



Leading Edge Acceleration Projects (LEAP) in Health Information Technology

Leading Edge Acceleration Projects (LEAP) in Health Information Technology
Notice of Funding Opportunity (NOFO) Information Session

Tuesday, June 28, 2022; 1:00 p.m. – 2:00 p.m. ET

The Office of the National Coordinator for
Health Information Technology



Agenda

- Introduction of Speakers
- Housekeeping
- Notice of Funding Opportunity (NOFO)
- Background: Leading Edge Acceleration Projects (LEAP) in Health Information Technology (Health IT)
- Funding, Eligibility, and Application Information
- Application Responsiveness and Merit Review Criteria

Introduction of Speakers

- **Yolonda Thompson**
Grants Management Specialist, ONC Procurement and Grants Division
- **Wei Chang**
Public Health Analyst, ONC Technical Strategy and Analysis Division
- **Stephanie Garcia**
Scientific Advancement Branch Chief, ONC Technical Strategy and Analysis Division
- **Jewel Love**
Moderator
ONC Procurement and Grants Division (Contractor)

Housekeeping

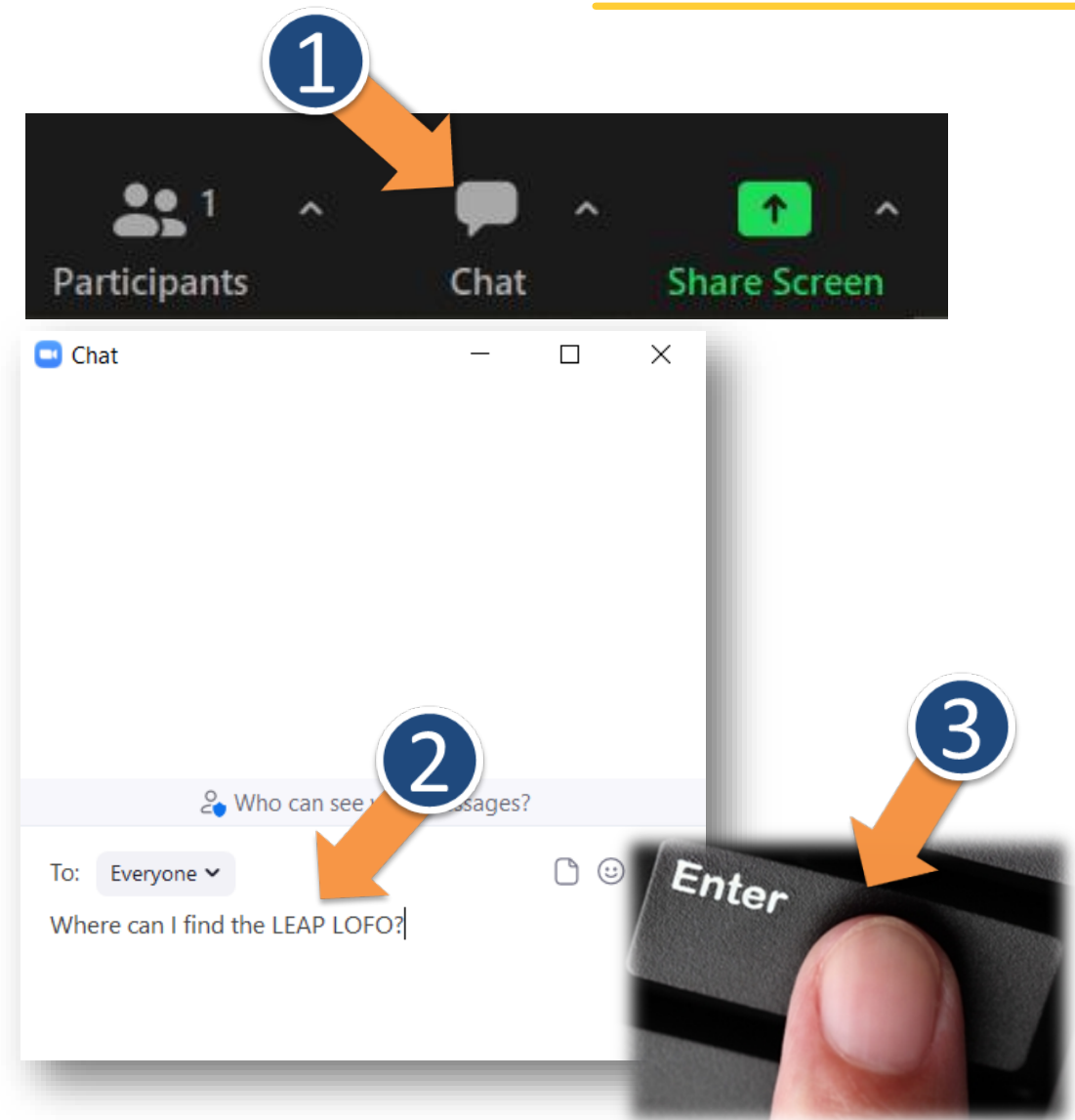
- This webinar is being recorded and will be made publicly available
- All phone lines will be muted during the presentation
- If you have questions, please enter them into the chat box
 - Note: All questions will be answered in FAQs made publicly available weekly
- Webinar and FAQs will be available 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



LEAP in Health IT Notice of Funding Opportunity (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 five-year budget period. Additional funding for years three to five may be provided, contingent upon availability of funds, meaningful progress, and ONC priorities.
- Letters of Intent (LOI) due by **June 30, 2022**
- Applications due by **August 15, 2022**



FY 2022 Areas of Interest

Area of Interest 1: Address health equity and social determinants of health (SDOH) through innovative, open-source technology tools, and electronic health records

Area of Interest 2: Demonstrate the use of equity-enhancing patient-generated health data (PGHD) for clinical care and research

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 NOFO FY 2022 – Area of Interest 1

Address health equity and social determinants of health (SDOH) through innovative, open-source technology tools, and electronic health records (one award up to \$1 million)

Goal: Advance the adoption and use of SDOH-related standards and data in underserved populations to address disparities, and to identify the challenges and opportunities inherent in scaling health IT solutions across communities.

LEAP NOFO FY 2022 – Area of Interest 1

Key Objectives

- Create specific use cases for the technology platform based on high-risk population factors like chronic diseases (which may include, but are not limited to, heart disease, hypertension, and cancer) and/or social risk factors (which may include, but are not limited to housing instability, food insecurity, and transportation insecurity) in underserved communities. While creating the use cases, the applicant must use standardized SDOH data collected within the EHR.
- Create and implement non-proprietary technical solutions for referring patients to CBOs that interface seamlessly with a health system or community health center's EHR.
- Create and implement technology that supports patient engagement, and at a minimum allows patients to manage their data by suggesting edits to their SDOH data and provide consent and authorization to use sensitive data.
- Coordinate forums to share implementation strategies, lessons learned, and recommendations with other healthcare providers and CBOs.¹ Forums may include, but are not limited to, workshops, webinars, and documents.

¹ <https://www.phe.gov/Preparedness/planning/abc/Pages/engaging-CBO.aspx>

LEAP NOFO FY 2022 – Area of Interest 1

Applicant Required Expertise

- Data standards development and balloting
- API development and EHR integration

Other Requirements:

- To be considered for an award in this Area of Interest, an applicant's proposal shall include a collaborative team of key stakeholders who will be directly involved in the project, which we refer to as the coalition.
- An applicant's proposal shall not rely on proprietary technology for apps or web portals. The proposed technical solution for this Area of Interest should leverage previous work funded by ONC (such as, but not limited to [ONC LEAP projects](#), [the Gravity Project](#), 360X) and not duplicate efforts.

LEAP NOFO FY 2022 – Area of Interest 2

Demonstrate the use of equity-enhancing patient-generated health data (PGHD) for clinical care and research (one award up to \$1 million)

Goal: Develop the infrastructure and standards-based PGHD technologies needed to demonstrate the scalable use of equity enhancing patient-generated health data for clinical care and research from the point of care to the researcher. The proposed PGHD technology solution can be comprised of apps, remote monitoring devices, or wearable technology that collect data to monitor and track health outside of the clinical care setting.

LEAP NOFO FY 2022 – Area of Interest 2

Key Objectives

- Perform a landscape analysis/environmental scan to understand the current standards and interoperability of PGHD technologies related to the proposed PGHD technology solution (such as across device manufacturers and different EHRs).
- Per the above landscape analysis/environmental scan, identify at least two separate healthcare locations and at least two use cases around clinical care and research that require PGHD and incorporate the needs of underserved communities.
- Create and develop plans for at least two demonstration projects with consideration on reuse and scalability of the proposed PGHD technology solution. To result in two demonstration projects, the proposed PGHD technology solution should be implemented at two separate healthcare locations affiliated with the awardee, and the proposed PGHD technology solution should be implemented for two different use cases (e.g. high blood pressure and respiratory diseases) that use the same underlying technology. This will show how the solution can be reused.
- Convene a coalition of key stakeholders (e.g. clinicians, researchers, technical experts, and/or patients) that will be directly involved in the development and implementation of the demonstration projects.

LEAP NOFO FY 2022 – Area of Interest 2

Key Objectives – Continued

- Engage standards development organizations (SDOs) to identify opportunities and practical solutions for the advancement of standards that are necessary to capture, exchange, integrate, and use PGHD in clinical and research settings. This includes leveraging and testing existing standards for the proposed PGHD technology solution and can also include balloting and updating implementation guides with information resulting from the demonstration projects.
- Develop the proposed PGHD technology solution (incorporating standards-based solutions) that collects and shares PGHD among patients, providers, and researchers.
- Prepare a final report that includes lessons learned and recommendations that provide experiential insights for others who wish to implement similar types of PGHD technology solutions at their organizations.
- Develop at least one manuscript that details the demonstration project results and submit to appropriate journal.

LEAP NOFO FY 2022 – Area of Interest 2

Applicant Required Expertise

- Demonstrate the use of equity-enhancing patient-generated health data for clinical care and research
- Demonstrate expertise in the following areas:
 - User-centered design
 - Workflow design
 - Data visualization
 - Cognitive support

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 NOFO 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 NOFO, **all other requirements, application instructions, and terms and conditions of NOFO NAP-AX-22-001 apply**

Eligible Applicants

- This is a competitive funding opportunity open to public or non-profit private institutions, such as a university, college, or a faith-based or community-based organization; units of local or state government, eligible agencies of the federal government, 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 sub-recipient 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 sub-recipient 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.

Project Activities

- Define a project plan that will include all key objectives.
- Document and report progress throughout the project timeframe.
- Utilize research methods to inform the demonstration projects.
- Publish (e.g., manuscript, report, blog post, and white paper) and disseminate project findings in a way that translates project outcomes into useable knowledge and insights for federal partners, health IT industry, SDOs, CBOs, developers, healthcare systems, and providers to maximize the accessibility of this knowledge to the entire health IT community.
- Select measurable outcomes that are specific to the project's Area of Interest and key objectives.
- Conduct virtual mid-point demonstrations and provide an update regarding any proposed approaches, prototype(s), and/or revisions to the project plan to illustrate their progress on the Area of Interest.

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.

Funding, Eligibility, and Application Information

Summary of Key Details

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	August 15, 2022
<u>Anticipated Award Date</u>	September 26, 2022
Performance Period	2 years
<u>Anticipated Start Date</u>	September 26, 2022
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 e-mail letter of intent to apply for this funding opportunity.
- Submit by June 30, 2022, 11:59 p.m. ET
- Send to: ONC-LEAP@hhs.gov
- Identify:
 - Title: LEAP FY 2022 NOFO
 - 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.
 - For assistance with submitting applications on [Grants.gov](https://www.grants.gov), please contact the [Grants.gov](https://www.grants.gov) Helpdesk at support@grants.gov or call at (800) 518-4726.
 - Have a Unique Entity Identifier (UEI). UEI can be obtained via registering at <http://fedgov.dnb.com/webformSAM.gov> 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 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 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 (two years) and challenges requiring a longer period (three to five years).
- Applicants shall clearly state which Area of Interest the proposed project will address.

2. Proposed Approach and Activities

- 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.
- 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 (continued)

- The approach should include as much details as possible given the page limitation.
- The plan for each activity, at a minimum, shall state
 - 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 comprised of, but is 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 outline in the NOFO**
 - For Area of Interest 2, the proposed research team must have expertise **in the areas outline in the NOFO**

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 include 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 on-going 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:
 - 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

- 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.
 - 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 towards 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.



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 Monday, August 15, 2022 at 12:00 noon ET through <http://www.grants.gov>
 - The application contains all required components (e.g., Program 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 review 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 two-year time frame. **(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 be 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://www.grants.gov) or to apply, go to <https://www.grants.gov/web/grants/search-grants.html?keywords=nap-ax-22-001>
- For assistance with submitting applications in [Grants.gov](https://www.grants.gov), please contact the [Grants.gov](https://www.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 NOFO FY 2022

Dates to remember:

- Release Date: June 14 , 2022
- Informational Session: June 28, 2022
- Letter of Intent (LOI): June 30, 2022
- Application Deadline: August 15, 2022
- Anticipated Award Date: September 26, 2022



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

Thank you for attending.