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

Notice of Funding Opportunity (NOFO) -

Trusted Exchange Framework and Common Agreement - Recognized Coordinating Entity (RCE) Cooperative Agreement

> Application Due Date: 06/17/2019 Anticipated Award Date: 08/30/2019

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Executive Summary

This NOFO describes a full and open competition to make a single, 4-year award, through a Cooperative Agreement, for a non-profit entity with appropriate approvals from ONC, to develop, update, implement, and maintain the Common Agreement¹ component of the Trusted Exchange Framework² and Common Agreement (TEFCA). This entity, known as the Recognized Coordinating Entity (RCE)² will also work with ONC to designate and monitor Qualified Health Information Networks (QHINs),³ modify and update an accompanying QHIN Technical Framework,⁴ engage with public stakeholders through virtual public listening sessions, adjudicate noncompliance with the Common Agreement, and propose sustainability strategies for an RCE to continue to support trusted data⁵ exchange through QHIN connectivity at the expiration of the term of the Cooperative Agreement. The program will be funded for the first year at \$900,000, with funding in additional years contingent upon availability of funds and satisfactory completion of milestones.

In the 21st Century Cures Act (Cures Act),⁶ Congress identified the importance of interoperability by laying out a path for the establishment of interoperable exchange of electronic health information (EHI) and charging the Office of the National Coordinator for Health

¹ Common Agreement: an agreement in the form published by ONC and signed by the RCE and a Provisional QHIN (which shall become a QHIN only upon Designation by the RCE as further described in the MRTCs). The Common Agreement shall consist of (a) the Minimum Required Terms and Conditions, (b) the Additional Required Terms and Conditions, and (c) such other terms as the RCE and the QHIN mutually agree upon; provided, however, that in the event of any conflict or inconsistency between or among Applicable Law, the MRTCs, the ARTCs, and any other terms and conditions, the following shall be the order of precedence to the extent of such conflict or inconsistency: (i) Applicable Law including the HIPAA Rules, (ii) the MRTCs, (iii) the ARTCs, and (iv) any other terms and conditions agreed to by the parties.

² TEF: the Trusted Exchange Framework published in the Federal Register and on ONC's website.

² Recognized Coordinating Entity (RCE): the entity selected by ONC that will enter into agreements with QHINs in order to impose, at a minimum, the requirements of the Common Agreement and the QHIN Technical Framework on the QHINs and administer such requirements on an ongoing basis.

³ Qualified HIN (QHIN): a Health Information Network that is a party to a Common Agreement signed by the RCE and has been Designated a QHIN by the RCE after satisfying all the conditions of the Common Agreement and the QHIN Technical Framework.

⁴ QHIN Technical Framework: the document approved by ONC pursuant to the Common Agreement that includes: (1) technical requirements, functional requirements, privacy and security related considerations required for the exchange of electronic health information (EHI) between QHINs; (2) intra-QHIN functional requirements; (3) technical, privacy, and security flow down requirements from the QHIN to the Participants and/or Participant Members (if any); and, (4) operational considerations that enable the exchange of EHI between QHINs.

⁵ Data: one or more elements of EHI (unless otherwise expressly specified).

⁶ Pub. L. 114–255 (Dec 13, 2016).

Information Technology (ONC) with the implementation of key interoperability provisions under Title IV of the Cures Act including advancing a Trusted Exchange Framework and Common Agreement to improve data exchange between health information networks (HINs).⁷ See § 4003(b) of the Cures Act, which added new subsection (9) to section 3001(c) of the Public Health Service Act (PHSA) (42 U.S.C. 300jj-11(c)).

The Cures Act's focus on trusted exchange is an important step toward advancing the establishment of an interoperable health system that empowers individuals to use EHI to the fullest extent; enables providers and communities to deliver smarter, safer, and more efficient care; and promotes innovation at all levels.⁸

The RCE will have an important role in realizing the vision of the TEFCA and will have responsibilities including:

- 1. Develop a Common Agreement that includes the Minimum Required Terms & Conditions⁹ (MRTCs) and Additional Required Terms & Conditions (ARTCs)¹⁰ developed by the RCE and approved by ONC. The Common Agreement will be published on HealthIT.gov and in the Federal Register.
- 2. Virtually convene public listening sessions that will allow industry stakeholders to provide objective and transparent feedback to the RCE.

(2) Provides, manages, controls, or substantially influences any technology or service that enables or facilitates the access, exchange, or use of electronic health information between or among two or more unaffiliated individuals or entities.

⁸ This Cooperative Agreement is authorized through the Consolidated Appropriations Act, 2018, Pub. L. 115-141, Division H, Title II "for the development and advancement of interoperable health information technology".

⁹ Minimum Required Terms and Conditions (MRTCs): ONC will develop the MRTCs, which will consist of mandatory minimum required terms and conditions with which Qualified Health Information Networks (QHINs) may voluntarily agree to comply. The MRTCs are not a full end-to-end trust agreement. Rather, the MRTCs focus on the areas of variation among currently existing trust agreements that impede nationwide interoperability. The Common Agreement would include the MRTCs, as well as additional required terms and conditions developed by the RCE. Draft 1 of the MRTCs was referred to as "Part B" in Draft 1 of the TEF. The MRTCs Draft 2 was released for public comment April 19, 2019 and can be found at https://www.healthit.gov/TEFCA.

¹⁰ Additional Required Terms and Conditions (ARTCs): the terms and conditions, written by the RCE and approved by ONC, which are in addition to the MRTCs.

⁷ Health Information Network or HIN means an individual or entity that satisfies one or both of the following—

⁽¹⁾ Determines, oversees, administers, controls, or substantially influences policies or agreements that define business, operational, technical, or other conditions or requirements for enabling or facilitating access, exchange, or use of electronic health information between or among two or more unaffiliated individuals or entities;

- 3. Designate and monitor QHINs that voluntarily agree to sign and adopt the Common Agreement.
- 4. Implement an ONC-approved process to adjudicate QHIN noncompliance with the Common Agreement, up to and including removal from ONC's public directory on HealthIT.gov.
- 5. Implement a process to update the Common Agreement, as needed, for ONC final approval and publication on HealthIT.gov and in the Federal Register.
- 6. Modify and update the QHIN Technical Framework Draft 1 (QTF), for ONC approval, to detail proposed technical components for exchange between QHINs.
- 7. Propose strategies that an RCE could employ to sustain the Common Agreement at a national level after the expiration of the term of the Cooperative Agreement.

Entities may enter into multi-organizational agreements to apply to this notice of funding opportunity. However, one singular entity must be the Applicant; act as the responsible agent; submit the application on behalf of all partners, who must provide written documentation affirming the Applicant's role as their agent; and maintain accountability for the proper use of federal funds.

1. Funding Opportunity Description

A. Purpose

The purpose of this NOFO is to support efforts to advance nationwide interoperability of Electronic Health Information (EHI)¹¹ through a Trusted Exchange Framework (TEF) and Common Agreement that (1) allows clinicians to access health information about their patients, regardless of where the patient received care; (2) empowers individuals to use their EHI to the fullest extent; (3) enables clinicians and communities to deliver smarter, safer, and more efficient care; and (4) promotes innovation at all levels. The TEF and the Common Agreement are two distinct components. ONC will maintain the TEF and will work with the RCE to develop, update, implement, and maintain the Common Agreement. ONC will have final approval of the Common Agreement and all subsequent updates. The TEF and the Common Agreement are further described below. The RCE will also work with ONC to identify and monitor QHINs, modify and update an accompanying QHIN Technical Framework, engage with public stakeholders through virtual public listening sessions, adjudicate noncompliance with the Common Agreement, and propose sustainability strategies for an RCE to continue to support trusted data exchange through QHIN connectivity at the expiration of the term of the Cooperative Agreement.

The Trusted Exchange Framework (TEF) – To support the Cures Act's goal of advancing health information exchange among health information networks, the TEF creates a common set of principles that are designed to facilitate trust between HINs and by which all HINs should abide in order to enable widespread data exchange. These principles are standardization; transparency; cooperation and non-discrimination; privacy, security, and patient safety; access; and data driven accountability. These principles are non-binding, but are the foundational concepts that guide the development of the Common Agreement to support the ability of stakeholders to access, exchange, and use relevant EHI across disparate HINs and sharing arrangements.

The Common Agreement – The RCE will collaborate with ONC to develop, update, implement, and maintain an ONC-approved Common Agreement. The Common Agreement will be comprised of three parts:

¹¹ Electronic Health Information (EHI): electronic protected health information, and any other information that identifies the individual, or with respect to which there is a reasonable basis to believe the information can be used to identify the individual and is transmitted by or maintained in "electronic media," as defined at 45 CFR § 160.103, that relates to the past, present, or future health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual.

- Minimum Required Terms and Conditions (MRTCs): ONC will develop the MRTCs, which will consist of mandatory minimum required terms and conditions with which QHINs may voluntarily agree to comply. The MRTCs are not a full end-to-end trust agreement. Rather, the MRTCs focus on the areas of variation among currently existing trust agreements that impede nationwide interoperability. The Common Agreement would include the MRTCs, as well as additional required terms and conditions developed by the RCE.
- Additional Required Terms and Conditions (ARTCs): In addition to the MRTCs, the Common Agreement will include additional required terms and conditions that are necessary for an effective data sharing agreement. These may include provisions that govern interactions between the RCE and the QHINs. For example, such provisions would cover determination of fee schedules and compliance; QHIN Application,¹² Onboarding,¹³ and Designation¹⁴ requirements; a process for surveilling and testing QHIN compliance with the Common Agreement; an arbitration process for adjudicating non-compliance; and an audit-appropriate process for accepting and investigating complaints, and for suspending and potentially terminating a non-compliant QHIN. The RCE will develop the ARTCs and will ensure that the ARTCs do not conflict with the MRTCs. ONC will have final approval of the Common Agreement.
- Qualified Health Information Network (QHIN) Technical Framework (QTF): the RCE will work with ONC to develop the QTF, which will be incorporated by reference in the Common Agreement. Where the Common Agreement will include and detail the underlying policies and expectations for exchange between QHINs, the QHIN Technical Framework will focus on the technical components for exchange among QHINs, including, but not limited to identity proofing and authentication, and utilization of Connectivity Services. ONC developed the QHIN

¹² QHIN Application: the written application of a HIN that wishes to become a QHIN that: (a) certifies which of the Common Agreement and QHIN Technical Framework requirements the HIN already satisfies with sufficient detail to allow the RCE to easily confirm such representations and (b) describes the HIN's plan to satisfy all other requirements of the Common Agreement and the QHIN Technical Framework within a stated period after signing the Common Agreement.

¹³ Onboarding (including its correlative meanings "Onboard" and "Onboarded"): all implementation and other actions necessary for a QHIN, a Participant, or Participant Member to become operational in the live environment of the Framework Agreements to which it is a party. For a QHIN, the Onboarding requirements shall be set forth in the Common Agreement. For a Participant, the Onboarding requirements shall be set forth in the Participant-QHIN Agreement. For a Participant Member, the Onboarding requirements shall be set forth in the Participant Member Agreement.

¹⁴ Designation (including its correlative meanings "Designate", "Designated", and "Designating"): the RCE's written confirmation to ONC that a Provisional QHIN has satisfied all the requirements of both the Common Agreement and the QHIN Technical Framework before the Provisional QHIN may become a QHIN.

Technical Framework Draft 1, and will work with the RCE and external stakeholders to modify and update Draft 1 per public comment.

B. Background

The U.S. Department of Health and Human Services (HHS) is committed to advancing the connectivity of patient health data and the interoperability of health information technology (health IT). In the Cures Act, Congress identified the importance of interoperability and directed ONC to work with federal agencies within HHS and with other federal partners to "develop or support a Trusted Exchange Framework, including a Common Agreement among health information networks nationally." The Cures Act provides that the Common Agreement may include:

- I. "a common method for authenticating trusted health information network participants;
- II. "a common set of rules for trusted exchange;
- III. "organizational and operational policies to enable the exchange of health information among networks, including minimum conditions for such exchange to occur; and
- IV. "a process for filing and adjudicating noncompliance with the terms of the common agreement."¹⁵

The first draft of the TEF was released for public comment on January 5, 2018 ("TEF Draft 1"). TEF Draft 1outlined the minimum set of principles, terms, and conditions to support the development of a Common Agreement that would enable data exchange across disparate networks. ONC reviewed all of the public comments on the TEF Draft 1 and released a modified draft for public comment on April 19, 2019. The modified draft is broken into three parts that are described further below. These parts include:

- 1. The TEF Draft 2, formerly "Part A-Principles for Trusted Exchange";
- 2. <u>The Minimum Required Terms and Conditions (MRTCs) Draft 2, formerly "Part</u> <u>B — Minimum Required Terms and Conditions for Trusted Exchange"; and</u>
- 3. <u>The QHIN Technical Framework Draft 1.</u>

C. Program Description

This Cooperative Agreement will fund a single award with a 4-year program period of performance.¹⁶ The program will be funded for fiscal year 2019 at \$900,000, with

¹⁵ Pub. L. 114-255 (Dec 13, 2016) (<u>https://www.congress.gov/114/bills/hr34/BILLS-114hr34enr.xml#toc-H920D7CEBEAB44045B3EC1233BB93E07A</u>).

funding in additional years contingent upon availability of funds, satisfactory completion of milestones, and a determination that continued funding is in the best interest of the federal government and the public.

To meet the goals of the Cures Act to build on existing work done by the industry, and to scale interoperability nationwide, ONC believes that an external entity is well suited to implement and monitor compliance with the Common Agreement on behalf of ONC. ONC intends to work closely with the chosen RCE and will be continually involved in implementation of the Common Agreement throughout the Cooperative Agreement.

ONC intends to select a single RCE, through a competitive process, to develop, update, implement, and maintain the Common Agreement for ONC approval. The RCE will work closely with ONC to develop a single, all-encompassing Common Agreement that incorporates the latest versions of the ONC-developed MRTCs and the ONC-approved ARTCs to operationalize the Common Agreement. The ARTCs may not conflict with the MRTCs and ONC must approve them before they can be added to the Common Agreement. The RCE will also work with ONC to update, implement, and maintain the QHIN Technical Framework as needed. ONC will update, implement, and maintain the TEF as needed. Updates to the TEF, Common Agreement, and QHIN Technical Framework will be based on feedback from public comment periods, at least semi-annual listening sessions, and the Health Information Technology Advisory Committee (HITAC). ONC will have final approval of all updates made to the TEF, the Common Agreement, and OHIN Technical Framework. At the expiration of the term of the Cooperative Agreement, in order to maintain the Common Agreement and related components as an ongoing concern, the RCE will need to comply in a timely manner with all applicable obligations set forth in Section C (Terms and Conditions) of this NOFO.

D. Program Approach

I. Program Overview

SCOPE OF SERVICES

The RCE will be responsible for developing, updating, implementing, and maintaining the ONC-approved Common Agreement, to which QHINs will agree to adhere. The RCE will also be responsible for soliciting and reviewing applications from HINs who wish to become QHINs, evaluating Provisional QHINs,¹⁷ and

¹⁶ All referenced terms in this Notice of Funding Opportunity pertain to the period of performance.

¹⁷ Provisional QHIN: A HIN that has signed a Common Agreement that has also been signed by the RCE after approval as described in Section 2 of the MRTCs. A Provisional QHIN has not yet completed all of the requirements of the Common Agreement and the QHIN Technical Framework, and has not been Designated by the RCE as a QHIN as described in Section 2 of the MRTCs.

providing Provisional QHINs with a final written Designation¹⁸ of their QHIN status. This process is described in detail in Milestone 3.

The RCE will monitor/surveil ongoing QHIN compliance with the Common Agreement's requirements and future updates throughout the period of performance Such monitoring will include collecting metrics from the QHINs.¹⁹ Through such efforts, the RCE will investigate and be responsible for addressing the QHIN's conduct per the processes and procedures developed in the Common Agreement. If a QHIN is found to be noncompliant by the RCE and if the QHIN disagrees, the RCE will implement an arbitration process, as established in the ARTCs, and shall notify ONC. If the QHIN does not disagree, the RCE may impose a corrective action plan on the QHIN. If such corrective action plan fails to bring the QHIN into compliance, the RCE may, if necessary, revoke a QHIN's Designation and terminate the Common Agreement with a QHIN, up to and including removal from ONC's public directory on HealthIT.gov. Additional details around the scope of services will be defined in the Principles of Proper Conduct (PoPC) and as mutually agreed upon between ONC and the RCE.

The RCE must make progress toward achieving the milestones below, as outlined in the RCE's budget and program narrative, over the course of the 4-year funding period. ONC will work with the RCE once awarded to determine the appropriate targets and reporting requirements. The RCE's milestones under the Cooperative Agreement include the following:

- 1. Develop a Common Agreement that includes the MRTCs and ARTCs, for ONC approval and publication on HealthIT.gov and in the Federal Register.
- 2. Virtually convene public listening sessions that will allow industry stakeholders to provide objective and transparent feedback to the RCE.
- 3. Designate and monitor QHINs that voluntarily agree to sign and adopt the Common Agreement.
- 4. Implement an ONC-approved process to adjudicate QHIN noncompliance with the Common Agreement, up to and including removal from ONC's public directory on HealthIT.gov.
- 5. Implement a process to update the Common Agreement, as needed, for ONC final approval and publication on HealthIT.gov and in the Federal Register.

¹⁸ Designation (including its correlative meanings "Designate", "Designated", and "Designating"): the RCE's written confirmation to ONC that a Provisional QHIN has satisfied all the requirements of both the Common Agreement and the QHIN Technical Framework before the Provisional QHIN may become a QHIN.

¹⁹ These metrics will be reported by the RCE to ONC to allow for ONC programmatic oversight. Such information will also be used by ONC for interoperability research purposes, including publication of relevant reports for the public's benefit. For example, metrics related to the number of QHINs connected to the network and the number of data transactions by each will allow ONC to monitor the success of the RCE and publish relevant reports.

- 6. Modify and update the QHIN Technical Framework Draft 1, for ONC approval, to detail proposed technical components for exchange between QHINs.
- 7. Propose strategies that an RCE could employ to sustain the Common Agreement at a national level after the expiration of the term of the Cooperative Agreement.

II. Program Evaluation and Measurement

ONC will measure the success of the RCE through the reporting of progress on milestones and metrics. The RCE will develop an audit-appropriate process for validating milestone achievement. ONC will evaluate the RCE's performance to ensure that the project is meeting stated objectives and that funding drawn down by the RCE is commensurate with milestones achieved. For each milestone, ONC will work with the RCE to determine the appropriate targets and reporting requirements.

Budget Year 1

Program Support and Engagement Funding (approximately 25% of Year 1 funds): Establish financial and reporting requirements, developing resources to conduct initial outreach, development of a program monitoring plan, and development of an audit appropriate process for validating each milestone. Milestone tasks include:

- Engage subject matter experts (SMEs) and program support staff, to include but not be limited to legal counsel.
- Create and submit a baseline Program Monitoring Plan to support the authorized level of total award from ONC.
- Sign and comply with the PoPC developed by ONC and incorporated by reference in the Notice of Grant Award (NGA) Terms and Conditions.²⁰
- Determine appropriate metrics for QHINs to report to the RCE to demonstrate compliance with the Common Agreement, including both process and outcome measures. This will also include appropriate timeframes for QHIN reporting to the RCE.
- Develop a public website that will keep the public abreast of pertinent information such as documents and updates including:
 - Listening session details (date, time, location, registration information, objectives, etc.)

²⁰ Details about the PoPC are further described in Section 2C of this NOFO, "Roles and Responsibilities Under a Cooperative Agreement".

- QHIN application and Designation processes
- QHIN members
- Other information as mutually agreed upon between the RCE and ONC
- Prepare for ongoing program monitoring activities throughout the Cooperative Agreement.
 - Bi-weekly calls with ONC
 - Quarterly and annual progress reports that provide updates on the Program Monitoring Plan
 - Perform other tasks as mutually agreed upon between the RCE and ONC.

Budget Year 1

Milestone 1 (approximately 50% of Year 1 funds): Develop a Common Agreement, for ONC approval and publication on HealthIT.gov and the Federal Register that includes the MRTCs and the ARTCs as described above in Section 1A. The RCE may modify their existing data sharing agreement to include the MRTCs. Completion of this milestone will require engagement of legal professionals. If the RCE does not have existing legal staff on board, they will need to bring such staff on board. ONC may assign ONC staff to provide technical assistance and subject matter expertise for development of the Common Agreement as needed. Milestone tasks include:

- Develop the initial draft of the Common Agreement ("Common Agreement Draft 1") for ONC approval:
 - Develop ARTCs, to include:
 - Administrative procedures for designating and terminating QHINs.
 - Provisions related to RCE monitoring/ surveillance of QHIN compliance with the Common Agreement.
 - An audit-appropriate process for accepting and investigating complaints regarding QHINs, including investigation of complaints regarding QHIN noncompliance with the Common Agreement. The RCE will also be responsible for making a determination regarding whether a QHIN's Designation should be terminated and for implementing such termination.
 - A process for adjudicating QHIN noncompliance with the Common Agreement, up to and including removal from ONC's public directory on HealthIT.gov.
 - A standard operating procedure (SOP) for placing a QHIN on a corrective action plan to address QHIN noncompliance with the Common Agreement. Such SOP shall also include the

procedures and timelines for an RCE to report such corrective action plan or loss of QHIN Designation to ONC. Such SOP shall also include procedures and timelines for QHINs to be notified of corrective action plan or loss of Designation.

- Additional terms and conditions, as mutually agreed upon by ONC and the RCE.
- Incorporate by reference in Common Agreement Draft 1, the QHIN Technical Framework. The RCE will also be required to attend ONC workgroup meetings to ensure alignment between the QHIN Technical Framework and the Common Agreement.
- Revise Common Agreement Draft 1 per ONC feedback.
- Revise Common Agreement Draft 1 per public comment and listening session feedback (see Milestone 2), per ONC approval.
- Submit final Common Agreement Version 1 to ONC for publication on HealthIT.gov and the Federal Register.
- Establish a process for updating the Common Agreement Version 1, as ONC deems necessary— throughout the Cooperative Agreement to account for new technologies, policies, and use cases.
- Coordinate and collaborate with ONC subject matter experts, collaborating organizations, and other critical stakeholders, such as the National Institute for Standards and Technology (NIST) to ensure alignment across the most updated versions of the TEF, the ONC-approved Common Agreement, and the ONC-approved QHIN Technical Framework.
- Perform other tasks as mutually agreed upon between the RCE and ONC.

Budget Years 1-4

Milestone 2 (approximately 20% of annual funds): Convene virtual public listening sessions at least on a semiannual basis that will allow the industry to provide objective and transparent feedback to the RCE around the development of updates to the Common Agreement, QHIN Technical Framework, and other activities, as needed. Listening sessions should be fairly balanced in terms of the points of view represented and should be made up of broad stakeholder representation. Stakeholders represented may include, but are not limited to, healthcare systems, payers, purchasers, care providers (e.g., long-term and post-acute care, behavioral health, community-based and safety net providers, and emergency medical services), health IT developers; QHINs, HINs, federal stakeholders, individuals, and/or other stakeholders that enable widespread health information exchange to occur. Milestone tasks include:

• Develop and publish ONC-approved procedures for holding virtual public listening sessions in coordination with ONC, including:

- Plans to solicit and convene stakeholders across the industry, including updating the RCE's website to inform stakeholders of listening sessions.
- Listening session objectives, which should include a commitment to neutrality, transparency, and non-preferential treatment of stakeholders.
- A process for recording stakeholder input.
- Coordinate and collaborate with ONC subject matter experts, collaborating organizations, and other stakeholders, such as the National Institute for Standards and Technology (NIST).
- Launch and maintain listening sessions in accordance with ONC-approved published procedures.
- Carryout other tasks as mutually agreed upon between the RCE and ONC.

Budget Years 2-4

Milestone 3 (approximately 50% of Year 2 funds and 40% of Years 3 & 4 funds): Designate and monitor QHINs that voluntarily agree to adopt and sign onto the Common Agreement. This includes reviewing and approving QHIN Applications and launching, at a minimum, semi-annual Cohorts²¹ for Provisional QHINs to be evaluated for compliance with the Common Agreement as a function of gaining QHIN Designation.²² Milestone tasks include:

• Solicit, collect, and evaluate QHIN Applications from HINs who wish to receive QHIN Designation.²³

²¹ Cohort: a group of one or more Provisional QHINs as specified in writing by the RCE that are attempting to be Designated by the RCE as QHINs by the same Cohort Deadline.

²² In order to apply for QHIN Designation, a HIN must meet certain prerequisites, including already operating a network that provides the ability to locate and transmit EHI between multiple persons or entities electronically, with existing persons or entities exchanging EHI in a live clinical environment; and providing the RCE with a written plan of how it will achieve all of the requirements of the Common Agreement within a specified time period. A HIN must submit a QHIN Application to the RCE documenting that it meets these prerequisites, and the RCE must certify in writing that the HIN in question has satisfied these prerequisites. Once the RCE has approved a QHIN Application, the HIN becomes a Provisional QHIN and is assigned to a Cohort to complete the remainder of the requirements in the Common Agreement and QHIN Technical Framework. A Provisional QHIN is only Designated a QHIN once the RCE has confirmed and documented that the Provisional QHIN in question has satisfied the requirements of the Common Agreement, up to and including removal from ONC's public directory on HealthIT.gov, when necessary.

²³ As described in Section 2.1 of the MRTCs.

- This includes updating the RCE's website to allow stakeholders to submit QHIN Applications, and for the RCE to publicly post QHIN members.
- Approve or reject each QHIN Application, in writing, within a stated period after receipt of a completed QHIN Application.
 - No QHIN Application shall be approved by the RCE unless the HIN certifies in writing and the RCE has confirmed and documented that the HIN in question has satisfied all applicable requirements of the Common Agreement and the QHIN Technical Framework only to the extent they are prerequisites²⁴ to the RCE signing the Common Agreement with the HIN.
- Provide written approval of each HIN's QHIN application, and provide each HIN with a copy of the Common Agreement for signature by each HIN.
 - Upon return to the RCE of the Common Agreement signed by the HIN, the RCE shall promptly sign it, return a fully executed copy to the HIN, and assign the HIN in writing to a Cohort, specifying the applicable Cohort Deadline.²⁵
- Launch Cohorts for Provisional QHINs that sign the Common Agreement.
 - The RCE may, in its reasonable discretion, assign the Provisional QHIN to other Cohorts with later Cohort Deadlines.
- Monitor and evaluate Provisional QHINs through collection of metrics and reports that confirm they meet the definition of a QHIN²⁶ and are in compliance with the Common Agreement.²⁷
 - This includes collection of Breach²⁸ notifications from QHINs and reporting them to ONC.
 - Designate QHINs after confirming and documenting that the Provisional QHIN in question has satisfied the applicable requirements of the Common Agreement and the QHIN Technical Framework.
- Simultaneously provide Provisional QHINs and ONC with written documentation of QHIN Designation.

²⁴ Minimum prerequisites are further described in Section 2.1.3 of the MRTCs.

²⁵ Cohort Deadline: the date established by the RCE for a completion of all Onboarding and other actions necessary for the Provisional QHINs in the Cohort to be designated by the RCE as QHINs.

²⁶ As described in Section 2 of the MRTCs.

²⁷ Metrics to be developed as part of Program Support and Engagement Funding.

²⁸ Breach: has the meaning assigned to such term in 45 CFR § 164.402 regarding PHI as if it applied to EHI and arises from an act or omission of a QHIN, Participant or Participant Member in the context of any of the Framework Agreements that involves the EHI that was exchanged, Used, or Disclosed pursuant to any of the Framework Agreements.

• Perform other tasks as mutually agreed upon between the RCE and ONC.

Budget Years 2-4

Milestone 4 (approximately 5% of Years 2-4 funds): Implement the ONC-approved Common Agreement developed in Milestone 1, including QHIN Designation and reviewing potential noncompliance by QHINs to the provisions of the Common Agreement. Milestone examples include, but are not limited to:

- Monitor ongoing QHIN compliance with the Common Agreement throughout the period of performance and implement an arbitration process for adjudicating noncompliance, up to and including removal from ONC's public directory on HealthIT.gov, when necessary.
- Conduct ongoing surveillance to assess whether QHINs comply with the Common Agreement. This includes collecting ONC-approved metrics developed in Milestone 1 and, if necessary, assessment, revision and/or updates of metrics (subject to ONC approval).

In the event that a QHIN is found to be noncompliant with the Common Agreement, the RCE will be responsible for implementing the processes and procedures in the Common Agreement (as described above for addressing QHIN noncompliance) and the PoPC. The RCE will also be responsible for other tasks that are mutually agreed upon by the RCE and ONC.

• Budget Years 2-4

Milestone 5 (approximately 15% of Years 2-4 funds): Implement an RCEestablished process to update the Common Agreement, for ONC final approval and publication on HealthIT.gov and the Federal Register, including:

- Collect listening session feedback.
- Revise Common Agreement per public comment feedback.
- Submit the revised Common Agreement to ONC for approval.
- Perform other tasks as mutually agreed upon between the RCE and ONC.

Budget Years 1-4

Milestone 6 (approximately 15% of Year 1 funds and 10% of Years 2-4 funds): Modify the QHIN Technical Framework Draft 1 developed by ONC and update it during the period of performance, for ONC approval. The RCE will be expected to collaborate with ONC, as needed, in Year 1 to ensure alignment of the Common Agreement with the draft QHIN Technical Framework (Milestone 1). ONC may assign staff to provide technical assistance and subject matter expertise for updates to the QHIN Technical Framework, as needed. Milestone tasks include:

- Modify and update QHIN Technical Framework Draft 1 for ONC approval, per listening session(s) and public comment feedback.
- After receiving ONC approval, release the final QHIN Technical Framework Version 1 for production.

- Establish and publish an ONC-approved process for ongoing receipt of comments on the QHIN Technical Framework Version 1, as well as a process for maintaining the QHIN Technical Framework and for providing suggestions to ONC on potential updates such as:
 - Adding population-level EHI exchange.
 - Adding and updating technical components and use cases over time and as necessary.
- Perform other tasks as mutually agreed upon between the RCE and ONC.

Budget Years 3 & 4

Milestone 7 (approximately 10% of Year 3 & 4 funds): Propose strategies that an RCE could employ to sustain the Common Agreement at a national level at the expiration of the term of the Cooperative Agreement.

- Submit a proposed sustainability strategy for an RCE to continue to support trusted data exchange through QHIN connectivity at the expiration of the term of the Cooperative Agreement.
- Revise sustainability strategy per ONC feedback.
- Perform other tasks as mutually agreed upon between the RCE and ONC.

Milestone	Examples for Milestone Achievement ²⁹	Due Dates
	Engage SMEs and program support staff, to include but not be limited to, legal counsel	
Program Support and Engagement Funding (approximately	Create and submit a baseline Program Monitoring Plan to support the authorized level of total award from ONC	September 30, 2019
(approximately 25% of Year 1 funds)	Sign and comply with the PoPC developed by ONC and incorporated by reference in the NGA Terms and Conditions	50, 2019
	Determine appropriate metrics for QHINs to report to the RCE to demonstrate compliance	

²⁹ Drawdowns of funds over the course of the program are contingent upon availability of funds, satisfactory completion of milestones, and a determination that continued funding is in the best interest of the federal government and the public.

Milestone	Examples for Milestone Achievement ²⁹	Due Dates
	with the Common Agreement, including both process and outcome measures.	
	Develop a public website that will keep the public abreast of pertinent information	
	Prepare for ongoing program monitoring activities throughout the Cooperative Agreement	
	Perform other tasks as mutually agreed upon between the RCE and ONC.	Ongoing
	Develop Common Agreement Draft 1 for ONC approval	November 29, 2019
	Revise Common Agreement Draft 1 per ONC feedback	March 30, 2020
	Revise Common Agreement Draft 1 per public comment and listening session feedback	June 29, 2020
Milestone 1 (approximately	Submit Common Agreement Version 1 to ONC	July 6, 2020
40% of Year 1 funds)	Establish a process for updating the Common Agreement, as ONC deems necessary— throughout the Cooperative Agreement – to account for new technologies, policies, and use cases.	July 13, 2020
	Coordinate and collaborate with ONC subject matter experts, collaborating organizations, and other critical stakeholders, such as the National Institute for Standards and Technology (NIST) to ensure alignment across the most updated versions of the TEF, the ONC-approved Common Agreement, and the ONC-approved QHIN Technical	Ongoing

Milestone	Examples for Milestone Achievement ²⁹	Due Dates
	Framework.	
	Perform other tasks as mutually agreed upon between the RCE and ONC.	Ongoing
	Develop and publish procedures for holding virtual public listening sessions in coordination with ONC	
Milestone 2 (approximately 20% of annual funds)	Coordinate and collaborate with ONC subject matter experts, collaborating organizations, and other critical stakeholders, such as the National Institute for Standards and Technology (NIST) to ensure alignment across the most updated versions of the TEF, the ONC-approved Common Agreement, and the ONC-approved QHIN Technical Framework.	Ongoing
	Launch and maintain listening sessions in accordance with published procedures	Ongoing
	Perform other tasks as mutually agreed upon between the RCE and ONC.	Ongoing
	Solicit, collect, and evaluate QHIN Applications from HINs who wish to receive QHIN Designation	
Milestone 3 (approximately 50% of Year 2 funds and 40% of	Approve or reject each QHIN Application, in writing, within a stated period after receipt of a completed QHIN Application	August 31, 2020 for first Cohort and ongoing
Years 3 & 4 funds)	Provide written approval of each HIN's QHIN application, and provide each HIN with a copy of the Common Agreement for signature by each HIN	

Milestone	Examples for Milestone Achievement ²⁹	Due Dates
	Launch Cohorts for Provisional QHINs that sign the Common Agreement	
	Monitor and evaluate Provisional QHINs through collection of metrics and reports that confirm they meet the definition of a QHIN and are in compliance with the Common Agreement and the QHIN Technical Framework	
	Designate QHINs after confirming and documenting that the Provisional QHIN in question has satisfied the applicable requirements of the Common Agreement and the QHIN Technical Framework	Ongoing
	Simultaneously provide Provisional QHINs and ONC with written documentation of QHIN Designation	
	Perform other tasks as mutually agreed upon between the RCE and ONC	
	Monitor ongoing QHIN compliance with the Common Agreement throughout the Cooperative Agreement and implement an arbitration process for adjudicating noncompliance.	
Milestone 4 (approximately 5% of Years 2-4 funds)	Conduct ongoing surveillance to assess whether QHINs comply with the Common Agreement. This includes collecting ONC- approved metrics developed in Milestone 1 and, if necessary, assessment, revision and/or updates of metrics (subject to ONC approval).	Ongoing
	In the event that a QHIN is found to be noncompliant with the Common Agreement, the RCE will be responsible for implementing the processes and procedures in the Common	

Milestone	Examples for Milestone Achievement ²⁹	Due Dates
	Agreement and the PoPC.	
	Perform other tasks as mutually agreed upon between the RCE and ONC.	
	Collect listening session feedback	
	Collect public comment feedback	
Milestone 5 (approximately	Revise Common Agreement per listening session feedback	
15% of Years 2-4 funds)	Revise Common Agreement per public comment feedback	Ongoing
	Submit revised Common Agreement to ONC for approval	
	Perform other tasks as mutually agreed upon between the RCE and ONC	
Milestone 6 (approximately 15% of Year 1 funds and 10% of Years 2-4 funds)	Modify and update the QHIN Technical Framework Draft 1 for ONC approval, per listening session(s) and public comment feedback	February 28, 2020
	After receiving ONC approval, release for production the final QHIN Technical Framework Version 1	April 29, 2020
	Establish and publish an ONC-approved process for ongoing receipt of comments on the QHIN Technical Framework Version 1, as well as a process for maintaining the QHIN Technical Framework and for providing suggestions to ONC on potential updates	July 29, 2020
	Perform other tasks as mutually agreed upon between the RCE and ONC	Ongoing

Milestone	Examples for Milestone Achievement ²⁹	Due Dates
Milestone 7 (approximately 10% of Year 3 & 4 funds)	Submit a proposed sustainability strategy for an RCE to continue to support trusted data exchange through QHIN connectivity at the expiration of the term of the Cooperative Agreement	No later than February 10, 2023
	Revise sustainability strategy per ONC feedback	No later than June 12, 2023
	Perform other tasks as mutually agreed upon between the RCE and ONC	Ongoing

2. Funding Opportunity Award Information

A. Key Award Parameters

Title: Trusted Exchange Framework and Common Agreement Recognized Coordinating Entity (RCE) Cooperative Agreement Program

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

Announcement Type: Cooperative Agreement

Application Type: New

Notice of Funding Opportunity Number: NAP-AX-19-001

Catalog of Federal Domestic Assistance (CFDA) Number: 93.347

Legislative Authority: Consolidated Appropriations Act, 2019, Pub. L. 115-245, Division B, Title II

Approximate Amount of Available Funding (inclusive of direct and indirect costs): \$900,000 for Year 1

Anticipated Number of Awards: 1

Approximately Amount of Award: \$900,000 for Year 1

Program Period: 08/30/2019-08/29/2023

Budget Period(s): 08/30/2019-08/29/2023

Funding of future noncompeting 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.

This will be a cost-based reimbursable award. It is important to note that progress must be made toward achieving the milestones as outlined in the RCE's approved budget and program narrative.

This NOFO does not overlap or otherwise duplicate other HHS or other federally funded health IT initiatives and is meant to leverage, supplement, and build upon existing efforts.

Cost-Sharing Requirements: There is no cost-sharing or matching requirement.

Program Income: There are four potential ways in which ONC may require that a recipient apply program income as specified in the NGA: 1) **deduct** it from total allowable 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 program, 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 program purposes **before** requesting additional payments of Federal funds. In the event program income remains at the end of the award, the additional income is considered part of the award funding and must be returned to ONC. **If program income is generated, the recipient must use the additive method.**

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

B. Key Dates

Milestone	Date
NOFO Released	04/19/2019
Informational Session	04/30/2019
Letter of Intent Due	05/17/2019

Milestone	Date
Applications Due	06/17/2019
Anticipated Award Date	08/30/2019
Anticipated Program Start Date	08/30/2019

C. Roles and Responsibilities Under a Cooperative Agreement

The funding instrument used for this program will be a Cooperative Agreement, an assistance mechanism in which substantial ONC programmatic involvement is anticipated throughout the program period. Under the Cooperative Agreement, ONC's purpose is for the development and advancement of interoperable health IT and support and stimulate the RCE's activities by involvement in, and otherwise working jointly with the RCE; it is not to assume direction, prime responsibility, or a dominant role in the activities. Consistent with this premise, the prime responsibility resides with the RCE for the program as a whole. To facilitate appropriate involvement, during the period of this Cooperative Agreement, ONC and the recipient will be in close, continuous contact.

ONC may provide technical assistance, including, but not limited to, federal guidance on the evolution of the Common Agreement and QHIN Technical Framework in accordance with current and future ONC regulatory efforts. ONC may also provide technical assistance to the RCE to support meeting programmatic goals. To facilitate compliance with the terms of the Cooperative Agreement and to more effectively support the RCE, ONC will actively coordinate and collaborate with critical stakeholders. In accordance with the Cooperative Agreement, ONC may assign staff to provide technical assistance and subject matter expertise throughout the period of performance of the Cooperative Agreement.

- The RCE will be required to sign and comply with Principles of Proper Conduct (PoPC) developed by ONC and incorporated by reference in the NGA Terms and Conditions. The PoPC will include:
 - Appropriate metrics and timeframes for the RCE to report to ONC to monitor milestone progress
 - Timeframes and process for notifying ONC of any QHIN noncompliance with the Common Agreement, including privacy and security breaches
 - Participants are to report any breaches to HINs, HINs are to report any breaches to QHINs, QHINs are to report any breaches to the RCE, and the RCE is to report any breaches to ONC.³⁰

³⁰ As described in Section 6 of the MRTCs.

- The RCE must also notify ONC of any QHIN being placed on corrective action and/or if the RCE intends to revoke a QHIN's Designation.
- A process by which requests, appeals, and notifications to ONC are received and addressed
- A process by which ONC would address RCE noncompliance with the PoPC
- Guidelines for communicating and collaborating with ONC subject matter experts, partners, and other critical stakeholders
- A process for ONC's administrative review of RCE actions, including Designation, corrective action, and/or termination decisions regarding QHINs
 - Reviewable actions will include whether the RCE continues to adhere to the following:
 - Be a United States-based non-profit entity
 - Proper execution of nondiscrimination and conflict of interest policies that demonstrate a commitment to transparent, fair, and nondiscriminatory treatment by the RCE of QHINs.
 - Does not serve as a QHIN so long as the applicant is the RCE, should the applicant be awarded as the RCE.
- Additional terms, as mutually agreed upon between ONC and the RCE

D. Information Session

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

- Discuss the background, purpose, scope, terms and conditions and other provisions in the NOFO
- Explain the eligibility and application requirements For example, if the applicant has an operating entity that would otherwise qualify as a prospective QHIN, that entity shall never serve as a QHIN during the time the applicant serves as the RCE, should they be awarded
- 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 <u>here</u>.

To ensure that ONC addresses all comments and questions regarding this announcement during the information session, please email any comments and questions, via email, to <u>TEFCA.NOFO@hhs.gov</u> no later than 3 days prior to the call.

E. Letter of Intent

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

The letter of intent is requested by 11:59 P.M. Eastern Time on 5/17/2019 and should be sent to <u>TEFCA.NOFO@hhs.gov</u>. The notice should identify the name of the applicant organization, the city and state in which the applicant organization is located, and the Notice of Funding Opportunity title and number.

3. Eligibility Information

A. Eligible Applicants

ONC is seeking an existing, industry-based organization that will be primarily responsible for developing, updating, implementing, and maintaining the Common Agreement component of the TEF and the Common Agreement, approved by ONC. The RCE will also work with ONC to identify and monitor QHINs, modify and update an accompanying QHIN Technical Framework, engage with public stakeholders through virtual public listening sessions, adjudicate noncompliance with the Common Agreement, and propose sustainability strategies for an RCE to continue to support trusted data exchange through QHIN connectivity at the expiration of the term of the Cooperative Agreement. This is an open competition to United States-based non-profit entities³¹ who can showcase the expertise and ability to execute the outlined requirements of this NOFO.

B. Cost-Sharing or Matching

There is no cost-sharing or matching requirement for this program.

C. Application Completeness Criteria

ONC will screen all applications to identify and eliminate those that do not meet criteria outlined below:

• The application is received by the deadline required under Section 4.C ("<u>Application</u> <u>Submission Instructions</u>")

³¹ United States: means all of the United States of America and its territories and possessions and any other location in which any Federal agency or Federal governmental entity operates.

• The application meets the formatting and length requirements found in Section 4.B ("<u>Content and Form of Application Submission</u>"). Appendices and attachments are allowed where noted but are not allowed as a mechanism to exceed page limits of the Program Narrative

D. Application Responsiveness Criteria

- Applications that do not meet the following responsiveness criteria will be administratively eliminated and will not be sent forward for merit review:
- The applicant meets the eligibility criteria, as required by Section 3.A ("<u>Eligible</u> <u>Applicants")</u>
- The application is complete and includes the required components, including all elements of Section 4.B ("<u>Content and Form of Application Submission</u>")

4. Application and Submission Information

A. Address to Request Application Package

The applicants will be able to download a copy of the application packet, complete it offline, and then upload and submit the application electronically via: <u>http://www.grants.gov</u> APPLICATIONS WILL NOT BE ACCEPTED THROUGH ANY OTHER WEBSITE, AND WILL NOT BE ACCEPTED THROUGH PAPER MAIL, COURIER, OR DELIVERY SERVICE.

THE APPLICANTS ARE STRONGLY ENCOURAGED TO COMPLETE AND SUBMIT APPLICATIONS AS FAR IN ADVANCE OF THE SUBMISSION DEADLINE AS POSSIBLE. THE APPLICATION INCLUDING ALL REQUIRED ATTACHMENTS AND INCLUDED FILES FOR POTENTIAL CONSIDERATION IN THE REVIEW PROCESS MUST BE RECEIVED BY 11:59 PM EASTERN TIME ON THE DATE SPECIFIED IN SECTION 4.C ("<u>APPLICATION SUBMISSION</u> <u>INSTRUCTIONS</u>"). All applicants should have a Dun and Bradstreet (D&B) Data Universal Numbering System (DUNS) number and register in the Systems for Award Management (SAM). Allow a minimum of five (5) days to complete the SAM registration.

Grants.gov will automatically send applicants a tracking number and date of receipt verification electronically once the application has been successfully received and validated in Grants.gov.

APPLICATION PROCEDURES:

- APPLICANTS MUST ACCESS THE ELECTRONIC APPLICATION FOR THIS PROGRAM VIA <u>HTTP://WWW.GRANTS.GOV</u>. SEARCH THE DOWNLOADABLE APPLICATION PAGE BY THE FUNDING OPPORTUNITY NUMBER **NAP-AX-19-001** OR CFDA NUMBER **93.347**
- Applicants should have a Dun and Bradstreet (D&B) Data Universal Numbering System (DUNS) number and register in the System for Award Management (SAM). Allow a minimum of seven days to complete the SAM registration. You can register with the SAM online at <u>http://sam.gov</u>. It is critical to know that SAM registration requires an annual renewal.
- Submit all documents electronically, including all information included on the SF424 and all necessary assurances and certifications.
- Ensure that the application complies with any page limitation requirements described in this Program Guidance.
- After electronically submitting your application, an automatic email notification will be sent to confirm that the application was received. This notification does not provide assurance that your application was complete, only that the application was received.

Key Contact for Applications: Inquiries should be addressed to: U.S. Department of Health and Human Services (HHS) Office of the National Coordinator for Health Information Technology (ONC)

Email: TEFCA.NOFO@hhs.gov

B. Content and Form of Application Submission

I. Program Abstract

Applicants must include an abstract of the application of no more than two pages single spaced and 500 words. This abstract is often distributed to provide information to the public and Congress and represents a high-level summary of the program. Applicants should prepare a clear, accurate, and concise abstract that can be understood without reference to other parts of the application. The abstract should give a description of the proposed program, including: the program theme addressed, the program's goal(s), objectives, overall approach (including target population and significant partnerships), anticipated outcomes, products, and duration.

The Program Abstract must have a font size of no less than 11 point Times New Roman font.

Applicants must place the following information at the top of the Program Abstract (this information is not included in the 500 word maximum):

- Program title
- Applicant name
- Address
- Contact name

- Contact phone numbers (voice, fax)
- E-mail address
- Web site address, if applicable

II. Program Narrative

The Program Narrative functions as the primary basis in determining if the application meets the minimum requirements for funding. The Program Narrative must provide a clear and concise description of the strategy that will be used to achieve intended milestones and outcomes. This includes description of who will have responsibility for key tasks such as: program leadership; monitoring the program's ongoing progress; milestone achievement; and engaging with public stakeholders and ONC. To that end, the program narrative should be in congruence with the elements articulated in Section 1 ("<u>Funding Opportunity Description</u>"). This includes alignment with Section 1.D ("<u>Program Approach</u>") and Section 1.D.II ("Program Evaluation and Measurement"). The program narrative should also be aligned with all other parts of the NOFO, including Section 5.A ("<u>Merit Review</u>").

The Program Narrative must be double-spaced, printable on 8 ¹/₂" x 11" pages with 1" margins on all sides, and use a font size no less than 11 point Times New Roman. Smaller font sizes may be used to fill in the Standard Forms and Sample Formats, as well as for exhibits and figures, however text in exhibits and figures must be no less than 8 point font. Program Narratives should be no more than 25 pages. ONC will not review Program Narrative pages beyond the allowed 25 pages. The Program Abstract will not be counted as part of the narrative but will be provided to reviewers. Key Staff Resumes/Curriculum Vitae (CV) are required and should be referenced in the Program Narrative, with resume/CV copies placed in Appendix B. Neither Appendix A nor Appendix B will be counted toward the Program Narrative's 25-page limit.

The program narrative must conform to the following outline and include the information required under each section:

- Problem Statement (1 page)
- Organizational Capacity and Technical Capabilities (4 pages)
- Program Management Acumen (1 page)
- Proposed Approach and Work Plan (8 pages)
- Collaborator Involvement and Partnerships (5 pages)
- Budget Overview and Sustainability (6 pages)
- a. Problem Statement (1 page)

In this section, applicants must demonstrate an understanding of the U.S. healthcare system, the 21st Century Cures Act (Cures Act), and the provisions in Section 4003 of the Cures Act related to the Trusted Exchange Framework and Common Agreement. This section must provide a clear assessment of the interoperability challenges that exist across the healthcare system and the current health information exchange

spectrum. Applicants must also show a clear understanding of how the Cures Act and the Common Agreement are expected to address those challenges.

This section must describe the need for a Common Agreement that is scalable across the entire nation. This section should describe how the Common Agreement will achieve the goal of establishing interoperability for all HINs. This section must describe how the Common Agreement can improve healthcare, including lowering costs, improving quality, and improving the health of the population.

b. Organizational Capacity and Technical Capabilities (4 pages)

Applicants must demonstrate they have the organizational and technical capabilities needed to support implementation of the program. It must demonstrate the applicant's ability to bring together all resources, including leveraging others existing infrastructure and capabilities required to perform the proposed work.

- Each applicant must have a mission statement or similar principal organizational goal indicating their commitment to the advancement of health care interoperability.
- A description of an existing agreement (or single collective set of existing policies) which the applicant currently determines, oversees, or administers that define business, operational, technical, or other conditions or requirements for enabling or facilitating access, exchange, or use of EHI between or among two or more unaffiliated individuals or entities. This agreement (or set of policies) must currently operate across two or more state jurisdictions. The applicant must be able to demonstrate governance over the data sharing that occurs across these jurisdictions through the agreement.
 - Applicants must identify the appropriateness, effectiveness, size, and scope of this agreement (or set of policies), to include, but not be limited to, broad nature of the geographic area covered by members, broad scope of participating entities, and the number of patient lives covered, all as a function of the United States as a whole.
- Demonstration of proficiency in building consensus amongst broad groups of stakeholders, particularly with regard to developing an existing participation agreement (or single collective set of policies). Examples of stakeholders may include payers, health care service providers, providers of other services that impact health, individuals, health information networks, health IT developers, state and local governments, federal agencies, and public health agencies. Letters of support included in the Appendix can provide substantiating evidence of meeting this requirement.
- A description of any prior governance, compliance and adjudicatory experience, including established processes for handling noncompliance in a rapid and judicious manner.
- Strong evidence of the organizational and personnel capabilities needed for successful program implementation, including, but not limited to:

- Qualified staff to govern the program, including a program manager and, if needed, partners/subcontractors;
- Legal expertise and experience, particularly around data sharing/use agreements;
- Financial management capabilities; and
- Technical expertise and experience, including relevant standards knowledge.
- Pertinent capabilities of the applicant not included in other portions of the program narrative, such as any current or previous applicable experience of the program team in conducting similar or applicable proposed activities (including technical expertise with data sharing and legal experience with participation agreements).
- Qualifications of the proposed key staff. Resumes/CVs are required and should be included as attachments within Appendix B.
- Demonstrated ability to develop, adopt, and implement nondiscrimination and conflict of interest policies that demonstrate a commitment to transparent, fair, and nondiscriminatory participation by members to a current or previous agreement or policies.
- c. Program Management Acumen (1 page)

This section must demonstrate the applicant's program management acumen. This section must describe:

- A clear delineation of the roles and responsibilities of program staff, partners, and collaborating organizations. This includes description of who will have responsibility for key tasks such as: program leadership; monitoring the program's ongoing progress; milestone achievement; and engaging with public stakeholders and ONC.
- A work breakdown structure and how each member of the program team will contribute to achieving milestones, completing deliverables, and achieving program outcomes.
- The approach for applying appropriate program management controls, including strategies for monitoring and tracking progress on the program's tasks and objectives, ensuring scope control, and communications methods/strategies.
- Strategies for monitoring contractors.
- Strategies for insulating the program from potential conflicts of interest.
- d. Proposed Approach and Work Plan (8 pages)

Applicants should provide a clear description of their approach to operationalizing the Common Agreement and addressing the challenges described in the "Problem Statement." This section must demonstrate the program's feasibility.

This section must include a program work plan that reflects and is consistent with the budget and sustainability plan, covering all 4 years of the program period. The work plan must identify important milestones and each major task or action step required to reach those milestones. These milestones must at a minimum include the milestones described in Section 1.D ("Program Approach"). For each major task or action step, the work plan must identify timeframes involved, included start and end dates. It must include clear benchmarks and performance metrics to achieve the program goals. Applicants must describe:

- The approach the applicant is proposing to take in conducting the program, including identifying the major challenges that will be addressed.
- The approach to complement, expand, and leverage existing national and statewide initiatives and other federally funded health IT programs, ensuring that efforts are not duplicative.
- An approach for how the applicant will incorporate the MRTCs into a Common Agreement.
 - Applicants must demonstrate an understanding of the second draft of the TEF ("TEF Draft 2"), and the MRTCs Draft 2.
- How the organization will work with ONC to finalize the QHIN Technical Framework and update it during the Cooperative Agreement.
- How the organization will onboard QHINs to the Common Agreement, as described in Milestone 3
- A clear strategy and approach on how the applicant will serve as a fair and effective governance body to QHINs, monitoring their compliance with the Common Agreement and taking necessary actions to address non-conformity or noncompliance by QHINs, up to and including removal from ONC's public directory on HealthIT.gov.
- Description of the applicant's experience with and understanding of technical compliance, as well as laws and regulations related to privacy and security of data services provided.
- Description of how applicant's governance model will ensure non-preferential treatment of stakeholders as it pertains to conducting public listening sessions.
- The applicant's plan for day-to-day management and governance of QHINs
 - How the proposed approach will be scalable and replicable to support the entire nation.
- Creation of a standard operating procedure (SOP) for placing a QHIN on a corrective action plan as needed and for the RCE to report revocation of QHIN Designation to ONC.
- How the proposed approach will build a competitive market allowing all to compete on information services, but not on ownership of the data itself. This section should describe the entities that would leverage the Common Agreement to better support providers.
- How it plans to work with ONC to update the Common Agreement as needed during the period of performance to account for new technologies, policies, and use cases.

- This section must align with the following section on how the applicant plans to work collaboratively with partners and stakeholders, including building and implementing new use cases that will use the Common Agreement as their foundation.
- e. Collaborator Involvement and Partnerships (5 pages)

Applicants must describe their existing and anticipated partnerships, including, but not limited to: relationships with payers, healthcare service providers, providers of other services that impact health, individuals, HINs, health IT developers, state and local governments, federal agencies, public health agencies, and others. This section must describe the role and composition of any collaborators or partners that applicants intend to involve in implementing the approach and work plan, as well as how their contributions will support program success. This section must clearly describe a strong, sound, and feasible approach.

Applicants shall demonstrate their understanding of existing activities carried out by public and private organizations related to exchange between health information exchanges. Applicants must describe how they have leveraged the business models of others for successful health information exchange, and how, if awarded, they will build on this work.

Demonstration of support from program collaborators and partners must include letters of support. If an entity (e.g., collaborator, partner, subrecipient or contractor) will be responsible for parts of the applicant's approach, a letter of support from those entities indicating their commitment is required. Copies of letters should be placed within Appendix A and will not count as part of the page limit stipulated in this section.

If applicable, applicants must disclose in this section any operating entities that would otherwise qualify as a QHIN. Applicants must provide confirmation that if they have an affiliation with an operating entity that would otherwise qualify as a prospective QHIN, that entity shall not serve as a QHIN so long as the applicant is the RCE, should the applicant be awarded as the RCE.

f. Budget Overview and Sustainability (6 pages)

Applicants are required to provide a description of their budget and overall financial plans. The duration of this award is for 48 months. While initial funding will be awarded for the first year of the program, the recipient must submit a budget to reflect the costs anticipated for the entire program period. Applicants must also propose strategies that an RCE could employ to sustain the Common Agreement at a national level after the expiration of the term of the Cooperative Agreement. This section complements the required Budget Forms and Budget Narrative, which are described below.

This section is to include a description of the costs that would be incurred in support of the program activities. This must include appropriate justifications of these costs. This section must include the allowable costs that will be incurred in support of the Cooperative Agreement. Cooperative Agreement costs may not be incurred until the beginning date of the award, as indicated on the official NGA. This section must include:

- An explanation of how the proposed budget supports the proposed program and is reasonable to meet the program's needs and is as cost-efficient as possible,
- The extent to which the proposed levels of effort and costs of personnel are adequate to advance the program in accordance with given timelines.
- Adequate justification to support costs included in budget.
 - A description of how the program income will supplement award funding.
- The intent is to ensure applicants can properly support implementation of the Common Agreement during the term of the Cooperative Agreement.
 - Applicants must also include descriptions of the overall financial health of the applicant and key partners.

III. Budget Forms:

All applicants are required to fill out the following budget forms to include the costs associated with the proposed program activities. These forms will be submitted through grants.gov as part of the application package and will include the following:

- Application for Federal Assistance SF424
- Budget Information for Non-Construction Programs SF424A
- Assurances for Non-Construction Programs SF424B
- Disclosure of Lobbying Activities SF-LLL
- Please note that these forms do not replace program-specific guidance provided in this funding opportunity. Additional instruction regarding budget forms can be found in Appendix A
 - a. Form SF424, 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 SF424.

b. Form SF424A, Budget Information for Non-Construction Programs

Appendix C provides line-by-line instructions to complete the form. Please note that the SF424A 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 SF424A. All direct and indirect costs must be allowable, allocable, reasonable, and necessary.

c. Form SF424B, Assurances for Non-Construction Programs

This form contains laws and other assurances applicants must comply with under the discretionary funds programs administered by ONC. Please note that a duly authorized representative of the applicant organization must certify that the organization is in compliance with these assurances.

d. 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.

IV. Budget Narrative

The budget narrative describes how the proposed budget, as articulated in the SF-424A, aligns with the applicant's program 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 program's total budget falls under a contractual expense, a detailed budget narrative/justification must be provided for each contractor or subrecipient. Applicants requesting funding for multi-year 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 $\frac{1}{2}$ " x 11" (letter-size) pages, 1" or larger margins on all sides, and a font size of not less than 11 point Times New Roman.

V. Proof of Non-Profit Status

All applicants must submit proof of non-profit status. Any of the following constitutes acceptable proof of such status:

- A copy of a currently valid IRS tax exemption certificate
- A statement from a state taxing body, state attorney general, or other appropriate state official certifying that the applicant organization has a non-profit status and that none of the net earnings accrue to any private shareholders or individuals

• A certified copy of the organization's certificate of incorporation or similar document that clearly establishes non-profit status

VI. 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 subrecipient are requesting indirect costs, copies of their indirect cost agreements must also be included with the application.

Nonfederal Entities (NFE) that have never received a negotiated indirect cost rate can charge a de minimis rate of 10% of modified total direct costs (MTDC). Please see 45 CFR 75.414(f) for further guidance.

VII. Appendix A: Letters of Support

Include letters of support confirming the support to the program (should it be funded) made by key collaborating individuals, organizations or agencies across the applicant's multi-state region, particularly those with which the applicant already has existing participation/legal/governance agreements. Letters of support that express commitments will be looked upon more favorably and letters that demonstrate a higher level of commitment will be considered with a higher degree of favorability. Similarly, letters that demonstrate proficiency in building consensus among broad groups of public and private stakeholders will be evaluated more favorably. Any organization that is specifically named to have a significant role in carrying out the program should be considered an essential collaborator. At a minimum, the letter must explain the demonstrate coordination and collaboration among critical stakeholders. See Appendix E for an example letter of support.

These letters are not included in the page limit. Signed letters of support should be scanned and included as attachments.

Appendix B: Key Staff and Key Partner Resumes/CVs

Include key staff and key partner staff resumes or CVs. Include only those resumes and CVs for individuals referenced under "Program Narrative" in Section 4.B.II above. These are not included in the page limit.

Appendix C: Optional Appendices(s)

Only the following additional information can be included in the optional appendices, not included in the page limit: Examples of metrics reports.

C. Application Submission Instructions

- Applicants must access the electronic application for this program via <u>http://www.grants.gov</u>. Applicants may search the downloadable application page by the Notice of Funding Opportunity Number NAP-AX-19-001 or CFDA number 93.347.
- 2) Applicants will be able to download a copy of the application packet and complete it offline. 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 <u>http://fedgov.dnb.com/webform</u> 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.

To upload applications into Grants.gov:

a) An applicant must be registered in the System for Award Management (SAM), at sam.gov, which requires having a DUNS number. The SAM registration process takes approximately 7 days so please plan accordingly. If you have already registered with SAM, but have not renewed your registration in the last 12 months, you will need to renew your registration.

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

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 <u>www.grants.gov</u>, please contact them at <u>support@Grants.gov</u> 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 <u>http://www.grants.gov/web/grants/applicants/apply-for-grants.html</u>

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

The deadline for the submission of applications under this Notice of Funding Opportunity is 11:59 Eastern Time on 06/17/2019. Applications that fail to meet the application deadline will not be reviewed and will receive no further consideration.

D. 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

5. Application Review Information

A. Merit Review

An independent review panel of at least three individuals will evaluate applications that meet the screening criteria identified above. These panelists will be experts in their field from academic institutions, private and non-profit organizations, and local and federal government agencies. Panelists will review, evaluate, and score applications in accordance with the criteria identified below. Applicants will be scored by assigning a maximum of 100 points.

- Understanding of Program Purpose and Scope (5 points)
- Organizational Capacity & Technical Capabilities & Program Management Acumen (20 points)
- Proposed Approach and Work Plan (35 points)
- Collaborator Involvement and Partnerships (20 points)
- Budget & Financials (20 points)

UNDERSTANDING OF PROGRAM PURPOSE AND SCOPE (5 POINTS)

Applicants will be scored based on the strength of its responsiveness to the requirements described in Section 4.B.II.a ("Problem Statement").

Applicants must demonstrate an understanding of the U.S. healthcare system, the 21st Century Cures Act (Cures Act), and the provisions in Section 4003 of the Cures Act related to the Trusted Exchange Framework and Common Agreement. This section must provide a clear assessment of the interoperability challenges that exist across the healthcare system and the current health information exchange spectrum. Applicants must also show a clear understanding of how the Cures Act and the Common Agreement are expected to address those challenges.

This section must describe the need for a Trusted Exchange Framework and Common Agreement that is scalable across the entire nation. This section should describe how the Common Agreement will achieve the goal of interoperability for all HINs. Applicants may also use this section to describe how the Common Agreement can improve healthcare, including lowering costs, improving quality, and improving the health of the population.

ORGANIZATIONAL CAPACITY & TECHNICAL CAPABILITIES & PROGRAM MANAGEMENT ACUMEN (20 POINTS)

Applicants will be scored based on the strength of its responsiveness to the requirements described in Sections 4.B.II.b ("Organizational Capacity and Technical Capabilities") and 4.B.II.c ("Program Management Acumen").

Applicants must demonstrate the organizational and technical capabilities needed to support implementation of the program. It must demonstrate the applicant's ability to bring together all resources, including leveraging others existing infrastructure and capabilities required to perform the proposed work. This section must include:

- The applicant must have a mission statement or similar principal organizational goal indicating their commitment to the advancement of health care interoperability.
- A description of an existing agreement (or single collective set of existing policies) which the applicant currently determines, oversees, or administers that define business, operational, technical, or other conditions or requirements for enabling or facilitating access, exchange, or use of EHI between or among two or more unaffiliated individuals or entities. This agreement (or set of policies) must currently operate across two (2) or more state jurisdictions. The applicant must be able to demonstrate governance over the data sharing that occurs across these jurisdictions through the agreement.
- Applicants must speak to the appropriateness, effectiveness, size, and scope of this agreement (or set of policies), to include, but not be limited to, broad nature of the geographic area covered by members, broad scope of participating entities, and the number of patient lives covered, all as a function of the United States as a whole.
- Demonstration of the applicant's proficiency in building consensus amongst broad groups of stakeholders, particularly with regard to developing an existing participation agreement (or single collective set of policies). Examples of stakeholders may include payers, health care service providers, providers of other services that impact health, individuals, HINs, health IT developers, state and local governments, federal agencies, and public health agencies.
 - Demonstrates, through letters of support, previous or current participation and membership in a public-private collaborative across two or more state jurisdictions and from multiple types of stakeholders. Such stakeholders can include, but are not limited to, healthcare systems, payers, purchasers,

care providers (i.e. long-term and post-acute care, behavioral health, community-based and safety net providers, and emergency medical services), health IT developers, HINs, and/or other stakeholders that enable widespread health information exchange to occur.

- A description of any prior governance, compliance and adjudicatory experience, including established processes for handling noncompliance in a rapid and judicious manner.
- Strong evidence of the organizational and personnel capabilities needed for successful program implementation, including, but not limited to:
 - Qualified staff to govern the program, including a program manager and, if needed, partners/subcontractors;
 - Legal expertise and experience, particularly around data sharing/use agreements;
 - Financial management capabilities; and
 - Technical expertise and experience, including relevant standards knowledge.
- Pertinent capabilities of the applicant not included in other portions of the program narrative, such as any current or previous applicable experience of the program team in conducting similar or applicable proposed activities (including technical expertise with data sharing and legal experience with data sharing agreements).
- Qualifications of the proposed key staff. Resumes/CVs are required and should be included as attachments within Appendix B.
- Demonstrated ability to develop, adopt, and implement nondiscrimination and conflict of interest policies that demonstrate a commitment to transparent, fair, and nondiscriminatory participation by members to a current or previous agreement or policies.

Applicants must also demonstrate their program management acumen. This section must describe:

- A clear delineation of the roles and responsibilities of program staff, partners, and collaborating organizations. This includes a description of who will have governance as well as day-to-day responsibility for key tasks such as: program leadership; monitoring the program's ongoing progress; preparation of the required Common Agreement; ensuring non-preferential treatment of stakeholders; and communications with other collaborating organizations and ONC.
- A work breakdown structure and how each member of the program team will contribute to achieving milestones, completing deliverables, and achieving program outcomes
- The approach for applying appropriate program management controls, including strategies for monitoring and tracking progress on the program's tasks and objectives, ensuring scope control, and communications methods/strategies
- Strategies for monitoring contractors

• Strategies for insulating the program from potential conflicts of interest

PROPOSED APPROACH AND WORK PLAN (35 points)

Applicants will be scored based on the strength of its responsiveness to the requirements described in Section 4.B.II.d ("Proposed Approach and Work Plan").

This section should provide a clear description of the applicant's approach to operationalizing the Common Agreement and addressing the challenges described in the "Problem Statement." This section must demonstrate the program's feasibility. This section must include a program work plan that reflects and is consistent with the budget and sustainability plan, covering all 4 years of the program period. The work plan must identify important milestones and each major task or action step required to reach those milestones. These milestones must at a minimum include the milestones described in Section 1.D ("Program Approach"). For each major task or action step, the work plan must identify timeframes involved, included start and end dates. It must include clear benchmarks and performance metrics to achieve the program goals. Applicants must describe:

- A description of the approach the applicant is proposing to take in conducting the program, including identifying the major challenges that will be addressed
- Approach to complement, expand, and leverage existing national and statewide initiatives and other federally funded health IT programs, ensuring that efforts are not duplicative.
- An approach for how the applicant will incorporate the MRTCs and the ARTCs into the Common Agreement.
 - Applicant must demonstrate an understanding of the TEF Draft 2 and the MRTCs Draft 2.
- How the organization will work with ONC to finalize the QHIN Technical Framework and update it during the Cooperative Agreement.
- How the organization will onboard QHINs to the Common Agreement, as described in Milestone 3
- A clear strategy and approach on how the applicant will serve as a fair and effective governance and adjudicatory body to QHINs, monitoring their compliance with the Common Agreement and taking necessary actions to address non-conformity or noncompliance by QHINs.
- Description of the applicant's experience with and understanding of laws and regulations related to privacy and security of data services provided.
- Description of how applicant's governance model will ensure non-preferential treatment of stakeholders as it pertains to conducting public listening sessions.
- The applicant's plan for day-to-day management and governance of QHINs. How the proposed approach will be scalable and replicable to support the entire nation.
- The applicant's plan for the creation of a standard operating procedure (SOP) for placing a QHIN on a corrective action plan as needed and for the RCE to report revocation of QHIN Designation to ONC.

- How the proposed approach will build a competitive market allowing all to compete on information services, but not on ownership of the data itself. This section should describe the entities that would leverage the Common Agreement to better support providers.
- How it plans to update the Common Agreement as needed during the term of the Cooperative Agreement to account for new technologies, policies, and use cases.
- This section must align with the following section on how applicants plan to work collaboratively with partners and stakeholders, including building and implementing new use cases that will use the Common Agreement as their foundation.

COLLABORATOR INVOLVEMENT AND PARTNERSHIPS (20 points)

Applicants will be scored based on the strength of its responsiveness to the requirements described in Section 4.B.II.e ("Collaborator Involvement and Partnerships"). Applicants must describe their existing and anticipated partnerships, including, but not limited to: partnerships with payers, healthcare service providers, providers of other services that impact health, individuals, HINs, health IT developers, state and local governments, federal agencies, public health agencies, and others.

Applicants must describe the role and composition of any collaborators or partners they intend to involve in implementing the approach and work plan, as well as how their contributions will support program success. This section must clearly describe a strong, sound, and feasible approach.

Applicants shall demonstrate an understanding of existing activities carried out by public and private organizations related to exchange between health information exchanges. Applicants must describe how they have leveraged the business models of others for successful health information exchange, and how, if awarded, they will build on this work.

Demonstration of support from program collaborators and partners must include letters of support. If an entity (e.g., collaborator, partner, subrecipient or contractor) will be responsible for parts of the applicant's approach, a letter of support from those entities indicating their commitment is required. Copies of letters should be placed within Appendix A.

If applicable, applicants must disclose in this section any operating entities that would otherwise qualify as a QHIN. Applicants must provide confirmation that if they have an affiliation with an operating entity that would otherwise qualify as a prospective QHIN, that entity shall not serve as a QHIN so long as the applicant is the RCE, should the applicant be awarded as the RCE.

BUDGET & FINANCIALS (20 points)

Applicants will be scored based on the strength of their responsiveness to the requirements described in Section 4.B.II.g ("Budget Overview and Sustainability"), Section 4.B.III ("Budget Forms"), Section 4.B.IV ("Budget Narrative"), and Section 4.B.VI ("Indirect Cost Agreement[s]").

Applicants are required to provide a description of their budget and overall financial plans. The duration of this award is for 48 months (4 years) and this section must reflect the costs and revenues for the entire program period. Applicants must also describe their sustainability plans for post-period of performance, and any anticipated changes to cost or revenue streams.

The budget narrative is to include a description of the costs that would be incurred in support of the program activities. This must include appropriate justifications of these costs. The narrative must include the allowable costs that will be incurred in support of the Cooperative Agreement. Cooperative Agreement costs may not be incurred until the beginning date of the award, as indicated on the official NGA. The budget narrative must include:

- An explanation of how the proposed budget supports the proposed program and is reasonable to meet the program's needs and is as cost-efficient as possible,
- The extent to which the proposed levels of effort and costs of personnel are adequate to advance the program in accordance with given timelines.
- Adequate justification to support costs included in budget.
- A description of how the program income will supplement award funding.

The intent is to ensure applicants can properly support implementation of the Common Agreement during the award period.

Applicants must also include descriptions of their overall financial health, as well as that of their key partners.

All applicants are required to fill out the following budget forms to include the costs associated with the proposed program activities. These forms will be submitted through grants.gov as part of the application package and will include the following:

- Application for Federal Assistance SF424
- Budget Information for Non-Construction Programs SF424A
- Assurances for Non-Construction Programs SF424B
- Disclosure of Lobbying Activities SF-LLL
- Please note that these forms do not replace program-specific guidance provided in this funding opportunity. Additional instruction regarding budget forms can be found in Appendix A.
- a. Form SF424, 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.

b. Form SF424A, 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.

c. Form SF424B, Assurances for Non-Construction Programs

This form contains laws and other assurances applicants must comply with under the discretionary funds programs administered by ONC. Please note that a duly authorized representative of the applicant organization must certify that the organization is in compliance with these assurances.

d. 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.

The budget narrative describes how the proposed budget, as articulated in the SF424A, aligns with the applicant's program 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 program's total budget (including program income) falls under a contractual expense, a detailed budget narrative/justification must be provided for each contractor or subrecipient. Applicants requesting funding for multi-year 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 $\frac{1}{2}$ " x 11" (letter-size) pages, 1" or larger margins on all sides, and a font size of not less than 11 point Times New Roman.

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 subcontractors or sub recipients are requesting indirect costs, copies of their indirect cost agreements must also be included with the application.

B. Pre-Award Risk Assessment

ONC is required to conduct a risk assessment to assess the risk posed by a potential RCE, 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 nonfederal entities. To facilitate this assessment, ONC may review information available in systems, such as the Excluded Parties List System, review documentation, such as previous audits, and/or desk reviews or site visits conducted from previous awards. ONC may elect not to fund applicants with management or financial instability that directly relates to the organization's ability to implement statutory, regulatory or other requirement s (45 CFR Part 75.205.)

6. Federal Award Administration Information

A. Award Decisions

The final award decision will be made by the National Coordinator for Health Information Technology (National Coordinator). The National Coordinator will take into consideration several factors, such as the results of the objective 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 program will result in the benefits expected. All applicants will receive a summary of the merit review panel's assessment of the application's strengths, weaknesses, and score.

B. Notice of Grant Award (NGA)

The recipient 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 an 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
- Program period, specifying the amount of time ONC intends to support the program without requiring re-competition for funds
- Total amount of financial assistance approved by ONC during the program period

- Budget period, specifying the increments in which the program will be funded, subject to the availability of funds
- Applicable award terms and conditions, to include Principles of Proper Conduct
- 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 recipient's Authorized Representative will receive the NGA electronically from ONC. The RCE accepts the award by drawing down funds. By accepting an ONC award, the RCE 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.

C. Terms and Conditions

I. 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: <u>https://www.ecfr.gov/cgi-bin/text-idx?node=pt45.1.75&rgn=div5#sg45.1.75_1411.sg12</u>
- HHS Grants Policy Statement <u>https://www.hhs.gov/sites/default/files/grants/policies-</u> 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.

II. Performance Reporting

All reporting requirements will be provided to the applicant of a successful application, adherence to which is a required condition of any award. ONC Program Progress Reports (PPR) are due quarterly and 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
- Sustainability approaches

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

III. Program-Specific Terms & Conditions

This performance-based payment structure describes the technical assistance services that the recipient will perform in order for milestone-based payments to occur. While this is a cost-based reimbursable award, it is important to note, that progress must be made towards achieving the milestone as outlined in the recipient's approved budget and project narrative/work plan. The recipient is required to provide milestone information for every programmatic metric stated and defined in: the Notice of Funding Opportunity (NOFO), including those included in or related to the latest version of the Common Agreement; the NGA terms and conditions; the ONC-approved budget and program narrative; and any additional information agreed upon by ONC and the recipient. The recipient will work with ONC to establish an audit appropriate process for validating each core programmatic milestone achievement. Additional instructions for milestone reporting will be provided post-award.

Additional recipient responsibilities include:

- Engaging SMEs and program support staff, including legal counsel
- Creating and submitting a baseline Program Monitoring Plan to support the authorized level of total award from ONC
- Signing and complying with Principles of Proper Conduct (PoPC) developed by ONC
- Determining appropriate metrics for QHINs to report to the RCE to demonstrate compliance with the Common Agreement, including both process and outcome measures.
- Partnering with ONC program staff and contractors to develop strategies to identify and mitigate potential barriers in order to ensure that programmatic objectives and timelines are met.
- Developing, implementing, updating, and maintaining an ONC-approved public website that will keep the public abreast of pertinent updates
- Preparing for ongoing program monitoring activities throughout the Cooperative Agreement.
- Perform other tasks as mutually agreed upon between ONC and the RCE.

The RCE will also be required to meet and maintain certain independence criteria throughout the Cooperative Agreement, in that, if the recipient has an affiliated

operating entity that would otherwise qualify as a prospective QHIN, such entity shall never serve as a QHIN during the time the recipient serves as the RCE.

In addition, should the recipient propose to carry out a portion of the activities funded under this award through a sub award, the recipient must request prior approval and must enter into a written agreement with each subrecipient that addresses the arrangements for meeting all of the programmatic, administrative, financial, and reporting requirements of the Cooperative Agreement, including those necessary to ensure compliance with all applicable Federal laws, regulations and policies.³²

Work Product/ Intellectual Property

Per the UNIFORM ADMINISTRATIVE REQUIREMENTS, COST PRINCIPLES, AND AUDIT REQUIREMENTS FOR HHS AWARDS, 45 CFR 75.322, 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 (Work Product). 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.

The RCE further agrees to the following:

- a. The Federal Government has the right to:
 - 1. Obtain, reproduce, publish, or otherwise use the Work Product produced under a Federal award; and
 - 2. Authorize others to receive, reproduce, publish, or otherwise use such Work Product for Federal purposes.
- b. The Work Product includes, but is not limited to:
 - 1. The Common Agreement (including all iterations of the ARTCs, MRTCs, and QHIN Technical Framework).
 - 2. QHIN Technical Framework.
 - 3. Program Monitoring Plan.
 - 4. A final list of the participating QHINs.
 - 5. All copies of executed Common Agreements and all amendments or attachments thereto.
 - 6. All ongoing processing materials for QHIN Application, Onboarding, and Designation, including QHIN Applications and the QHIN applicant's written plan for achieving the requirements of the Common

³² 45 CFR 75.351-2; HHS Grants Policy Statement, p. II-78.

Agreement, written documentation of QHIN Application approval, and written documentation of QHIN Designation.

- 7. Any SOP detailing corrective action procedures or processes for adjudicating QHIN non-compliance, and any ongoing corrective action plans with QHINs.
- 8. Other Work Product developed during the Cooperative Agreement as mutually agreed upon between ONC and the RCE.
- 9. Work Product includes all materials developed under this award whether in partial or final form.

The RCE agrees to the following upon the completion/termination of this award:

- 1. The RCE agrees to authorize ONC to obtain, reproduce, publish, or otherwise use any Work Product developed under this award immediately upon completion/termination of award.
- 2. The RCE agrees that ONC and any successor RCEs will have a royalty-free nonexclusive and irrevocable right to reproduce, publish, or otherwise use the Work Product for any purpose.
- 3. For any work owned by a third party that was licensed by the RCE under this award, RCE will ensure that said license also reserves for the Government and any successor RCE 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.

Program Evaluation

The recipient must comply with requirements as outlined in this NOFO. The recipient is required to cooperate with the ONC-directed evaluation and auditing activities, including but not limited to reporting standardized performance measures and milestones on regular basis; and, participating in ONC-led formal assessments, such as site visits, desk audits and/or teleconferences.

IV. 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).

V. 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 subawards and executive compensation under Federal assistance awards issued in FY2011 or later. All recipients of ONC grants and Cooperative Agreements are required to report to the Federal Subaward Reporting System (FSRS) available at www.fsrs.gov on all subawards over \$25,000.

Federal Awardee Performance and Integrity Information System (FAPIIS)

As of January 1, 2016, recipients of Federal grants and Cooperative Agreements are subject to new mandatory disclosure requirements. Recipients that have Federal contracts, grants, and Cooperative Agreement awards with a cumulative total value greater than \$10,000,000 must disclose in FAPIIS, semiannually, any information about criminal, civil, and administrative proceedings for the most recent 5-year period in connection with the award or performance of a grant, cooperative, agreement, or procurement contract from the Federal Government. All information posted in FAPIIS on or after April 15, 2011, except past performance reviews required for Federal procurement contracts, will be publicly available.

VI. 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 program
- To purchase or improve land, or to purchase, construct, or make permanent improvements to any building
- To reimburse pre-award costs

VII. Conflict of Interest

The term "organizational conflict of interest" means that the applicant, including its chief executives, directors, consultants, subrecipients, 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 nonfederal 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, the RCE 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 RCE has taken, or proposed to take, to avoid, eliminate, or neutralize the conflict.

In the event the RCE 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 RCE shall not be entitled to reimbursement of any costs incurred in performing the assistance agreement.

For the purpose of this program, please note that ONC will not have any direct affiliation with the participating QHINs. Any conflict of interest issues will be handled in accordance to the RCE's organizational policy, between the RCE and the QHIN, as applicable. Further, if an RCE has an operating entity that would otherwise qualify as a QHIN, that operating entity shall never be a QHIN during the time the applicant serves as the RCE. Additional terms will be included in the Common 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.

VIII. 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 RCE shall ensure that all its personnel, including chief executives, directors, consultants, subrecipients, 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, the recipient 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.

IX. Mandatory Disclosures

In accordance with Section 75.113, Mandatory Disclosures, of the Uniform Administrative Requirements, Cost Principles, and Audit Requirements for HHS Awards. The nonfederal 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.

X. Records Retention

Recipients generally must retain financial and programmatic records, supporting documents, statistical records, and all other records that are required by the terms of a grant, or may reasonably be considered pertinent to a grant, for a period of three years from the date the final FFR is submitted. For awards where the FFR is submitted at the end of the competitive segment, the 3-year retention period will be calculated from the date the final FFR, for the entire competitive segment, is submitted.

45 CFR Part 75.361 provides exceptions and qualifications to the three-year retention requirement. For example, if any litigation, claim, financial management review, or audit is started before the expiration of the three-year period, the records must be retained until all litigation, claims, or audit findings involving the records have been resolved and final action taken. This section also specifies the retention period for other types of grant-related records, including indirect cost proposals and property records. See 45 CFR 75.335 for record retention and access requirements for contracts under grants.

For the purpose of this program and by accepting this award, the RCE agrees to retain the following (but not limited to) documents upon the completion/termination of this award, as specified in the Program-Specific Terms and Conditions above:

• Any financial reports submitted during the period of performance (Federal Financial Reports SF-425, Federal Cash Transaction Reports)

- Proof of expenditures and general ledgers supporting those expenditures
- Any policies and procedures that are pertinent to the execution of this award
- The Common Agreement (including the ARTCs and incorporating the MRTCs, as developed by ONC.)
- QHIN Technical Framework
- Program Monitoring Plan
- A final list of the participating QHINs
- All copies of executed Common Agreements and amendments thereto,
- All ongoing processing materials for QHIN Application, Onboarding, and Designation, including QHIN Applications and the QHIN applicant's written plan for achieving the requirements of the Common Agreement, written documentation of QHIN Application approval, and written documentation of QHIN Designation.
- Any SOP detailing corrective action procedures or processes for adjudicating QHIN non-compliance, and any ongoing corrective action plans with QHINs
- Other Work Product developed during the Cooperative Agreement as mutually agreed upon between ONC and the RCE.

XI. 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.

XII. 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 nonfederal entities expending Federal awards. In general, a nonfederal entity that expends \$750,000 or more during the nonfederal entity's fiscal year in Federal awards must have a single or program-specific audit. Subpart F provides further guidance including the manner in which expenditures are determined, the distinction between a single audit and a program-specific audit, frequency of audits, and roles and responsibilities in the conduct of audits.

The 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 <u>hhstips@oig.hhs.gov</u> 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.

XIII. Enforcement Actions/Termination

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

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

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

For the purpose of this program, if an RCE is terminated, the RCE agrees to the transfer of and future use by ONC and any successor RCE of any Work Products developed under this Cooperative Agreement, per Section III, Program-Specific Terms & Conditions.

XIV. Steven's Amendment

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

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

- 1. the percentage of the total costs of the program or program which will be financed with Federal money;
- 2. the dollar amount of Federal funds for the program or program; and
- 3. percentage and dollar amount of the total costs of the program or program that will be financed by non-governmental sources.

ONC requires recipients to use the following acknowledgement and disclaimer on all products produced by ONC grant funds:

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

Recipients are required to use this language when issuing statements, press releases, requests for proposals, bid solicitations, and other ONC supported publications and

forums describing programs or programs funded in whole or in part with ONC funding. Examples of ONC supported publications include, but are not limited to, manuals, toolkits, resource guides, case studies and issues briefs.

XV. 508 Compliance

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

7. Points of Contact

ONC GRANTS MANAGEMENT OFFICER Carmel Halloun 330 C Street, S.W. Washington, D.C. 20201 oncgrants@hhs.gov

ONC GRANTS MANAGEMENT SPECIALIST Yolonda Thompson 330 C Street, S.W. Washington, D.C. 20201 oncgrants@hhs.gov ONC PROGRAM MANAGER Michael Berry 330 C Street, S.W. Washington, D.C. 20201 Michael.Berry@hhs.gov

ONC E-MAIL ADDRESS

In addition, a separate ONC e-mail address has been established for this Cooperative Agreement to which all comments and inquiries can be directed. The e-mail address is <u>TEFCA.NOFO@hhs.gov</u>

DUN AND BRADSTREET http://www.DNB.com 800.234.3867

SYSTEM FOR AWARD MANAGEMENT (SAM) CUSTOMER SUPPORT https://www.sam.gov Federal Service Desk—<u>www.fsd.gov</u> 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: <u>support@grants.gov</u>

Appendix A – 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 <u>http://www.dunandbradstreet.com</u> 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 RCE 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 RCE or because parts of the application do not fit together.

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

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

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

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

Appendix B – Instructions, SF-424, Application for Federal Assistance

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

Item	Field Name	Information
1.	Type of Submission:	(Required) Select one type of submission in accordance with agency instructions.
		• Pre-application
		Application
		• Changed/Corrected Application - Check if this submission is to change or correct a previously submitted application. Unless requested by the agency, applicants may not use this form to submit changes after the closing date.
2.	Type of Application:	(Required) Select one type of application in accordance with agency instructions.
		• New - An application that is being submitted to an agency for the first time.
		• Continuation - An extension for an additional funding/budget period for a program with a programed completion date. This can include renewals.
		• Revision - Any change in the federal government's financial obligation or contingent liability from an existing obligation. If a revision, enter the appropriate letter(s). More than one may be selected. If "Other" is selected, please specify in text box provided.
		A. Increase Award
		B. Decrease Award C. Increase Duration

Item	Field Name	Information				
		D. Decrease Duration E. Other (specify)				
3.	Date Received:	Leave this field blank. This date will be assigned by the Federal agency.				
4.	Applicant Identifier:	Enter the entity identifier assigned by the Federal agency, if any, or the applicant's control number if applicable.				
5a.	Federal Entity Identifier:	Enter the number assigned to your organization by the federal agency, if any.				
5b.	Federal Award Identifier:					
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 <u>www.Grants.gov</u> .				
	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 <u>www.Grants.gov</u> .				

Item	Field Name	Information
	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.
9.	Type of Applicant: (Required) Select up to three applicant type(s) in accordance with agency instructions.	 A. State Government B. County Government C. City or Township Government D. Special District Government E. Regional Organization F. U.S. Territory or Possession G. Independent School District H. Public/State Controlled Institution of Higher Education I. Indian/Native American Tribal Government (Federally Recognized) J. Indian/Native American Tribal Government (Other than Federally Recognized) K. Indian/Native American Tribal Government (Other than Federally Recognized) K. Indian/Native American Tribal J Designated Organization L. Public/Indian Housing M. Nonprofit N. Private Institution of Higher Education O. Individual P. For-Profit Organization (Other than Small Business) Q. Small Business R. Hispanic-serving Institution S. Historically Black Colleges and Universities (HBCUs) T. Tribally Controlled Colleges and Universities (TCCUs) U. Alaska Native and Native Hawaiian Serving Institutions V. Non-US Entity

Item	Field Name	Information			
		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 Program:	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 Program/Performance Site Location(s) Form. Add attachment to enter additional areas, if needed.			
15.	Descriptive Title of Applicant's Program:	(Required) Enter a brief descriptive title of the program. If appropriate, attach a map showing program location (e.g., construction or real property programs). For pre- applications, attach a summary description of the program.			
16.	Congressional Districts Of:	15a. (Required) Enter the applicant's congressional district. 15b. Enter all district(s) affected by the program or program. Enter in the format: 2 characters state abbreviation - 3 characters district number, e.g., CA-005 for California 5 th 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/program 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			

Item	Field Name	Information
		SF-424 Program/Performance Site Location(s) Form. Attach an additional list of program/program congressional districts, if needed.
17.	Proposed Program Start and End Dates:	(Required) Enter the proposed start date and end date of the program.
18.	Estimated Funding:	

(Required) Enter the amount requested, or to be contributed during the first funding/budget period by each contributor. Value of in-kind contributions should be included on appropriate lines, as applicable. If the action will result in a dollar change to an existing award, indicate only the amount of the change. For decreases, enclose the amounts in parentheses.

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 subcontractors or subrecipients are requesting indirect costs, copies of their indirect cost agreements must also be included with the application.

19.	Is Application Subject to Review by State Under Executive Order 12372 Process?	(Required) Applicants should contact the State Single Point of Contact (SPOC) for Federal Executive Order 12372 to determine whether the application is subject to the State intergovernmental review process. Select the appropriate box. If "a." is selected, enter the date the application was submitted to the State.
20.	Is the Applicant Delinquent on any Federal Debt?	(Required) Select the appropriate box. This question applies to the applicant organization, not the person who signs as the authorized representative. Categories of federal debt include; but may not be limited to: delinquent audit disallowances, loans and taxes. If yes, include an explanation in an attachment.
21.	Authorized Representative:	To be signed and dated by the authorized representative of the applicant organization. Enter the first and last name (Required); prefix, middle name, suffix. Enter title, telephone number, email (Required); and fax number. A copy of the governing body's authorization for you to sign this application as the official

Item	Field Name	Information
		representative must be on file in the applicant's office. (Certain federal agencies may require that this authorization be submitted as part of the application.)

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

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

Section A Budget Summary

<u>Line 5:</u> Leave columns \bigcirc and (d) blank. Enter TOTAL federal costs in column (e) and total nonfederal costs (including third party in-kind contributions and any program income to be used as part of the recipient match) in column (f). Enter the sum of columns (e) and (f) in column (g).

Section B Budget Categories

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

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

Column 5: Enter the total funds required for the program (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 program's total budget falls under a contractual expense, a detailed budget narrative/justification must be provided for each subcontractor or subrecipient. 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; nonfederal cash; and nonfederal in-kind. Cost breakdowns, or justifications, are required for any cost of \$1,000 or more. The Budget Narratives/Justifications should fully explain and justify the costs in each of the major budget items for each of the object class categories, as described below. Nonfederal cash as well as, subcontractor or subrecipient (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.

<u>Line 6a: Personnel:</u> 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 program director, if known. Specify the key staff, their titles, brief summary of program related duties, and the percent of their time commitments to the program in the Budget Narrative/Justification.

Some Points to Consider:

◆Is the basis for determining each employee's compensation described (annual salary and percentage 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

<u>Line 6b: Fringe Benefits:</u> 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?

<u>Line 6c: Travel:</u> Enter total costs of out-of-town travel (travel requiring per diem) for staff of the program. 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 program. For all recipient, "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 program. The equipment must be used for program-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 program ends.

Some Points to Consider:

- •Are equipment items specified by unit and cost?
- ◆Is the request reasonable and allowable under the program?
- •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?

<u>Line 6e: Supplies:</u> 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.). 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 program'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 subcontractor or subrecipient, and separate Budget Narrative/Justification for each subcontractor or subrecipient 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. Subawards are made to entities carrying out part of the program effort, goals and objectives. Subawards 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 program 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 program. 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 subaward and amount of award
- Provide description of activities to be performed
- •Describe method used to select the subaward and type of agreement to be awarded
- •Provide a separate budget and budget narrative for each subaward

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 subcontractors or subrecipients 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.

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

Section C Nonfederal Resources - Not applicable

Section D Forecasted Cash Needs - Not applicable.

Section E Budget Estimate of Federal Funds Needed for Balance of the Program

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

Section F Other Budget Information

<u>Line 22: Indirect Charges:</u> 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.

Appendix D – Budget Narrative/Justification Template (with SAMPLE information)

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

Object Class	Federal	Nonfederal	Nonfederal		
Category	Funds	Cash	In-Kind	TOTAL	Justification
					(.75%) = \$338 Unemployment Insurance (.6%) = \$270
					TOTAL: \$12,600 (\$45,000 * 28%)
					◆Travel to two annual RCE meetings: All Federal funds.
					Airfare: 2 people x 2 trips \$750/per round trip = \$3,000
					Lodging: 2 nights per trip x 2 people x \$100/night x 2 trips = \$800
				• • • • •	Per Diem: 2 days per trip x 2 people x \$40/day x 2 trips = \$320
Travel	\$4,120	\$1,547		\$5,667	Subtotal: \$4,120
					♦Out-of-town site visits. Nonfederal cash.
					Car mileage: 3 trips x 2 people x 350 miles/trip x \$.365/mile = \$767
					Lodging: 3 trips x 2 people x 1 night/trip x \$50/night = \$300
					Per Diem: 3 trips x 2 people x 2days/trip x

Object Class Category	Federal Funds	Nonfederal Cash	Nonfederal In-Kind	TOTAL	Justification
					\$40/day = \$480 Subtotal: \$1,547
					TOTAL: \$5,667
Equipment	0	0	0	0	No equipment requested
Supplies	\$1,340	\$2,160		\$3,500	 Laptop computer for use in client intakes – Federal Funds = \$1,340 Consumable supplies (paper, pens, etc.) – Nonfederal cash \$100/mo x 12 months = \$1,200 Copying – Nonfederal cash \$80/mo x 12 months = \$960
Contractual	\$150,000		\$50,000	\$200,000	\$3,500 Contracts to A,B,C Contractor A to deliver supplies – Federal funds = \$75,000 Contractor B to print materials – Federal funds= \$75,000 Contractor C for logistical support–

Object Class	Federal	Nonfederal	Nonfederal		
Category	Funds	Cash	In-Kind	TOTAL	Justification
					Nonfederal = \$50,000
					TOTAL: \$200,000
					◆Subaward to ABC to conduct training – Federal funds = \$10,000
					 ♦Printing brochures – Federal funds (25,000 @ \$0.05 each) = \$1,250
Other	\$11,250	\$2,000		\$13,250	 ♦Registration fee for annual ABC conference – Nonfederal cash = \$200
					◆Postage – Nonfederal Cash (\$150/mo x 12 months) = \$1,800
					TOTAL \$3,250
					 ♦Rent – Federal funds (\$1,000/mos. x 12 months) = \$12,000
					♦Utilities – Nonfederal cash = \$1,000
Indirect Costs	\$12,000	\$1,000	\$1,000	\$14,000	◆Administrative Support – Nonfederal In-Kind
					100 hours x \$10/hour = \$1,000
					TOTAL \$14,000

Appendix E – Letter of Intent Template

Donald W. Rucker, MD National Coordinator for Health Information Technology Department of Health and Human Services 330 C Street SW Washington, DC 20201

Date

Dear Dr. Rucker,

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

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

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

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

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

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

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

(Provide the following information for the point of contact in the supporting organization).

Name Title Agency Division (if applicable) State Address Phone Fax Number Email