ONC Announces Interest in Applications to Address Standardization of Patient Information for Seamless Access, Exchange, and Use

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Key Dates
Release Date: March 11, 2019
Expiration Date: May 28, 2019

Issued by
Office of the National Coordinator for Health Information Technology (ONC)

Purpose

This Notice announces ONC's interest in funding projects under the Leading Edge Acceleration Projects (LEAP) in Health Information Technology (IT) funding opportunity (see NAP-AX-18-003 at https://www.grants.gov/web/grants/view-opportunity.html?oppId=306704) in fiscal year 2019 to address standardization of patient information for seamless access, exchange, and use.

Areas of Interest

The Office of the National Coordinator for Health Information Technology (ONC) is the principal federal entity charged with coordination of nationwide efforts to implement and use the most advanced health information technology (IT) and the electronic exchange of health information. Created in 2004, through Executive Order 13335[1] and legislatively mandated in the Health Information Technology for Economic and Clinical Health Act (HITECH Act) of 2009,[2] ONC is at the forefront of the federal government's health IT efforts and is a resource to the entire health system to support the adoption of health IT and the promotion of nationwide health information exchange to improve health care.

The goal of the LEAP in Health IT funding opportunity is to address well-documented and fast emerging challenges inhibiting the development, use, and/or advancement of well-designed, interoperable health IT, which is scalable across the health care industry. Solutions are expected to further a new generation of health IT research and inform the development, implementation, and refinement of standards, methods, and techniques for overcoming major barriers and challenges in an innovative fashion as they are identified.

It is critical that the field of health care innovate and leverage the latest technological advancements and breakthroughs far quicker than it currently does to optimize real-time solutions, especially in areas which are ripe for acceleration.

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[1] https://www.govinfo.gov/content/pkg/WCPD-2004-05-03/pdf/WCPD-2004-05-03-Pg702.pdf
[2] https://www.healthit.gov/sites/default/files/hitech_act_excerpt_from_arra_with_index.pdf

In fiscal year 2019, ONC is particularly interested in applications whose specific aims addresses one of the following areas of interest:

- **Area 1:** Standardization and Implementation of Scalable Health Level 7 International's (HL7®) Fast Healthcare Interoperability Resources (FHIR®) Consent Resource[3]
- **Area 2:** Design, Develop, and Demonstrate Enhanced Patient Engagement Technologies for Care and Research

ONC anticipates issuing one award per area of interest (for a total of 2 awards), up to $1 million per award (for a total of up to $2 million in funding in fiscal year 2019). Please note that all applicants must explicitly state which area of interest they are applying for.

Area 1: Standardization and Implementation of Scalable HL7® FHIR® Consent Resource

One of the most significant ONC responsibilities is to implement provisions in Title IV of the 21st Century Cures Act, Pub.L. 114-255 (Cures Act).[4] The Cures Act promotes the use of application programming interfaces (APIs) to support patients' secure and seamless access to their health information and facilitate patients using mobile applications (apps) to access their electronic health information (EHI) at home or their doctor's office. However, APIs built without standards force developers to develop unique solutions for each health care provider or electronic health record (EHR) product, which in turn makes it difficult to achieve seamless interoperability.

On March 4, 2019, the ONC Cures Act Notice of Proposed Rulemaking (NPRM)[5] was released, which intends to advance and support seamless and secure access to, exchange of, and use of EHI, particularly through apps. The FHIR® standard[6] has emerged as a clear choice for EHR developers as the marketplace moves towards providing patients and their health care providers safe and secure access to health information and new tools.

As patients and consumers obtain access to their health data stored in different provider databases, they will be able to gain insights into their own health and wellbeing to prevent and manage illness. Additionally, they will be able to combine them in a single app, or share their data with other providers as they manage the rising costs of health care.

While we do not know exactly what a secure, standardized API future will bring, we anticipate that patients will demand much more control over how their data are shared with apps, providers, and payers, based on their own choices and market competition.

The FHIR® standard has established the Consent Resource to record the health care consumer's choices in a computationally tractable manner. It is used to express written or verbal agreements

[3] http://hl7.org/fhir/R4/consent.html
[4] https://www.congress.gov/114/plaws/publ255/PLAW-114publ255.pdf
[5] https://healthit.gov/nprm

[6] http://hl7.org/fhir/R4/

that authorize or restrict actions based on purpose of use, and provide handling instructions to which a recipient of the patient's health information must comply.

The FHIR® Consent Resource has been developed to address the following use cases:

- **Privacy Consent Directive:** Agreement to collect, access, use, or disclosure (sharing) of information
- **Medical Treatment Consent Directive:** Consent to undergo a specific treatment (or record of refusal to consent)
- **Research Consent Directive:** Consent to participate in research protocol and information sharing required
- **Advance Care Directives:** Consent to instructions for potentially needed medical treatment (e.g, DNR)

While the Consent Resource along with the "Security and Privacy" module within the FHIR® standard are envisioned to support the use cases specified above, there has not yet been a focused investigation to determine if they are appropriately designed to meet consumer needs.

The goal of this area of interest is for the recipient to perform this deep investigation of the current capabilities of the FHIR® standard, and provide the necessary guidance for industry to implement the standard in a scalable manner.

More specifically, the recipient will:

- Familiarize itself with the current state of standards and industry approaches, assess the current limitations of existing approaches and the pros and cons of the alternatives currently being considered
- Implement all the use cases specified above using FHIR® Consent Resource and document any limitations of using the Consent Resource
- Identify and update the FHIR® Consent Resource based on the implementation results
- Identify and document the use of any additional parts of the FHIR® standard, required for successful implementation of use cases, including, but not limited to:
    - FHIR® Security and Privacy Modules[7]
    - FHIR® Contract Resource[8]
    - FHIR® Provenance Resource[9]
- Develop working prototypes accessible to the general public
- Provide additional insight to support successful adoption of the FHIR® Consent Resource standard by industry

For successful consideration in this area of interest, applicants must also be able to demonstrate expertise in the following:

- Current privacy and consent regulations at the federal and state level

[7] http://hl7.org/fhir/R4/secpriv-module.html
[8] http://hl7.org/fhir/R4/contract.html
[9] http://hl7.org/fhir/R4/provenance.html

- Consent management
- FHIR® standard
- Balloting of standards in HL7® Standards Development Organization
- Use of FHIR® standard-based API in apps

Area 2: Design, Develop, and Demonstrate Enhanced Patient Engagement Technologies for Care and Research

For decades, clinicians and researchers have worked to improve patient outcomes and reduce costs through the use of tools meant to engage patients beyond clinical walls. More recently, health IT has been a significant driver in this space, via patient engagement technologies including, but not limited to patient portals[10] and secure messaging platforms.[11] These tools allow patients to engage with their health care data electronically,[12] and communicate with providers while demonstrating improved outcomes and reduced costs.[13] The HITECH Act and Cures Act requirements represent a watershed moment for the increased adoption and implementation of such tools for patients and caregivers to manage their and other's health.

Simultaneously, rapid growth of mobile technologies and wearables, and adoption of APIs – a technology that allows one software app to directly access the services provided by another software app – are driving a new generation of patient engagement technologies and possibilities. The ensuing proposed rule[5] to support seamless and secure access, exchange, and use of EHI will only add fuel to these efforts.[14-15] Yet, there is still much to learn about delivering and presenting information to patients, reinforcing positive feedback loops, all while transporting knowledge and emergent data types[16] to and from clinical and non-clinical settings, in addition to supporting research.

Leveraging engagement tools for research presents a unique and exciting opportunity to involve patients and facilitate contribution from many populations, especially those that are underserved and underrepresented. The National Institutes of Health's (NIH) *All of Us* Research Program,[17] the cornerstone of the Precision Medicine Initiative, is actively working towards enabling a new period of medicine through research, technology, and policies that empower patients, researchers, and providers to work together toward development of individualized care. Specifically, *All of Us* is leveraging Sync for Science[18] (S4S) to promote patient-mediated data access and sharing. S4S uses the FHIR® specification as the basis for data exchange. S4S's goal is to standardize an easier way for patients to share medical records with researchers through a secure, standardized API. S4S and the underlying standards can be utilized far beyond *All of Us*, and the market has taken notice.[19]

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[10] https://www.healthit.gov/faq/what-patient-portal
[11] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6334683/
[12] https://www.gao.gov/assets/690/683388.pdf
[13] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4376181/
[14] https://docs.house.gov/billsthisweek/20161128/CPRT-114-HPRT-RU00-SAHR34.pdf
[15] https://www.healthaffairs.org/do/10.1377/hblog20180618.138568/full/
[16] https://academic.oup.com/jamia/article/25/6/759/4869761?searchresult=1
[17] https://allofus.nih.gov/
[18] http://syncfor.science/
[19] https://developer.apple.com/documentation/healthkit/samples/accessing_health_records

Currently, the design and functionality of patient engagement technologies vary greatly in their purpose and ease of use, which may explain slower than expected adoption and usage by patients, especially those most likely to benefit.[20] Complicating matters, as seen with patients need to sign up for and use multiple portals, the expected number of newer technologies being rushed to market could overwhelm patients, and be underwhelming in function. Due to the sheer pace of these changing technologies, there is an opportunity to demonstrate solutions to help the field keep pace and utilize consistent standards and processes. How well these technologies reach their intended audience and perform in a seamless and ubiquitous manner will rely on a variety of factors such as navigating complex privacy policies, incorporating user-centered design and data standards, as well as harmonizing disparate health data.

There is an expectation that future engagement technologies coupled with sophisticated algorithms will improve outcomes, while propelling new waves of research leading to evidence and knowledge to be shared back with participants. However, leading and informing the field of best practices around designing, developing and implementing a new spectrum of engagement technologies will be essential in ensuring products achieve the lofty expectations of a 21st century care system.

This area of interest seeks to transform patient engagement technologies for a 21st century care system through innovative design, development, and demonstrations. Applicants will explore approaches for state-of-the-art engagement solutions that:

- Modernize patient engagement tools;
- Engage diverse populations, including the underserved;
- Enhance opportunities for underrepresented populations to participate in research;
    - Leverage standards to develop a common centralized patient profile for research
    - Integrate unique ID and e-consent management platforms
- Address security and privacy concerns;
- Utilize user-centered design principles;
- Allow for data transport from various devices (sharable in machine-readable format and directed by the patient);
- Support secure cross-system communication with researchers and/or clinicians; and
- Support the return of information to individual research participants.

For successful consideration in this area of interest, applicants must also be able to demonstrate expertise in the following:

- User-Centered Design
- Data Visualization
- Cognitive Support
- Health Literacy
- Patient and Family Engagement

[20] https://www.gao.gov/assets/690/683388.pdf

Further Guidance

Use of Funding Mechanism. ONC will use the existing Leading Edge Acceleration Projects (LEAP) in Health Information Technology Notice of Funding Opportunity (NOFO) to support applications submitted in response to this Notice. This NOFO, NAP-AX-18-003 can be found at https://www.healthit.gov/topic/onc-funding-opportunities/leading-edge-acceleration-projects-leap-health-information or https://www.grants.gov/web/grants/view-opportunity.html?oppId=306704. Outside of the Area of Interests and updated dates described in this Special Emphasis Notice, all other requirements, application instructions, and terms and conditions of NOFO NAP-AX-18-003 apply.

Limitations on Timelines and Funds. ONC currently limits the total (direct plus indirect) costs for these applications to no more than $1,000,000 for the entire project period. The project period can be up to two years.

Application Submission and Special Application Receipt Date. Information about the application process can be found at https://www.healthit.gov/topic/onc-funding-opportunities/leading-edge-acceleration-projects-leap-health-information or https://www.grants.gov/web/grants/view-opportunity.html?oppId=306704.

An Informational Session will be held on April 2, 2019. Further details about the informational session – including the date, time, and instructions for joining – are available at: https://www.healthit.gov/topic/onc-funding-opportunities/leading-edge-acceleration-projects-leap-notice-fundingopportunity.

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. When submitting your letter of intent, please identify which area of interest your organization plans to apply for. The letter of intent is requested by 11:59 P.M. Eastern Standard Time on April 11, 2019, and should be sent to ONC-LEAP@hhs.gov. The letter 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.

Applications focused on areas identified in this Notice must be submitted by **11:59 P.M. Eastern Standard Time on May 28, 2019. This Notice will expire on May 28, 2019.**

Inquiries

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