

**Requests for OMB Review and Approval For  
Office of the National Coordinator for Health Information  
Technology  
National Survey of Health Information Exchange Organizations**

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**Supporting Statement for  
Office of the National Coordinator for Health Information  
Technology  
National Survey of Health Information Exchange Organizations**

**A. Justification**

**1. Circumstances Making the Collection of Information Necessary**

The Office of the National Coordinator for Health Information Technology is seeking the approval for a reinstatement with change to collection the “National Survey of Health Information Exchange Organizations (HIO)”, OMB No. 0955-0019 Exp 05/30/2022.

Electronic health information exchange (HIE) was one of three goals specified by Congress in the 2009 Health Information Technology for Economic and Clinical Health (HITECH) Act to ensure that the \$30 billion federal investment in certified electronic health records (CEHRTs) resulted in higher-quality, lower-cost care. In subsequent rulemaking and regulations, ensuring that providers can share data electronically across EHRs and other health information systems has been a top priority. The [State HIE program](#) supported states to engage state, regional and local health information exchange organizations to develop governance, policies, technical services, business operations, and financing mechanisms for HIE during the performance period (which ended in 2014). Health information exchange organizations facilitate electronic exchange of health information across disparate providers, labs, pharmacies, public health departments, health plans and other stakeholders. [Evaluations of the State HIE program](#) indicated variability across states in the abilities of organizations enabling HIE (and in particular, health information organizations – HIOs) to support exchange within their respective states, though progress was made overall.

Beginning prior to HITECH, there has been substantial ongoing assessment of trends in the capabilities of health information organizations to support clinical exchange. These surveys have collected data on organizational structure, financial viability, geographic coverage, scope of services, scope of participants, perceptions of information blocking, and participation in national networks and TEFCA. While past surveys assessed HIOs’ capacity to support HIE in a variety of ways, they did not closely examine how HIOs support public health exchange. Each of these areas of data collection will be useful to constructing a current and more comprehensive picture of HIOs’ role in addressing public health emergencies.

The most recently conducted survey, in 2019, was funded by ONC (OMB # 0955-0019). The 2019 national HIO survey sought to assess the existing capabilities, and examine the evolution, of these organizations. However, the pandemic has created an urgent need to

capture measures of current exchange capabilities among HIOs and to ask new, targeted questions specifically about health information exchange relevant to COVID-19 and public health reporting more broadly. The revised survey will therefore report on the capacity of these organizations to aid in specifically supporting response to the COVID-19 pandemic and future public health emergencies. The survey will also determine how HIOs capture demographic data so that ONC can assist in addressing disparities that were exasperated by the pandemic.

We have revised the survey to better understand the role of HIOs in supporting public health reporting and response to the pandemic. HIOs, given their unique role in convening data across stakeholders in their region, may be able to support linking data from disparate sources together to help monitor the use of strategies to prevent and treat COVID-19. HIEs may also be able to leverage clinical and demographic data they have access to with other data to monitoring community/state-level vaccination rates, transmission rates and breakthrough infection rates among subpopulations (e.g., immunocompromised), along with supporting providers meeting public health reporting requirements via electronic means (rather than paper-based).

The newly revised survey will provide insights that will help us determine the extent to which HIOs are positioned to meet COVID-19 and other public health information sharing needs. The survey assesses the geographic coverage of HIOs, HIOs engagement with federal, state and local public health entities; and their capabilities to support public health reporting and exchange of information. Barriers HIOs have encountered in providing these capabilities to frontline clinicians and public health agencies is also measured. Today there is no data source that comprehensively measures the status of these critical capabilities across HIOs.

There is an array of policy efforts that are primed to leverage the results from the survey. For example, ONC's Health IT Advisory Committee Public Health Data Systems Task Force is working to address issues with data exchange between public health data systems and clinical data sources. The task force has recommended key data types to be updated to use published standards and implementation guides and that the deployment of these prioritize demographic and social determinants of health. The HIO survey results will help inform prioritization and selection of data types and standards. Furthermore, the CARES Act's STAR HIE Program has dedicated \$5 million to improve the capacity of a select set of HIOs to support public health agencies' response to public health emergencies and pandemics. In January 2021, the STAR HIE Program expanded to provide additional awards to amplify immunization information sharing collaboration. Initial investments seek to guide us on how to best support vaccine-related efforts. The HIO survey results will identify how progress made under the STAR HIE Program can be best leveraged to enhance public health related HIE for HIOs across the country. To guide these efforts, it is critical to assess the current state of HIOs, which are uniquely positioned to expand to meet public health information sharing needs.

Beyond examining these critical capabilities specific to supporting public health exchange, it is necessary to understand the broader picture of HIO capabilities as well as maturity and challenges. There are four key areas that require this broader assessment: (1) adoption of technical standards; (2) perceptions related to information blocking; (3) HIE coordination at the federal level; and (4) organizational demographics, including technical capabilities offered by HIOs and the challenges they face in supporting electronic health information exchange.

First, in the domain of technical standards for transporting and codifying health information, ensuring that HIOs adopt and conform to standards is critical to enable the sharing of information across systems and to ensure that information can be easily integrated once received. There are often multiple standards available to accomplish the same HIE use case and, even when the same standard is selected, there is often ambiguity and optionality in the implementation guide that result in poor standards conformance. Unfortunately, when implementing standards, there is little room for flexibility and even one small difference in how a standard is implemented results in failure. It is therefore critical to assess not only which standards are being implemented but the extent to which implementations use the same implementation guide and where there are gaps in conformance. Such assessment is necessary to inform policy and private-sector efforts to promote better coordination among stakeholders on standards selection and conformance. Specifically relevant to COVID-19, it is critical to assess which standards are in use for tracking lab test results. Standards used to encode laboratory test results can be difficult to implement though ultimately coded results would be helpful to public health reporting and surveillance. Examining the extent to which HIEs have these data encoded and the barriers associated with this process would be informative to ONC's efforts related to enabling lab interoperability. Collecting data on standards from HIOs provides important new information on both HIO activities and how HIOs are responding to standards development and implementation approaches by CEHRT developers and other HIE vendors. ONC currently has a cooperative agreement with a standards development organization that is responsible for the laboratory results. Thus, the results from this survey could help inform future standards development.

Second, recently implemented federal regulations prohibiting information blocking should result in more engagement in HIE and more rapid growth of HIOs. HIOs offer a key source of data to inform an understanding of whether this is happening and the extent to which different forms of information blocking may be persisting, among CEHRT developers and among provider organizations. Information blocking findings from the 2019 HIO survey helped establish baseline levels prior to enforcement of the new rules. Results showed that over half of HIOs reported that some, most, or all EHR developers engage in information blocking. In terms of frequency, the majority of HIOs also indicated that EHR vendors sometimes, often, or routinely engage in information blocking. The most common type of information blocking behavior EHR vendors engaged in was setting unreasonably high prices, which 42% of HIOs reported routinely observing. [These findings](#) on how and when information blocking occurs informed implementation of the 21<sup>st</sup> Century Cures Act and have potential to inform future policy

initiatives. In addition to assessing the early impact of the new rules, understanding the current state of information blocking will help reveal whether the pandemic shifted some of the related barriers to HIE, such as competition as an inhibitor to information sharing.

Third, it is important to assess approaches to HIE coordination at the federal level. As the number of HIE networks has grown from just a handful of local HIOs a decade ago to more than 100 disparate networks at local, regional, and national levels, the result is that healthcare providers have to use a variety of different networks and methods to exchange health information, increasing the complexity and costs of health information exchange. New approaches to HIE in response to the pandemic could worsen the already fragmented HIE landscape. Current efforts, notably the Trusted Exchange Framework and Common Agreement (TEFCA), seek to better coordinate varied approaches to HIE. The goal of TEFCA is to have a single “on ramp” to nationwide connectivity. Since participation in TEFCA is voluntary, it is critical to assess how HIOs anticipate participating in TEFCA, and their engagement in related activities such as connecting to each other, in order to gain insight into progress towards nationwide connectivity under TEFCA. A recently published goal is to have the TEFCA operational in 2022. This timeline was accelerated given that the exchange of patient health information is even more important now given the acute need for public health data exchange across geographical regions.

Fourth, it is important to assess the overall capabilities offered by HIOs and to assess the challenges they face. With many options available for how providers, public health agencies, labs, and other key healthcare stakeholders can engage in HIE, and a growing number of newer approaches scaling rapidly, it is critical to track how HIOs are positioning themselves. Thus, collecting the latest data on HIO services, sustainability, and related issues such as governance and use cases, will provide important insights into the evolution of our national HIE infrastructure. In turn, this will reveal gaps and areas that require renewed policy attention. Collecting current data on HIO sustainability will also reveal whether these efforts are continuing the trend that began in 2015 of aligning their value proposition with new models of care delivery and payment. That is, with the rise of alternative HIE approaches (particularly those provided by EHR vendors), HIOs may no longer be able to sustain themselves by only supporting simple HIE transactions that move data across organizations. Instead, they may need to demonstrate added value through functionalities and analytics that support health system transformation efforts (e.g., ADT notifications, PDMP integration and alerting, quality reporting, MIPS). Understanding the specific approaches to sustainability pursued by HIOs today in the context of support for delivery system reform efforts will speak not only to their viability but also to the infrastructure to support broader health policy and public health goals.

The timely collection of national data from our survey will assess current capabilities to support effective electronic information sharing within our healthcare system related to COVID-19 and other public health relevant data. Further, data collected in other areas, such as on information blocking behaviors, create the needed early assessment of the impact of policies that recently went into effect to increase the flow of information across

the healthcare system. The HIO survey results will inform potential modifications to the rules and related activities.

## **2. Purpose and Use of Information Collection**

The ultimate goal of this project is to generate the most current national statistics and associated actionable insights to inform policy efforts to address the ongoing pandemic. This timely collection of data through the lens of the COVID-19 pandemic will most critically assess public health emergency reporting and response.

Our survey will accomplish this goal by asking HIOs to report current activities in the following domains:

1. Public health information sharing capabilities, with a specific focus on COVID-19 response
2. Implementation of and use of standards to enable exchange and interoperability, with a focus on lab interoperability critical to the pandemic response
3. Information blocking practices undertaken by provider organizations and health IT developers, including those related to laboratories that could hamper efforts to get timely results for pandemic response
4. Planned responses to TEFCA, and current engagement with inter-HIO and national network connectivity
5. HIO sustainability and related demographics that capture the role of HIOs in supporting exchange and interoperability through their provision of various services and engagement with various types of stakeholders and participants, along with delivery system reform efforts (e.g. MIPS)

By developing a survey instrument addressing these domains, collecting national data from a census of HIOs, and analyzing the data to identify important new insights, the proposed project fills a critical gap in current knowledge and will provide policymakers with actionable results to inform progress towards greater interoperability and exchange of clinical data, with a focus on COVID response.

## **3. Use of Improved Information Technology and Burden Reduction**

This study will rely on data gathered from a self-administered, web-based survey of leaders of Healthcare Information Exchange Organizations. The survey will be administered electronically to alleviate burden on the respondents. The web-based survey permits respondents to complete the instrument at their preferred time. Respondents who begin the survey and are unable to complete it in one attempt will be able to save their responses and resume work on the survey at a later time.

We will be using the web-based survey tool Qualtrics©. This tool has been used previously for past surveys of HIOs and it has strong capabilities to support complex survey design (e.g., branching logic) as well as respondent communication and tracking. The tool will be extensively tested to ensure accuracy of branching and skip logic, accuracy of piped text, clarity of question display, and adherence to other survey usability

guidelines.

In addition, in order to increase response rate, respondents will also be offered the option to complete the survey via MS Word or over the phone with a Research Assistant or Project Manager if they prefer that to the online platform.

#### **4. Efforts to Identify Duplication and Use of Similar Information**

Dr. Julia Adler-Milstein, with the support of the Robert Wood Johnson Foundation, conducted a survey of HIO leaders bi-annually, and published key findings in a series of publications in Health Affairs. The Robert Wood Johnson Foundation no longer funds the bi-annual survey. Separately, in 2015, Dr. Adler-Milstein conducted a survey consisting of 60 leaders of HIOs regarding information blocking practices. This survey was independently funded with some consultation provided by ONC staff. In 2019, with ONC support, Dr. Julia Adler-Milstein conducted another round of the HIO survey which included the following topics: information blocking, standards implementation and use, readiness for TEFCA as well as questions that relate to the organizational characteristics and services provided by HIOs for their communities. Results papers were published in the Journal of the American Medical Informatics Association ([April 2021](#)) and in Health Affairs ([May 2021](#)).

In addition to these survey efforts, Civitas Networks for Health (CIVITAS) (formally known as Strategic Health Information Exchange Collaborative (SHIEC)) has conducted an annual survey of its membership that includes more than 70 HIOs. CIVITAS presented the most recent results at the 2020 ONC annual meeting.

CIVITAS and ONC have agreed to collaborate on this proposed survey to reduce duplication and build on each other's separate efforts to produce a comprehensive measurement strategy. Therefore, with the administration of this proposed survey, CIVITAS will not separately conduct their annual survey in 2021.

ONC considers it critical to continue supporting the HIO survey to examine how HIOs evolve and the role they play in enabling interoperability and the success of various policy initiatives. This information will be key to retrospectively analyzing the COVID-19 pandemic response and to informing policy strategies to advance HIE infrastructure related to testing, containment, and vaccination information sharing going forward. Furthermore, repeating elements of the 2019 survey can provide insights into the early implementation of the TEFCA and information blocking rule, as well as the evolution of standards.

#### **5. Impact on Small Businesses or Other Small Entities**

Health information exchange organizations vary in size; it is possible that some may be considered small businesses. The survey is voluntary, and the information being requested or required has been held to the absolute minimum required for the intended use of the data.

**6. Consequences of Not Collecting the Information**

The survey of HIO leaders has occurred almost bi-annually since 2005 with the most recent survey conducted in 2019. Data collection will occur once every two years beginning late 2022-early 2023.

If information is not collected in 2022-2023, ONC will lack the needed information to understand the current state of HIOs to support pandemic response and public health preparedness, limiting their ability to tailor investments in public health data infrastructure in the near-term that could impact our ability to monitor the pandemic and improve information exchange to support public health capabilities to address COVID-19 pandemic information sharing needs. Such information is critical to guide specific efforts under the Health IT Advisory Committee Public Health Data Systems Task Force, the STAR HIE Program, and investments in training, certification and degree programs in public health informatics. Broader ONC efforts, particularly around TEFCA as it gets finalized, also require timely data on the current state of HIOs, information blocking behaviors, and planned TEFCA participation. Additionally, this information is critical to guide ONC's efforts to support CDC's modernization efforts.

**7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5**

This data collection request is fully consistent with the guidelines. There are no special circumstances required for the collection of information in this data collection.

**8. Comments in Response to the Federal Register Notice/Outside Consultation**

The notice soliciting public comment on this survey data collection, required in 5 CFR 1320.8(d), was published in the Federal Register on June 3, 2022, at 87 FR 33797. There were no comments received from the public.

**9. Explanation of any Payment/Gift to Respondents**

As with prior years, respondents will be offered a small incentive (\$10) for completing the screening questions that enable us to determine whether they are operational, planning, or defunct and a larger incentive (\$50) for completing the entire survey if they are eligible (i.e., not defunct). We have found with previous surveys that financial incentives help improve response rate.

**10. Assurance of Confidentiality Provided to Respondents**

We will not make ANY responses to questions publicly available or attribute responses to any specific organization. These data will only be presented in aggregate and will be published in a peer-reviewed journal and shared on the ONC website.



The information for this study is being collected by the University of California, San Francisco (UCSF) Center for Clinical Informatics and Improvement Research (CLIIR), on behalf of ONC and in partnership with CIVITAS. Based on the UCSF's Human Research Protection Program Institutional Review Board (IRB) review, an exempt certification was granted for this study.

**11. Justification for Sensitive Questions**

No questions of a sensitive nature are asked in this data collection.

**12. Estimates of Annualized Hour and Cost Burden**

We will target sending the survey to approximately 124 key senior respondents from Health Information Organizations such as Executive Directors who will be knowledgeable about the topic areas covered in the survey. We assume an 85% response rate of 105 respondents. The survey was pre-tested with a total of 7 separate respondents. The first 4 respondents took approximately 4 hours to complete the survey. We incorporated their feedback and shortened the survey. The second 3 respondents then tested the survey, from which we derived the 45-minute burden per respondent burden estimate.

**Exhibit 1. Estimated Annualized Burden Hours**

<b>Type of Respondent</b>	<b>Form Name</b>	<b>No. of Respondents</b>	<b>No. of Responses per Respondent</b>	<b>Average Burden per Response (in hours)</b>	<b>Total Burden Hours</b>
Executive Director	HIO Survey	105	1	45/60	79
<b>Total</b>					79

**Exhibit 2. Estimated Annualized Burden Costs**

<b>Type of Respondent</b>	<b>Total Burden Hours</b>	<b>Hourly Wage Rate</b>	<b>Total Respondent Costs</b>
Executive Director	79	\$102.41	\$8090.39
<b>Total</b>			<b>\$8090.39<sup>1</sup></b>

<sup>1</sup> Based on US Bureau of Labor Statistics average hourly wage for Chief Executives (<https://www.bls.gov/oes/current/oes111011.htm>).

**13. Estimates of other Total Annual Cost Burden to Respondents or Recordkeepers/Capital Costs**

There are no annualized capital/startup or ongoing operation and maintenance costs involved in collecting the information.

**14. Annualized Cost to Federal Government**

The estimated cost to the Federal Government for the *National Survey of Health Information Exchange Organizations (HIO): Analyzing COVID-19 Readiness and Ongoing Needs* data collection activities is \$246,600.00 over 2 years or \$123,300.00 annually. The contractual costs to the University of California, San Francisco (UCSF), for data collection activities associated with this submission is \$202,131.00 over 2 years or \$101,065.50 annually. The cost of federal employees providing oversight and some analysis is \$44,468.00 over 2 years or \$22,234.00 annually.

**15. Explanation for Program Changes or Adjustments**

This a request for reinstatement with change to OMB No. 0955-0019 exp 05/30/2022.

We have updated the number of respondents based on the most recent available estimates, which reflect the consolidation of HIOs over time. To accommodate the need to ask new COVID and public health focused questions, the survey expanded in length, accounting for the additional response time.

**16. Plans for Tabulation and Publication and Project Time Schedule**

ONC and UCSF will jointly conduct three types of analyses that will comprise our survey results. First, we will describe response rate and assess longitudinal trends in the number of HIOs in the U.S. Since 2006 we have tracked the number of operational, planning, and defunct efforts. These analyses will enable us to assess whether the number of HIOs has continued to decline since its peak in 2011 or is leveling off at a stable level.

Second, we will conduct descriptive analyses that provide national estimates on survey items. These have traditionally comprised the majority of our results and they describe U.S. HIO characteristics. This includes general demographics – such as the number and types of participants engaged, the types of data exchanged, the HIE services supported, and geographic coverage – as well as specific measures in the domains of interest. For example, in the public health capabilities domain, we will calculate the proportion of HIOs that are supporting state public health agencies in varied ways (e.g., test result reporting, immunization tracking and reporting). In the standards domain, we will calculate the prevalence of adoption of each standard and associated implementation guide – overall as well as by specific characteristics, such as geography or HIO type. In the information blocking domain, we will calculate the proportion of respondents who indicated that information blocking was routine, occasional, and rare as well as, for each

form of information blocking, the proportion of respondents who indicated it occurred “routinely/often”, “sometimes”, and “rarely/never”. In the sustainability domain, we will calculate the overall proportion of HIOs that are financially sustainable (using our previous definition of revenue from participants that is equal to or greater than operating costs) and then examine other measures of sustainability, such as the proportion of respondents reporting different barriers to progress, engaged in different governance models, supporting different models of payment and delivery reform efforts.

Finally, we will conduct more advanced bivariate and multivariate regression analyses that identify factors associated with key measures of “success” or “sophistication”. These may include support for public health reporting, use of particular standards, reporting of infrequent information blocking, achievement of financial sustainability, and support for value-based payment. Predictors will include various HIO and contextual demographics.

Peer-reviewed papers were published in the Journal of Medical Informatics Association and Health Affairs using the 2019 HIO survey results on two key topics: [information blocking practices](#) associated with electronic exchange of health information and the current state of HIOs and [their role in supporting exchange](#), including factors associated with planning to participate in TEFCA, a major ONC initiative. These findings were also presented at conferences such as Academy Health and AMIA, and a [blogpost](#) was published as well to widely disseminate findings. Given that the national HIO maturity has increased and the TEFCA is now live and operational, analyses can further shed light on how information blocking practices and support for exchange and specifically TEFCA have evolved. We will also be able to examine factors associated with greater support for public health reporting capabilities.

We will conduct preliminary analyses and solicit input internally within ONC and federal partners (such as CDC) and also solicit input and feedback on the analyses from CIVITAS to ensure that they reflect the breadth of experience from these organizations. The results will be published, similar to the 2019 findings in peer-reviewed publications or other public documents, shared via conferences and through blog posts to ensure they are widely disseminated.

The entire project timeline is 3 years, starting in September of 2020 and ending in August of 2023. Data collection will occur over 3 months and is scheduled to begin in immediately upon receiving OMB approval.

**17. Reason(s) Display of OMB Expiration Date is Inappropriate**

All data collection materials will display the OMB expiration date.

**18. Exceptions to Certification for Paperwork Reduction Act Submissions**

There are no exceptions to the certification.

