



Special Emphasis Notice (SEN) Applications to (1) Develop Innovative Ways to Evaluate and Improve the Quality of Healthcare Data Used by Artificial Intelligence (AI) Tools in Healthcare and (2) Accelerate Adoption of Health Information Technology in Behavioral Health

Informational Session for SEN Applications Under the Leading Edge Acceleration Projects (LEAP) in Health Information Technology (Health IT) Notice of Funding Opportunity (NOFO)

May 21, 2024

The Office of the National Coordinator for
Health Information Technology



Agenda

- Introduction of Speakers.
- Reminders.
- Background: Leading Edge Acceleration Projects (LEAP) in Health Information Technology (Health IT).
- Special Emphasis Notice for Applications to (1) Develop Innovative Ways to Evaluate and Improve the Quality of Healthcare Data Used by Artificial Intelligence (AI) Tools in Healthcare and (2) Accelerate Adoption of Health Information Technology in Behavioral Health.
- Funding, Eligibility, and Application Information.
- Application Responsiveness and Merit Review Criteria.

Introduction of Speakers

- **Tevon Taylor**
Grants Management Specialist, ONC Procurement and Grants Division
- **Lolita Kachay**
ONC Office of Technology, Strategic Initiatives

Reminders

- This webinar is being recorded and will be made publicly available.
- All participants will be muted during the presentation.
- If you have questions, please enter them into the chat box.
 - Note: All questions will be answered in FAQs made publicly available weekly.
- Webinar and FAQs will be available at <https://www.healthit.gov/topic/onc-funding-opportunities/leading-edge-acceleration-projects-leap-health-information>.

How to Ask a Question

If you have any questions during the presentation, please follow the instructions below.

Use the Chat function to ask a question:

1. Along the bottom of the webinar window, find and click the Chat button.
2. Input your question into the Chat box.
3. Press “Enter” or “Return” to **Send**.



Additional Questions

If you have additional questions after today's webinar session, please direct them to the following email address:

ONC-LEAP@hhs.gov



Background: LEAP in Health IT NOFO

Background: LEAP in Health IT NOFO

LEAP in Health IT seeks to address well-documented and fast-emerging challenges that inhibit the development, use, and/or advancement of well-designed, interoperable health IT.



Background: LEAP in Health IT NOFO

- Applications submitted under this SEN will be funded under the LEAP in Health IT NOFO (NAP-AX-22-001).
- Aside from Areas of Interest, required expertise, and deadlines listed in the SEN, **all other requirements, application instructions, and terms and conditions of NOFO NAP-AX-22-001 apply, with the exception of the applicant capabilities.**

Eligible Applicants

- This is a competitive funding opportunity open to public or nonprofit private institutions—such as a university, college, or faith-based or community-based organization—units of local or State government, eligible agencies of the Federal Government, and Indian/Native American Tribal governments (federally recognized, other than federally recognized, and tribally designated organizations).
- For-profit organizations may participate in projects as members of a consortia or as a subrecipient only. Because the purpose of this NOFO is to improve healthcare in the United States, foreign institutions may participate in projects as members of a consortia or as a subrecipient only. Applications submitted by for-profit organizations or foreign institutions will not be reviewed.
 - Organizations described in section 501(c)4 of the Internal Revenue Code that engage in lobbying activities are not eligible.
- HHS grants policy requires that the grant recipient perform a substantive role in the conduct of the planned project activity and not merely serve as a conduit of funds to another party or parties. If consortium/contractual activities represent a significant portion of the overall project, the applicant shall justify why the applicant organization, rather than the party(s) performing this portion of the overall project, should be the recipient and what substantive role the applicant organization will play.
 - Applicant organizations may submit more than one application, provided that each application is scientifically distinct.

A large, abstract graphic on the left side of the slide, composed of numerous overlapping triangles and polygons in various shades of blue, green, yellow, and orange. The shapes are arranged in a way that creates a sense of depth and movement, resembling a stylized map or a complex data visualization.

SEN for Applications Under the LEAP in Health IT NOFO

Overview

- Two Areas of Interest.
- One award per Area of Interest.
- Up to \$1M per award.
- Period of Performance: 2 years.
- Applicants are encouraged to submit their applications based on a 5-year budget period. Additional funding for Years 3 to 5 may be provided, contingent upon availability of funds, meaningful progress, and ONC priorities.
- Letters of Intent (LOI) due by **May 28, 2024**.
- Applications due by **July 12, 2024**.



FY 2024 Areas of Interest

Area of Interest 1: Develop innovative ways to evaluate and improve the quality of healthcare data used by artificial intelligence (AI) tools in healthcare.

Area of Interest 2: Accelerate adoption of health information technology in behavioral health.

Important Note: Applicants shall clearly state which Area of Interest the proposed project will address. Application packages addressing more than one Area of Interest will not be considered for award.



LEAP SEN FY 2024 – Area of Interest 1

Develop innovative ways to evaluate and improve the quality of healthcare data used by artificial intelligence (AI) tools in healthcare (one award up to \$1 million)

Goal:

Develop scalable solutions that can evaluate and improve the quality of healthcare data available in electronic health records (EHRs) that are used by AI tools. This goal aligns with the intentions of Executive Order 14110 (EO 14110) Safe, Secure, and Trustworthy Development and Use of Artificial Intelligence and ONC's Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing (HTI-1) Final Rule.

LEAP SEN FY 2024 – Area of Interest 1

Key Objectives

- Development of scalable solutions to evaluate and improve the quality of healthcare data available in EHR technologies used by AI tools.
 - Applicants may propose approaches that are targeted for health IT developers, healthcare providers, or both.
- Applicants must identify and explore specific requirements related to EO 14110 and the HTI-1 final rule’s “source attributes” as part of proposing solutions to address this area of interest.
- Applicants will also need to describe ways to scale their proposed solution across the health IT industry.
- Applicants have wide flexibility to propose evaluation and improvement activities related to data quality and AI tools.

LEAP SEN FY 2024 – Area of Interest 1

Applicant Required Expertise

Applicants shall demonstrate familiarity with and understanding of the following:

- EO 14110, the Executive Order on the Safe, Secure, and Trustworthy Development and Use of Artificial Intelligence.
- ONC HTI-1 final rule and specifically the requirements for Predictive DSI.
- Experience evaluating and developing improvement strategies for data quality.
- Experience in developing and deploying AI tools using data derived from EHRs.

Other Requirements:

- To be considered for an award in this Area of Interest, an applicant's proposal shall:
 - Propose at least one activity related to the goal and key objectives of Area 1 and
 - Provide a detailed project plan and explanation of how the applicant intends to meet the goal of this Area of Interest.

LEAP SEN FY 2024 – Area of Interest 2

Accelerate adoption of health information technology in behavioral health (one award up to \$1 million)

Goal:

Support the development of lightweight health information technology (IT) solutions, using open standards, that can enhance health IT capabilities in behavioral health settings with limited technical and financial resources and improve care coordination between behavioral health and clinical healthcare settings.

LEAP SEN FY 2024 – Area of Interest 2

Key Objectives

- Design and develop one or more lightweight application(s), such as SMART on FHIR applications and FHIR-based APIs, to solve a specific behavioral health use case or multiple use cases. The lightweight application must also enable a behavioral healthcare setting to access and integrate health information from other healthcare settings that use ONC-certified health IT.
 - The application must be developed using open FHIR-based APIs. Applicants may also consider the standards adopted in HTI-1 as applicable for the lightweight application to access data from ONC-certified health IT.
- Pilot the application(s) at behavioral healthcare settings to make the application(s) ready for adoption by behavioral health providers.
 - Document approaches used for testing the application(s) at behavioral healthcare settings to make the tool production ready.
- Coordinate input and dialogue with health IT industry and behavioral healthcare community/providers to inform development of the application(s) and share lessons learned and best practices.

LEAP SEN FY 2024 – Area of Interest 2

Applicant Required Expertise

Applicants shall demonstrate familiarity with the following:

- Health IT standards and health IT including content and exchange standards, implementation specifications.
- Behavioral healthcare systems and technology, behavioral healthcare settings, and interoperability gaps and needs.

LEAP SEN FY 2024 – Area of Interest 2

Other Requirements

Applicants for an award in this area of interest shall include the following in their application:

- Provide a detailed project plan and explanation of how the applicant intends to meet the goal and objectives of this Area of Interest. In the project plan, the applicant should:
 - Describe the attributes of the application(s) that make the solution “lightweight” in behavioral healthcare settings, including but not limited to the resources required to maintain and support the application in production, and
 - Identify all the behavioral healthcare settings that the proposed solution is applicable, with preference given to under-resourced providers who have generally lower adoption of health IT, such as residential treatment centers, substance use disorders/detoxification facilities, and outpatient mental health facilities.
- Identify at least one behavioral healthcare clinical use case based on the challenges facing behavioral healthcare providers and provide an explanation on how the applicant plans to build a scalable lightweight tool or resource to solve the problem associated with the use case effectively.
- Identify at least one behavioral healthcare setting and a data exchange partner to test and pilot the tool associated with the use case(s) identified.
- Provide a plan for engaging with the open-source community for long-term sustainability of the tool(s).

A large, abstract graphic composed of overlapping, semi-transparent geometric shapes (triangles, squares, hexagons) in various shades of blue, green, yellow, and orange. The shapes are arranged in a way that creates a sense of depth and movement, with some shapes appearing to be layered on top of others.

Funding, Eligibility, and Application Information

Summary of Key Details

SEN FOR APPLICATIONS UNDER LEAP IN HEALTH IT NOFO

Type of Award	Cooperative Agreement
Available Funding	Up to \$2,000,000
Number of Awards	2 awards
Application Due Date	July 12, 2024
<u>Anticipated Award Date</u>	August 30, 2024
Performance Period	2 years
<u>Anticipated Start Date</u>	August 30, 2024
No. of Awards and Available Funding by Project Topic	Area of Interest 1: One award, up to \$1 million Area of Interest 2: One award, up to \$1 million

Letter of Intent (LOI)

- Applicants are strongly encouraged to submit a non-binding email LOI to apply for this funding opportunity.
- Submit by May 28, 2024, 11:59 p.m. ET.
- Send to ONC-LEAP@hhs.gov.
- Identify:
 - Title: LEAP Special Emphasis Notice (SEN) Applications to Develop Innovative Ways to Evaluate and Improve the Quality of Healthcare Data Used by Artificial Intelligence (AI) Tools in Healthcare and Accelerate Adoption of Health Information Technology in Behavioral Health.
 - Area of Interest (1 or 2).
 - Name of applicant organization.
 - City and State of applicant organization.
 - NOFO No. NAP-AX-22-001.

Application Process

- Applicants must:
 - Submit all material electronically through [Grants.gov](https://www.grants.gov); this process is outlined in the NOFO.
 - Contact the [Grants.gov](https://www.grants.gov) Helpdesk at Support@grants.gov or call at (800) 518-4726 for assistance with submitting applications on [Grants.gov](https://www.grants.gov).
 - Have a Unique Entity Identifier (UEI). UEIs can be obtained via registering at <https://sam.gov/content/entity-registration> and typically takes 7 to 10 business days. Please plan accordingly.
 - Register in the System for Award Management (SAM) at www.sam.gov and use their UEI. The SAM registration process takes 7 to 10 business days so please plan accordingly. If you have already registered with the SAM but have not renewed your registration in the last 12 months, you will need to renew your registration.
 - Ensure that the application meets application requirements and page limits.

Application Components

COMPONENT	LIMIT
Project Abstract	< 500 words
Project Narrative	35 pages
Form SF-424, Application for Federal Assistance	No limit
Form SF-424 A, Budget Information for Non-Construction Programs	No limit
Form SF-424 B, Assurances for Non-Construction Programs	No limit
Form SF-LLL, Disclosure of Lobbying Activities	No limit
Budget Narrative	No limit
Letter of Commitment	No limit

Project Abstract

- The abstract represents a high-level summary of the project that can be understood without reference to other parts of the application and that provides a description of the proposed project, including the project's goal(s), objectives, overall approach, anticipated outcomes, products, and duration.
- Format:
 - No more than 500 words.
 - Project title.
 - Applicant name.
 - Physical address.
 - Contact name.
 - Contact phone numbers (voice, fax).
 - Email address.
 - Website address, if applicable.

Project Narrative

- The project narrative should address the elements articulated in the Areas of Interest section of this NOFO.
- The project narrative should also align with the Performance Goals and Objectives and Merit Review criteria presented in this NOFO.
- Applications that did not follow the outlined format must be reviewed by an ONC Designated Official.
- Format:
 - Double-spaced and no more than 35 pages.
 - Formatted to 8 ½" x 11" (letter size) plain white pages.
 - Either Cambria or Times New Roman font.
 - 1" or larger margins and font size 11 pt. or greater.

Project Narrative (Continued)

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

1. Understanding of Project Purpose (2–3 pages).
2. Proposed Approach and Activities (10–14 pages).
3. Applicant Capabilities (9–15 pages).
4. Budget Narrative (2–3 Pages).

1. Understanding of Project Purpose

- This section should offer the applicant's conceptualization of the selected Area of Interest.
- This should include, from the applicant's perspective, a **specific delineation of the objectives and research challenges** the proposed project will address, specifically distinguishing between challenges that can be addressed in the self-contained project period (2 years) and challenges requiring a longer period (3 to 5 years).
- Applicants shall clearly state which Area of Interest the proposed project will address.

2. Proposed Approach and Activities

- This section should provide a **clear and concise description** of the approach the applicant is proposing to use to conduct the research and development work, including **identifying the major challenges and proposed activities** used in the approach.
- This should be organized so that **each element of the project plan is clear and aligns to the project's key objectives and project goals**.
- The applicant should include the usage of novel concepts, approaches, methodologies, tools, and/or technologies and provide insight as to how their usage will inform the field of health IT.
- The approach should also include proposed strategies on how the results of the project may be disseminated and transitioned to field at large.

2. Proposed Approach and Activities (Continued)

- The approach should include as much details as possible given the page limitation.
- The plan for each activity, at a minimum, shall state the following:
 - Specific aims.
 - Previous work of the investigative team on which the proposed research is directly based.
 - The methods that will be applied, the anticipated outcomes of the work, and their potential significance in addressing the challenges of the selected Area of Interest.
 - The key personnel who will be involved.

3. Applicant Capabilities

- This section should describe the applicant's project team, personnel qualifications, and past performance demonstrating experience consistent with successfully meeting the goals of the cooperative agreement. It is recommended that the project team be composed of, but not limited to, the following roles:
 - Project Director/Principal Investigator (PD/PI).
 - At least one person on the proposed team shall possess health IT expertise.
 - For Area of Interest 1, the proposed research team must have expertise **in the areas outlined in the SEN.**
 - For Area of Interest 2, the proposed research team must have expertise **in the areas outlined in the SEN.**

3a. Plan for Disseminating and Transitioning Appropriate Research Results Into Practice

- This section should include a plan for engaging industry stakeholders to adopt, disseminate, and transition findings from the project into data standards, data infrastructures, health IT products, tools, and best practices.
- Collaborative arrangements with industry and other groups outside of the applicant institution should be accompanied by appropriate letters of support.
- In the event an applicant's solution includes the development of a prototype, the applicant should also submit a plan for approval by ONC, illustrating how the prototype will be made and maintained in a publicly available and acceptable domain at no cost to the general public.

3b. Stakeholder Coordination

- This section should describe plans to establish and operate a technical expert panel of relevant and appropriate stakeholders, including names of members who have committed to join or proposed to join to help inform the work to be conducted on the relevant Area of Interest.

3c. Project Management

- This section should include a clear delineation of the roles and responsibilities of the principal investigator, participating researchers, project staff, consultants, and collaborating organizations and how they will contribute to achieving the research objectives and outcomes.
 - If the application includes subcontractors, plans for coordinating activities across multiple organizations should be described.
 - This section should specify who would have day-to-day responsibilities for key tasks such as leadership of project, monitoring the project's ongoing progress, preparation of reports, and communications with other collaborating organizations and ONC.
 - Recipients will be required to maintain information relevant to executing the proposed project plan and performance-based outcomes.

3c. Project Management (Continued)

- The application should describe the approach that will be used to assess project performance and monitor and track progress toward meeting key objectives.
- The application should include the following:
 - A detailed project timeline as an appendix that incorporates those objectives.
 - An organizational chart as an appendix that reflects roles and responsibilities.

3d. Organizational Capability Statement

- This section should describe the organization's capabilities, qualifications, and approach to address the work to be completed.
- The statement should highlight potential strategies the organization may employ in an effort to sustain research efforts beyond the scope of the project timeframe.
- The statement should include the relevant organizational resources available to perform the proposed project (e.g., facilities, equipment, and other resources).
- Applicants who are working with project counterparts as part of a consortia shall also provide letters of commitment from them.
 - The letters of commitment shall be included with the appendices and will not count toward the 35-page limit.

4. Budget Narrative

- This section should include a detailed breakdown of how the applicant plans to spend the allotted resources to complete the activities detailed in the NOFO:
 - Budget Narrative on how the proposed budget, as articulated in the SF-424A, aligns with the applicant's project narrative.
 - Application for Federal Assistance, Form SF-424.
 - Budget Information for Non-Construction Programs, Form SF-424A.
 - Assurances for Non-Construction Programs, Form SF-424B.
 - Disclosure of Lobbying Activities, Form SF-LLL.
- Detailed budget instructions are provided in the NOFO.

A large, abstract graphic on the left side of the slide, composed of numerous overlapping triangles and polygons in various shades of blue, green, yellow, and orange, creating a complex, multi-dimensional geometric pattern.

Application Responsiveness and Merit Review Criteria

Application Review Process

- Submit all application materials electronically through [Grants.gov](https://www.Grants.gov).
- [Grants.gov](https://www.Grants.gov) issues an email receipt upon successful submission.
- Applications are reviewed for responsiveness and categorized as pass/fail.
- All applications that pass the review for responsiveness are forwarded for merit review.
- Once the merit review is complete, ONC may make an award.
- ONC is not obligated to make an award if none of the applications meet the intent of program requirements or if there is a change in funding levels or availability of funds.

Application Responsiveness Criteria

- All applicants **must** meet the following completeness criteria or they will be administratively eliminated and not sent forward for merit review:
 - The applicant meets the eligibility criteria.
 - The application is received by the deadline of Friday, July 12, 2024, at 12:00 p.m. ET through <https://grants.gov/>.
 - The application contains all required components (e.g., Project Narrative, SF-424, etc.).
 - The application meets all formatting and length requirements.
 - Appendices and attachments are not used as a mechanism to exceed page limits of the Project Narrative.

Merit Review Criteria

- Responsive applications are forwarded for merit review.
- Merit reviews will be conducted by a review panel of at least three experts in their field from academic institutions, nonprofits, and local and Federal Government agencies.
- Applications can receive a maximum of 100 points, using the following scale:

MERIT REVIEW CRITERIA	POINTS
Understanding of Project Purpose	10
Proposed Approach and Activities	40
Applicant Capabilities	30
Budget Narrative	20
Total	100

Merit Review Criteria: Understanding of Project Purpose (10 Points)

- The extent to which the application addresses the objectives and project goals of this NOFO.
- The extent to which the application identifies a project plan and activities that align with one of the two identified Areas of Interest within the NOFO.
- The extent to which the application identifies barriers and ways to mitigate those barriers with one of the two identified Areas of Interest within the NOFO.
- The extent to which the applicant describes how the project, expected outcomes, and results will inform future health IT development, research, and implementation.

Merit Review Criteria: Approach and Activities (40 Points)

- The extent to which the approach, design, methods, and analyses are specifically stated, adequately developed, well-integrated, well-reasoned, and appropriate to the project goals/key objectives of the Area of Interest. **(20 points)**.
- The extent to which the applicant proposes a clear and detailed plan for disseminating and transitioning appropriate research results into practice. This section of the application should include a plan for engaging industry stakeholders to adopt, disseminate, and transition findings from the project to stakeholders who will continue to advance the work. **(15 points)**.
- The extent to which the plan describes a project management approach for ensuring project success **(5 points)**.

Merit Review Criteria: Applicant Capabilities (30 Points)

- The extent to which the applicant identifies all the resources necessary to perform the proposed work and outline strategies to complete this work within a 2-year timeframe **(5 points)**.
- The extent to which the scientific environment(s) in which the work will be done contributes to the probability of success, employs useful collaborative arrangements, and has evidence of institutional support **(5 points)**.
- The extent to which the project proposal integrates and provides an appropriate level of research and technical knowledge and subject matter expertise **(20 points)**.

Merit Review Criteria: Budget Narrative (20 Points)

- Does the application provide the proposed levels of effort of the project team and consultants (if needed) and describe how they are adequate and appropriate to advance the project in accordance with the project plan?
- Does the application include an explanation of how the proposed budget supports the project and is cost-efficient and reasonable for meeting the project activities?

Questions

- All questions must be submitted in writing either via the Chat during this Webinar or emailed to ONC-LEAP@hhs.gov.
 - Questions submitted today in the Chat will not be answered today.
- All questions will be answered in the form of an FAQ and made publicly available each Monday at <https://www.healthit.gov/topic/onc-funding-opportunities/leading-edge-acceleration-projects-leap-health-information>.

Q&As

- Thank you for attending!
- We will remain online for 5 minutes—please submit any remaining questions via the Chat on this webinar page.
- To see the NOFO on [Grants.gov](https://grants.gov) or to apply, go to <https://grants.gov/search-results-detail/341131>.
- For assistance with submitting applications in [Grants.gov](https://grants.gov), please contact the [Grants.gov](https://grants.gov) Helpdesk at Support@grants.gov or call (800) 518-4726.

Please submit your questions.

5 Minutes Remaining

Please submit your questions.

3 Minutes Remaining

Please submit your questions.

1 Minute Remaining

LEAP SEN FY 2024

Dates to Remember:

- Release Date: May 13, 2024.
- Informational Session: May 21, 2024.
- Letter of Intent (LOI): May 28, 2024.
- Application Deadline: July 12, 2024.
- Anticipated Award Date: August 30, 2024.



**The moderator will now
end this session.**

Thank you for attending.