program is [excluded](#) from Executive Order 12372

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## Key Dates

| Milestone                      | Date                               |
|--------------------------------|------------------------------------|
| FOA Released                   | <a href="#">July 13, 2017</a>      |
| Informational Session          | <a href="#">July 20, 2017</a>      |
| Notice of Intent Due           | <a href="#">July 27, 2017</a>      |
| Applications Due               | <a href="#">August 14, 2017</a>    |
| Anticipated Award Date         | <a href="#">September 18, 2017</a> |
| Anticipated Project Start Date | <a href="#">September 18, 2017</a> |

## 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 tasks and activities may be shared between the recipients and ONC. ONC will assist each recipient in the planning and implementation of the four domains to enhance the effectiveness of the recipient's surveillance/real-world testing of certified health IT.

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
- ◆ 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

## **Informational Session**

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

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

Further details about the informational session – including the date, time, and instructions for joining – are available at <https://www.healthit.gov/>.

To ensure that ONC addresses all comments and questions regarding this announcement during the information session, please submit any comments and questions, via email, to [ONC.Certification@hhs.gov](mailto:ONC.Certification@hhs.gov), subject line: “Certified Health IT Surveillance Capacity and Infrastructure Improvement Cooperative Agreement Program” no later than three (3) days prior to the call.

## **Notice of Intent**

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

The Notice of Intent is requested by 11:59 P.M. Eastern Standard Time on July 27, 2017 and should be sent to [ONC.Certification@hhs.gov](mailto:ONC.Certification@hhs.gov), subject line: “Certified Health IT Surveillance Capacity and Infrastructure Improvement Cooperative Agreement Program.” The notice should identify the name of the applicant organization, the city and state in which the applicant organization is located, and the Funding Opportunity Announcement title and number.

## **C. Eligibility Information**

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

## **D. Application and Submission Information**

### **Application Package**

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

- Project Abstract
- Project Narrative
- Form SF-424, Application for Federal Assistance
- Form SF-424A, Budget Information for Non-Construction Programs
- Form SF-424B, Assurances for Non-Construction Programs
- Form SF-LLL, Disclosure of Lobbying Activities
- Budget Narrative
- Letters of Commitment
- Proof of Non-Profit Status (if, applicable)
- Indirect Cost Agreement(s) – including recipient, sub-recipient, and contractors agreements (if applicable)
- Proof of ISO/IEC17065 Accreditation in good standing through the American National Standards Institute (ANSI) and the applicant is expected to maintain this accreditation through the project period and beyond the performance period of the cooperative agreement.

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 FOA. The project narrative should also align with the Performance Goals/Program Milestones and Merit Review Evaluation criteria presented in this FOA (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 20 pages. A Project Narrative that exceeds the 20-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 20-page limit. The specific sections that must be included in the Project Narrative are detailed below.

**Problem Statement**

The Problem Statement must describe, from the applicant's perspective, identified gaps and other challenges in current in-the-field surveillance and testing activities of certified health IT. (<1 page)

**Project Scope**

The Project Scope must include a proposed strategy to improve and expand the in-the-field surveillance/real-world testing capacity and infrastructure for certified health IT ( i.e., the scale at which surveillance can be performed and the technology and techniques necessary to track and/or conduct new real-world testing, respectively), with a particular focus on capabilities that are directly related to interoperability and, thus, have the greatest potential impact to the health IT consumers and individuals (e.g., providers, hospitals, individual users).

Applicants must also describe their approach to develop the capability to effectively generate funding and manage the resources necessary to implement the Strategic and Operational Plans during the full period-of-performance of the cooperative agreement as well as ways it intends to sustain its investments beyond the period-of-performance. This should include addressing financial policies and implementing procedures to generate revenue, monitor spending, and overall fiscal responsibility so that investments made during the period-of-performance would be able to continue to be maintained after the cooperative agreement. Recipients will also address their strategy to establish a long-term strategic financial model that will consider that the costs of surveillance are distributed across health IT developers relative to their different types, sizes, technologies, past performance and market share.

(10-15 pages)

**Organizational Experience and Knowledge of Health IT Certification and Surveillance**

The applicant must be able to demonstrate organizational experience in achieving the programmatic goals and objectives of this FOA. This includes an assessment of the applicant's current business model and proposed expansion and enhancements to the surveillance of certified health IT in order to evaluate continued conformance and recommendations for ongoing improvement. This will ensure effective, accurate, reliable, and financially sustainable in-the-field surveillance and testing of certified health IT within the scope of the health IT's certification. The applicant must also demonstrate plans to support the long-term capabilities for surveillance and real-world testing activities, for a more comprehensive approach for assessing continued conformance of certified health IT, in order to advance interoperable exchange of health information across the health care continuum. (3-4 pages)

## **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**

Include letters of commitment confirming the support to the project (should it be funded) made by key collaborating organizations and agencies. Any organization that is specifically named to have a significant coordination role in carrying out the project should be considered an essential collaborator such as interstate, intrastate, and regional partners. At a minimum, the letter must explain the demonstrated commitment to the project and how they will advance coordination and collaboration among critical stakeholders. See Appendix E for an example letter of commitment.

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

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

### **Indirect Cost Agreement(s)**

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

## **Application Submission Instructions**

- 1) You must access the electronic application for this program via <http://www.grants.gov>. You can search the downloadable application page by the Funding Opportunity Announcement Number [NAP-AX-17-003](#) or CFDA number [93.355](#).
- 2) Applicants will be able to download a copy of the application packet and complete it off-line. In order to complete the application, an organization must have a Dun and Bradstreet (D&B) Data Universal Numbering System (DUNS) number. A DUNS number can be obtained via <http://fedgov.dnb.com/webform> and typically takes 1 to 2 business days. Please plan accordingly.
- 3) Completed applications are uploaded into Grants.gov. APPLICATIONS WILL NOT BE ACCEPTED THROUGH ANY OTHER WEBSITE, AND WILL NOT BE ACCEPTED THROUGH PAPER MAIL, COURIER, OR DELIVERY SERVICE.

In order to upload applications into Grants.gov:

- a) An applicant must be registered in the System for Award Management (SAM), at [sam.gov](http://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 must renew your registration.

The following website depicts the SAM registration process:

<http://www.grants.gov/web/grants/applicants/organization-registration.html>

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

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

- 4) After electronically submitting your application, Grants.gov will generate an email 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.
- 5) ONC opens the application submission in Grants.gov, to ensure the application can be downloaded and read during the application review processes. ONC issues an email to the applicant indicating the files were received and able to be successfully opened and read.

**The deadline for the submission of applications under this Funding Opportunity Announcement is 12:00 NOON (PM) Eastern Standard Time on August 14, 2017. Applications that fail to meet the application deadline will not be reviewed and will receive no further consideration.**

## **Restrictions on Oral Conversations**

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

This restriction applies unless:

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

## E. Application Review Information

### Screening Review

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

- The applicant meets the eligibility criteria
- The application is received by the required deadline through <http://www.grants.gov>
- The application contains all required components (e.g., Project Abstract, Project Narrative, SF-424)
- The application meets the formatting and length requirements. The Project Narrative must not exceed 20 pages. The Project Abstract and resumes do not count as part of the Project Narrative length limitation.
- Appendices and attachments are not used as a mechanism to exceed page limits of the Project Narrative

### Merit Review

An independent review panel, of at least three individuals, will evaluate applications that meet the screening criteria identified above. These reviewers will be experts in their field from academic institutions, non-profit organizations, and local and Federal government agencies. Reviewers will review, evaluate, and score applications, in accordance with the criteria identified below:

#### Understanding the Requirements (25 Points)

- The extent to which the applicant has addressed the vision, goals, objectives, business, and technical strategies to enhance their ability to perform in-the-field surveillance of certified health IT.
- The extent to which the applicant has identified gaps and challenges in current marketplace surveillance activities of certified health IT and how they propose to address these gaps and challenges in order to assess continued conformance of ONC certified health IT in the implementation setting and thus improve interoperability nationwide.
- The extent to which the applicant is able to clearly communicate its strategy to improve current surveillance capacity and infrastructure relative to certified health IT, and includes identified baseline measurements and evaluation metrics for surveillance activities currently occurring (if applicable) to track progress over the duration of the cooperative agreement period.
- The extent to which the applicant communicates how they plan to support the long-term capabilities for surveillance/real-world testing activities that provides for a more comprehensive approach for planning how to assess continued conformance of certified health IT.

#### Innovative Business and Technical Approach for Enhanced Surveillance (25 Points)

- The extent to which the applicant demonstrates the assessment of their current business model and proposed expansion and enhancements to the surveillance of certified health IT.
- The approach to which the applicant intends to develop the capability to effectively generate and manage funding necessary to implement their Strategic and Operational Plans during the full period-of-performance of the cooperative agreement.
  - This capability should include establishing financial policies and implementing procedures to generate revenue, monitor spending and overall fiscal responsibility so

that investments made during the period-of-performance would be able to continue to be maintained after the cooperative agreement.

### **Organizational Experience and Knowledge of Health IT Certification and Surveillance (40 Points)**

- The extent to which the applicant is able to clearly demonstrate they have the organizational experience to achieve the programmatic goals and objectives of this FOA. The following credentials and/or documentation must be included in order for an applicant to be successfully considered for this award:
  - Proof of current ISO/IEC17065 Accreditation in good standing through the American National Standards Institute (ANSI);
  - Three years minimum experience with certified health IT surveillance;
  - An active mechanism to publicly list health IT certificates and relevant surveillance results; and
  - A certified health IT surveillance plan that meets the most recent ONC Health IT Certification Program guidance.<sup>5</sup>
- The extent to which organizational roles and responsibilities are clearly defined and aligned with the goals and outcomes of this cooperative agreement.
- The extent to which the applicant brings or plans to involve personnel with appropriate experience and backgrounds to support the successful planning and implementation of its proposed strategy for enhanced surveillance in order to meet the goals and objectives of this FOA.
- The extent to which the applicant can clearly address how to qualitatively and quantitatively improve surveillance activities of certified health IT with a focus on certified capabilities that directly support interoperability as those capabilities have the greatest potential impact to the health IT consumers and individuals (e.g., providers, hospitals, individual users).
- The extent to which the applicant can address continuous improvement in ensuring the effective, accurate, reliable, and financially sustainable surveillance/real-world testing of certified health IT within the scope of the health IT's certification.

### **Reasonableness of Budget Narrative (10 Points)**

- The extent to which the budget is justified with respect to adequacy and reasonableness of resources requested.

### **Pre-Award Risk Assessment**

ONC is required to conduct a risk assessment to assess the risk posed by a potential recipient, prior to issuing an award. In doing so, ONC will take into account the applicant's financial stability, quality of management systems, history of performance, reports and findings from audits, and the applicant's ability to effectively implement statutory, regulatory, or other requirements imposed on non-Federal entities. To facilitate this assessment, ONC may review information available in systems, such as the Excluded Parties List System, review documentation, such as previous audits, and/or desk reviews or site visits conducted from previous awards. ONC may elect not to fund applicants with management or financial instability that directly relates to the organization's ability to implement statutory, regulatory or other requirements (45 CFR Part 75.205.)

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<sup>5</sup> Note that at the time of publication, the most recent ONC surveillance guidance may be found at [https://www.healthit.gov/sites/default/files/policy/2015-11-02\\_supp\\_cy\\_16\\_surveillance\\_guidance\\_to\\_onc-acb\\_15-01a\\_final.pdf](https://www.healthit.gov/sites/default/files/policy/2015-11-02_supp_cy_16_surveillance_guidance_to_onc-acb_15-01a_final.pdf). Recipients will be expected to develop surveillance plans that address the most recent ONC surveillance guidance.

## **F. Federal Award Administration Information**

### **Award Decisions**

The final award decision will be made by the National Coordinator for Health Information Technology taking into consideration several factors such as the results of the merit review process, results of the pre-award risk assessment, compliance with programmatic and grants management requirements; the reasonableness of the estimated costs, available funding, geographical dispersion, program priorities; and the likelihood that the proposed project will result in the benefits expected. All applicants will receive a summary of the objective review panel's assessment of the application's strengths, weaknesses, and score.

### **Notice of Grant Award**

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

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

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

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

## Terms and Conditions

### Incorporated by Reference

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

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

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

### Performance Reporting

ONC Program Progress Reports (PPR) are due semi-annually. 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 Online Data Collection (OLDC) system. ONC will not accept reports sent directly to the ONC Grants mailbox.

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

## **Federal Funding and Accountability and Transparency Act of 2006**

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

## **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**

Intangible property, as defined in OMB's, Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards means property having no physical existence, such as trademarks, copyrights, patents and patent applications and property, such as loans, notes and other debt instruments, lease agreements, stock, and other instruments of property, ownership (whether the property is tangible or intangible).

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

(b) The non-Federal entity may copyright any work that is subject to copyright and was developed, or for which ownership was acquired, under a Federal award. The HHS awarding agency reserves a royalty-free, nonexclusive and irrevocable right to reproduce, publish, or otherwise use the work for Federal purposes, and to authorize others to do so.

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

(d) The Federal Government has the right to:

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

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

(e) Freedom of Information Act (FOIA). (1) In response to a Freedom of Information Act (FOIA) request for research data relating to published research findings produced under a Federal award that were used by the Federal Government in developing an agency action that has the force and effect of law, the HHS awarding agency must request, and the non-Federal entity must provide, within a reasonable time, the research data so that they can be made available to the public through the

procedures established under the FOIA. If the HHS awarding agency obtains the research data solely in response to a FOIA request, the HHS awarding agency may charge the requester a reasonable fee equaling the full incremental cost of obtaining the research data. This fee should reflect costs incurred by the Federal agency and the non-Federal entity. This fee is in addition to any fees the HHS awarding agency may assess under the FOIA (5 U.S.C. 552(a)(4)(A)).

(2) Published research findings means when:

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

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

(i) Trade secrets, commercial information, materials necessary to be held confidential by a researcher until they are published, or similar information which is protected under law; and  
(ii) Personnel and medical information and similar information the disclosure of which would constitute a clearly unwarranted invasion of personal privacy, such as information that could be used to identify a particular person in a research study.  
(f) The requirements set forth in paragraph (e)(1) of this section do not apply to commercial organizations

For any work owned by a third party that was licensed by the recipient under this award, 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.

## **G. Points of Contact**

### **ONC Grants Management Officer**

Carmel Halloun  
330 C Street, S.W.  
Washington, D.C. 20201

### **ONC Grants Management Specialist**

Tevon Taylor  
330 C Street, S.W.  
Washington, D.C. 20201

### **ONC Project Officer**

Alicia Morton  
330 C Street, S.W.  
Washington, D.C. 20201

### **ONC E-Mail Address**

Comments and inquiries can be directed to the e-mail address: [ONC.Certification@hhs.gov](mailto:ONC.Certification@hhs.gov), with the specific subject line: "Certified Health IT Surveillance Capacity and Infrastructure Improvement Cooperative Agreement Program".

### **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](http://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](mailto:support@grants.gov)

### **HHS Office of the Inspector General**

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

## Tips for Writing a Strong Application

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

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

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

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

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

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

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

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

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

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

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

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

| Item | Field Name                 | Information                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
|------|----------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1.   | Type of Submission:        | (Required) Select one type of submission in accordance with agency instructions. <ul style="list-style-type: none"> <li>• Pre-application</li> <li>• Application</li> <li>• 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.</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| 2.   | Type of Application:       | (Required) Select one type of application in accordance with agency instructions. <ul style="list-style-type: none"> <li>• New - An application that is being submitted to an agency for the first time.</li> <li>• Continuation - An extension for an additional funding/budget period for a project with a projected completion date. This can include renewals.</li> <li>• Revision - Any change in the federal government's financial obligation or contingent liability from an existing obligation. If a revision, enter the appropriate letter(s). More than one may be selected. If "Other" is selected, please specify in text box provided. <ul style="list-style-type: none"> <li>A. Increase Award</li> <li>B. Decrease Award</li> <li>C. Increase Duration</li> <li>D. Decrease Duration</li> <li>E. Other (specify)</li> </ul> </li> </ul> |
| 3.   | Date Received:             | Leave this field blank. This date will be assigned by the Federal agency.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| 4.   | Applicant Identifier:      | Enter the entity identifier assigned by the Federal agency, if any, or the applicant's control number if applicable.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| 5a.  | Federal Entity Identifier: | Enter the number assigned to your organization by the federal agency, if any.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| 5b.  | Federal Award Identifier:  | For new applications leave blank. For a continuation or revision to an existing award, enter the previously assigned federal award identifier number. If a changed/corrected application, enter the federal identifier in accordance with agency instructions.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |

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

| Item | Field Name                                                                                                    | Information                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
|------|---------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 9.   | Type of Applicant: (Required)<br>Select up to three applicant type(s) in accordance with agency instructions. | A. State Government<br>B. County Government<br>C. City or Township Government<br>D. Special District Government<br>E. Regional Organization<br>F. U.S. Territory or Possession<br>G. Independent School District<br>H. Public/State Controlled Institution of Higher Education<br>I. Indian/Native American Tribal Government (Federally Recognized)<br>J. Indian/Native American Tribal Government (Other than Federally Recognized)<br>K. Indian/Native American Tribally Designated Organization<br>L. Public/Indian Housing<br>M. Nonprofit<br>N. Private Institution of Higher Education<br>O. Individual<br>P. For-Profit Organization (Other than Small Business)<br>Q. Small Business<br>R. Hispanic-serving Institution<br>S. Historically Black Colleges and Universities (HBCUs)<br>T. Tribally Controlled Colleges and Universities (TCCUs)<br>U. Alaska Native and Native Hawaiian Serving Institutions<br>V. Non-US Entity<br>W. Other (specify) |
| 10.  | Name Of Federal Agency:                                                                                       | (Required) Enter the name of the federal agency from which assistance is being requested with this application.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| 11.  | Catalog Of Federal Domestic Assistance Number/Title:                                                          | Enter the Catalog of Federal Domestic Assistance number and title of the program under which assistance is requested, as found in the program announcement, if applicable.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| 12.  | Funding Opportunity Number/Title:                                                                             | (Required) Enter the Funding Opportunity Number and title of the opportunity under which assistance is requested, as found in the program announcement.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| 13.  | Competition Identification Number/Title:                                                                      | Enter the competition identification number and title of the competition under which assistance is requested, if applicable.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| 14.  | Areas Affected By Project:                                                                                    | This data element is intended for use only by programs for which the area(s) affected are likely to be different than the place(s) of performance reported on the SF-424 Project/Performance Site Location(s) Form. Add attachment to enter additional areas, if needed.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| 15.  | Descriptive Title of Applicant's Project:                                                                     | (Required) Enter a brief descriptive title of the project. If appropriate, attach a map showing project location (e.g., construction or real property projects). For pre-applications, attach a summary description of the project.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |

| Item | Field Name                            | Information                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
|------|---------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 16.  | Congressional Districts Of:           | 15a. (Required) Enter the applicant's congressional district. 15b. Enter all district(s) affected by the program or project. Enter in the format: 2 characters state abbreviation - 3 characters district number, e.g., CA-005 for California 5th district, CA-012 for California 12 district, NC-103 for North Carolina's 103 district. If all congressional districts in a state are affected, enter "all" for the district number, e.g., MD-all for all congressional districts in Maryland. If nationwide, i.e. all districts within all states are affected, enter US-all. If the program/project is outside the US, enter 00-000. This optional data element is intended for use only by programs for which the area(s) affected are likely to be different than place(s) of performance reported on the SF-424 Project/Performance Site Location(s) Form. Attach an additional list of program/project congressional districts, if needed.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| 17.  | Proposed Project Start and End Dates: | (Required) Enter the proposed start date and end date of the project.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| 18.  | Estimated Funding:                    | <p>(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.</p> <p>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 <u>[cite percentage or fraction]</u> of the amount of federal funds being requested (the amount in 18a). For sub-item 18f, enter only the amount, if any, which is will be used as part of the required match.</p> <p>There are two types of match: 1) non-federal cash and 2) non-federal in-kind. In general, costs borne by the applicant and cash contributions of any and all third parties involved in the project, including sub-recipients, contractors and consultants, are considered matching funds. Generally, most contributions from sub-contractors or sub-recipients (third parties) will be non-federal in-kind matching funds. Volunteered time and use of facilities to hold meetings or conduct project activities may be considered in-kind (third party) donations. Examples of non-federal cash match include budgetary funds provided from the applicant agency's budget for costs associated with the project.</p> <p>Indirect charges may only be requested if: (1) the applicant has a current indirect cost rate agreement approved by the Department of Health and Human Services or another federal agency; or (2) the applicant is a state or local government agency. State governments should enter the amount of indirect costs determined in accordance with HHS requirements. If indirect costs are to be included in the application, a copy of the approved indirect cost agreement must be included with the application. Further, if any sub-contractors or sub-recipients are requesting indirect costs, copies of their indirect cost agreements must also be included with the application.</p> |

| Item | Field Name                                                                     | Information                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
|------|--------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 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 non-federal in-kind. Cost breakdowns, or justifications, are required for any cost of \$1,000 or more. The Budget Narratives/Justifications should fully explain and justify the costs in each of the major budget items for each of the object class categories, as described below. Non-federal cash as well as, sub-contractor or sub-recipient (third party) in-kind contributions designated as match must be clearly identified and explained in the Budget Narrative/Justification. The full Budget Narrative/Justification should be included in the application immediately following the SF 424 forms.

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

Some Points to Consider:

- ◆ Is the basis for determining each employee's compensation described (annual salary and % time devoted)?
- ◆ Is each position identified by title/responsibility?
- ◆ Are time commitments and the amount of compensation stated and reasonable?
- ◆ Are salary increases anticipated during the grant period and are they justified (COLA, etc.)?
- ◆ Are any personnel costs unallowable?
  - Dual Compensation
  - 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?
  - Office
  - Training
  - Research
  - Other types of supplies
- ◆ How was cost determined?
- ◆ Is the basis for the cost reasonable? Monthly estimates are sufficient
- ◆ Are costs consistently treated?

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

Some Points to Consider:

- ◆ Is the type of each service to be rendered described?
- ◆ For Consultants/Individuals
  - Is an hourly, daily or weekly base rate given?
  - Are rates allowable, justified, reasonable and comparable to market?
- ◆ Is the total amount for any contract in excess of \$150,000?
  - Is procurement method described?
  - If the contract is not competitively bid, has a sole source justification been provided?

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

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

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

Some Points to Consider:

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

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

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

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

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

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

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

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

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

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

***Section E Budget Estimate of Federal Funds Needed for Balance of the Project***

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

***Section F Other Budget Information***

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

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

## Budget Narrative/Justification Template (with SAMPLE information)

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

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

| Object Class Category | Federal Funds | Non-Federal Cash | Non-Federal In-Kind | TOTAL     | Justification                                                                                                                                                                                                                                                                                                                                                                                |
|-----------------------|---------------|------------------|---------------------|-----------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Other                 | \$11,250      | \$2,000          | --                  | \$13,250  | <ul style="list-style-type: none"> <li>◆ Subaward to ABC to conduct training – Federal funds = \$10,000</li> <li>◆ Printing brochures – Federal funds (25,000 @ \$0.05 each) = \$1,250</li> <li>◆ Registration fee for annual ABC conference – Non-federal cash = \$200</li> <li>◆ Postage – Non-Federal Cash (\$150/mo x 12 months) = \$1,800</li> </ul> <p><b>TOTAL</b> <b>\$3,250</b></p> |
| Indirect Costs        | \$12,000      | \$1,000          | \$1,000             | \$14,000  | <ul style="list-style-type: none"> <li>◆ Rent – Federal funds (\$1,000/mos. x 12 months) = \$12,000</li> <li>◆ Utilities – Non-federal cash = \$1,000</li> <li>◆ Administrative Support – Non-Federal In-Kind<br/>100 hours x \$10/hour = \$1,000</li> </ul> <p><b>TOTAL</b> <b>\$14,000</b></p>                                                                                             |
| TOTALS                | \$231,310     | \$11,707         | \$51,000            | \$294,017 | --                                                                                                                                                                                                                                                                                                                                                                                           |

## Letter of Commitment Template

CAPT Alicia A. Morton DNP, RN-BC  
Director, Health IT Certification Program  
Office of the National Coordinator for Health Information Technology  
Department of Health and Human Services  
330 C. Street, 7<sup>th</sup> Floor, Office, S.W.  
Washington, DC 20201

Date

Dear CAPT Morton,

[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