



HIMSSSM

CIVITAS
Networks for Health

Dr. Lawrence A. Tabak, D.D.S., PhD.
Director National Institutes of Health
Office of the Director
One Center Drive
Bethesda, MD 20892

Notice Number: NOT-PM-22-004

[Re: NIH Request for Information \(RFI\) on Acquiring Electronic Health Record Data from health information networks \(HINs\) and health information exchanges \(HIEs\) for the All of Us Research Program.](#)

Dear Director Tabak:

The Healthcare Information and Management Systems Society (HIMSS) and Civitas Networks for Health (Civitas) are pleased to jointly submit comments to the All of Us Research Program on how to best acquire and integrate Electronic Health Record (EHR) data from health information networks (HINs) and health information exchanges (HIEs). Our organizations represent nationwide stakeholders that share a common goal of improving health information exchange across the country. The comments provided reflect our collective expertise and interest in these issues, and we are grateful for the opportunity to work with the NIH on this critical research program.

Below we provide jointly supported feedback and information relevant to the questions presented in the NIH RFI.

Thank you again for the opportunity to provide comments, and please do not hesitate to reach out to our organizations if you have any questions or would like to further dialogue about these topics.

Sincerely,

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Information Requested

We are seeking information about innovative ways to fill in the data gaps in our EHR data through utilization of HINs and/or HIEs. Respondents may address one or more of the following topics of interest. You may voluntarily include your organization name, a contact person and contact information for a person at your organization, and your organization type. All responses will be considered whether or not organization and contact information is provided.

1. Your Organization

- Organizational name

Healthcare Information and Management Systems Society ([HIMSS](#)) & [Civitas Networks for Health](#)

- Your name and contact information

For HIMSS- Evan Dunne; edunne@himss.org

For Civitas- Jolie Ritzo; jritzo@civitasforhealth.org

- Organizational type (e.g., academic, consultant, contract research organization, government, HIN, HIE, hospital, service provider, software developer, systems integrator)

HIMSS: Non-profit (501(c)6)

Civitas: Non-profit (501(c)3)

2. Electronic Health Record Acquisition

- **HIN and HIE Population Characteristics:** Describe the general population coverage for HINs and HIEs by demographic groupings. If available, please provide basic descriptive statistics showing population counts for specific HINs and HIEs by groupings such as age, county of residence, disability, education, gender identity, income, race and ethnicity, sex at birth, sexual orientation, urban/rural, and state of residence.

In general, the organization of HINs and HIEs at the state and local level can make a collection of these demographic groupings difficult. Variations in business processes, state, and federal regulations, as well as data collected at the point of encounter complicate the ability to get clear demographics of the population coverage.

- **Match Rate:** Which data elements (e.g., first name, last name, SSN) are required to increase the sensitivity and specificity of making a match between an individual and their EHR through an HIN or HIE?

Patient Identity, identity matching and match rates remain a complex and evolving area of success for health information exchanges. With patient right of access and patient-directed queries, HIEs/HINs must comply with Cures Act requirements while providing assurance that data is not inadvertently disclosed improperly. To complicate matters further, patient identity and matching have been recognized as an equity issue in care delivery – more stringent specifications for matching invariably impact populations without adequate demographic information.

Typical demographics used to identify resolve patients across organizational boundaries include:

- First Name
- Last Name
- Middle Name
- Date of Birth
- Address - Street, City, State, Zip Code
- Gender Identity
- Phone
- Last 4 of SSN
- Email
- Ethnicity
- Race
- Suffix

Typically, the minimum demographics required to provide high confidence identity resolutions services are:

- First Name
- Last Name
- Date of Birth
- Gender Identity
- At least one of:
 - Address
 - Phone
 - Last 4 SSN

At a high level, there are three categorizations of HIE/HIN efforts to address patient identity and matching:

- The Trusted Exchange Framework and Common Agreement (TEFCA) specifies that Qualified Health Information Networks (QHINs) must prescribe a patient matching process and align to industry best practices for patient matching as part of QHIN certification.
- The HL7/ONC Patient Identity Work Group is working on a patient identity and matching FHIR implementation guide (IG) to help standardize matching and match rates to improve standardization of identity management.
- Consortiums such as Carequality and Commonwell are leveraging the NIST Special Publication 800-63 specifications for Identity assurance level (IAL) 2 threshold of identity matching for all patients and providers as part of data exchange.

There is a collection of steps that should be considered as best practices for considering patient matching and match rates:

- Establishing rules that automatically queue a record out for manual review and decisioning. For example, first name does not match.
- Using referential matching to match patient records against a reference database vs comparing it to a "Golden Record". Referential matching allows matches to be made against out-of-date or older records.
- Providing patient identifier cross-referencing capabilities to record and manage all known identifiers for a patient.
- Conforming to [Integrating the Healthcare Enterprise \(IHE\)](#) Patient Data Management Protocols - PIX, PDQ, etc.
- Maintaining collections of blacklisted values or patterns for specific fields - 0000 for SSN 4, email@email.com for email, etc.
- Using several matching techniques including exact matches, synonym matches, phonetic matches, single character match, single digit mismatch, day-month transposition, day only mismatch, etc.

- Using probabilistic machine learning matching algorithms - cosine similarity, etc.
- Processing patient demographic updates from source systems to manage currency of identity records.
- **Mobility Considerations:** Individuals may move several times over the course of their life and receive care in different locations. What is the most efficient manner to query an HIN or HIE for EHR data based on individual mobility?

HIEs receive and retain data in multiple formats, varying levels of completeness, and varying data standards. A best practice approach is working on the data quality, conformance, and performance storage or retrieve, couple with an authorization mechanism like Active Care Relationship Service (ACRS) and using an Intelligent Query Broker (IQB) to be able to accept multiple query formats and return the data regardless.

Using Fast Healthcare Interoperability Resources (FHIR) servers for patient identifier cross-referencing capabilities would allow a client to discover all known identifiers for a patient. Once discovered, those identifiers could be used to query an organizations FHIR server directly assuming the server supported query for patient resources by the patient identifier.

Lastly, it should be noted that the “most efficient manner to query” also varies based on the organization and operations of the HIN/HIE. As more HIEs/HINs implement the Trusted Exchange Framework or adopt yet-to-be finalized operational principles for Health Data Utilities (HDUs), patient data queries will ideally become further standardized.

- **Data Quality:** What are the primary data quality issues using an HIN or HIE for EHR data collection? What are the known data gaps or biases with HINs or HIEs? How can these issues be mitigated?

There is significant variation in clinical documentation workflows from one EHR to another and from one healthcare organization to another. When data must be mapped from many diverse resources using customized mapping based on the needs of individual EHRs and organizations, the possibility of error is introduced. Digital measures require adding more layers of data mapping challenges as result of a much larger ecosystem of data sources currently without harmonized standards or models. Standards do not harmonize quality data. Additional data sources, mapping and collection methodologies, and the lack of context within the standards can result in measure scores that do not accurately reflect the quality of care being delivered. Inaccurate data also can drive decision-making and process changes that do not reflect the highest quality of care. Incentive programs with data conformance requirements can help mitigate data quality issues.

Smaller local practices may not have the option (or cannot afford) to share data with a national network. A focus on regional interoperability testing and Implementation Guide development for eCase reporting and other public-health focused IHE profiles would be solutions to be considered for enhanced EHR connectivity.

Overall, we believe that health information technology improves access to data from disparate sources and ensures that key data is consistently available to the right person, at the right place, and at the right time across the care continuum. A key building block to improving access to data is through greater use of technical standards, integration profiles, and implementation guides for exchanging health information. We generally recommend continuing to follow the established direction of standards and specifications that are developed and maintained through Standards Development Organizations (SDOs), such as IHE International or Health Level Seven International (HL7®).

Data governance and stakeholder relationships must also be considered as a means for solutions. The technical foundation will ensure that data is used for the right purposes, as well as respecting patient consent and privacy. A potential resource to NIH is the [HIMSS Adoption Model for Analytics Maturity \(AMAM\)](#) which measures the analytics capabilities that healthcare organizations have gained from having a strong analytics strategy and competency, and advances an organization's healthcare analytics system. Organizations can leverage the AMAM to improve the predictive analytics and governance and workforce dimensions of digital health.

- **Platforms:** Describe platforms and tools for acquiring EHR data through HINs and HIEs. What are the pros and cons of these platforms?

At a high level, HIEs and HINs acquire data via either push or pull processes. They often receive data (HL7® v2, or v3 C-CDA) over a VPN tunnel (standard for v2 messages) or Data sharing model (DSM), or C-CDAs can also be sent via IHE cross-enterprise document sharing (XDS.b) using the provider and register profile. They can also query and pull information back from an EHR; most commonly using IHE Cross-community community access (XCA) or XDS.b profiles or FHIR.

Data quality is always going to be one of the biggest challenges when acquiring data from the EHRs. Each implementation is going to be different, which causes the format, structure, codes, etc., to vary. Mapping tables and normalization are critical to help standardize as much as possible. Incentive programs and conformance are equally important to working with stakeholders to increase data quality in key areas over time and working together to define these thresholds.

- **Cost:** What is the estimated cost to query for and acquire EHR data through HINs or HIEs for 500,000 and 1,000,000 individuals twice per year?

Cost considerations vary widely based on the operating model and sustainability strategy of each HIE or HIN.

- **Trusted Exchange Framework and Common Agreement (TEFCA) Implications:** What are the short- and intermediate-term implications of TEFCA on HINs or HIEs to facilitate the needs of the All of Us Research Program?

HIMSS wants to ensure that the community has TEFCA and the broader interoperability that it enables as an available tool. Further advancing TEFCA and guidance around this measure presents another opportunity for NIH to collaborate with the Office of the National Coordinator (ONC) to better enable bi-directional health information exchange in the future. TEFCA infrastructure should not disrupt existing successful health data interoperability processes, including the business models of state and regional health information exchanges (HIEs) and health information networks (HINs) as well as other exchange entities. HIMSS has encouraged ONC to use the current HIE and HIN infrastructure as a foundation to empower information exchange by enabling market-driven solutions and removing participation barriers.

The use of an HIE means that essential health information should nearly always be available for care team members—the COVID-19 crisis has highlighted the need to encourage implementation of interoperable HIE infrastructure and bi-directional exchange across the country. The requirements of the QHINs may be outside the scope/capabilities of several HIEs that are community based and the technical competence and sustainability models may not make becoming a QHIN something that is possible. The number of QHIN's awarded will be far below the number of HIE/HINs in place today. Subsequently, part of that challenge will be how the requirements for participating with a QHIN will impact the HIE/HINs as you are only allowed to participate with one QHIN and that alignment may impact their business model.

3. Data Elements

- Describe how data are likely to be sent to *All of Us* from HINs or HIEs. For example, will it be a Clinical Document Architecture (CDA) document, FHIR Bundle, OMOP compatible file, or something else?

Data format can vary based on data availability. However, HINs/HIEs have begun to standardize on specific FHIR formats and use of Observational Medical Outcomes Partnership (OMOP) data. All of Us may also want to consider whether additional work needs to be done through HL7, IHE or Observational Health Data Sciences and Informatics (OHDSI) to develop specific formats for your use case.

A data sharing agreement is required with a trusted entity and is a limiting factor. Within a given HIE geography, trusted entities are authorized to query and retrieve information, but outside of that geography stewardship of the data is currently not the responsibility of the HIE. That said, HIEs could pick up responsibility leveraging current verification processes that ask an HIE for data related to treatment, payment, and operations. This would require appropriate legal agreements for compliance to be implemented.

Related to identity standards, and as earlier mentioned in this submission, the NIST Special Publication 800-63 specifications for Identity assurance level (IAL) 2 threshold of identity matching for all patients and providers serves as a guideline for patient identification. This comes with stipulations on the rigor of ID-proofing, based on the type of data that will be made available.

- Below is a list of data classes that are part of the United States Core Data for Interoperability (USCDI). There are three variations of USCDI, namely, [version 1](#), [version 2](#) and [draft version 3](#). USCDI is a standardized set of health data classes and related data elements for nationwide, interoperable exchange of health data. If the *All of Us* Research Program successfully queried and matched a study participant in an HIN or HIE, which USCDI data items would currently be returned:
 - Allergies and intolerances
 - Assessment and plan of treatment
 - Clinical notes such as consultation notes, discharge summary notes, history and physical, procedure notes, progress notes
 - Clinical tests and results
 - Diagnostic imaging tests and reports
 - Encounter information, such as date and time of encounter, diagnosis, disposition, location, and type
 - Health insurance information
 - Health status, such as concerns, functional status, disability status, mental function, pregnancy status, and smoking status
 - Immunizations
 - Laboratory tests, values, specimen type, and results
 - Medications
 - Patient demographics, such as name, address, date of birth, race and/or ethnicity, education, sex (assigned at birth), sexual orientation, gender identity, and others
 - Patient implantable devices
 - Problems
 - Procedures
 - Provenance of the data
 - Vital signs such as blood pressure, height, weight, respiratory rate, body temperature, and pulse oximetry
 - Social determinants of health data elements included in USCDI

- Other - other data that is not currently USCDI data classes and elements. Examples of areas of interest to the *All of Us* include claims, dental, genetic, microbiology testing, mortality, pathology, patient reported outcomes, and registry data.
- Which of these items do you anticipate could be returned by December 31, 2024?

We anticipate, at a minimum, all data elements to be returned that have been adopted in USCDI V2 from ONC.

4. Policy and Security

- *All of Us* obtains a HIPAA authorization from participants who agree to share their electronic health record (see the program's [initial HIPAA authorization](#) and [new version](#)). Are these sufficient to qualify requests we would make to HINs and/or HIEs?
 - If not, what additional authorizations, measures, or language would you suggest?

HIMSS emphasizes that de-identification of protected health information, which is permitted under HIPAA, is critically important to the increasing use of genomic data in scientific research. However, re-identification of protected health information would give value to bad actors who would like to use this information for profit and other nefarious reasons. Researchers have previously shown that de-identified data can be using publicly available databases. Modern techniques, such as privacy enhancing cryptography (PEC) and differential privacy, should be leveraged to ensure that such information cannot be re-identified. According to NIST, "The PEC and the differential privacy paradigms can be composed to enable better privacy protection, namely in scenarios where sensitive data should remain confidential in each individual original source. Differential privacy adjusts the query result into a noisy approximation of the accurate answer, which PEC can compute without exfiltrating additional information to any party."

In addition, the HIPAA authorizations need to be written in a digestible, concise format that could include audio or video options to accommodate a patient's needs. For the patient to be given meaningful notice, the patient must first be presented with information that is transparent about how the protected health information or other personally identifiable information is created, received, transmitted, maintained, and disclosed. The patient must understand who will have access to this information, and organizations must be prepared to work with the government and the community on reasonable expectations and administrative burden incurred fulfilling such requests.

Often, patients either do not have the time, or are not given enough time to read the HIPAA authorization in its entirety. Additionally, the lack of transparency in terms of what happens with the patient's data is troubling. There is an attempt in both versions of the HIPAA authorization to state that the information is de-identified, but this is not precisely spelled out. Additionally, while the patient may revoke consent at any time, it is unclear how the patient can either provide or revoke consent (i.e., the specific mechanism for revoking consent – a specific form or what one needs to otherwise do) and it is unclear whether the patient has the opportunity to request to have the information destroyed in every location it may reside.

In addition, language may also be a barrier for non-native English speakers. HIPAA authorization forms should be available in multiple languages and accommodate individual patient capabilities through the Section 508 Compliance process.

We recommend NIH consider developing sub-regulatory guidance on what types of data can be used in different scenarios. NIH already has an active program for consent in research efforts, such as the National Heart, Lung, and Blood Institute (NHLBI), which leverages the Global Alliance for Genomics and Health (GA4GH) consent framework for research. Leveraging legislative change that has occurred after the implementation of the Genomic Data Sharing Policy, can further provide a framework for tighter security. The Genetic Information Non-Discrimination Act of 2008 (GINA) is one example. GINA prohibits discrimination of individuals based on genetic information with respect to health insurance and employment. One method of ensuring that individuals are not discriminated against is with the use of

privacy enhancing cryptography and differential privacy techniques with the de-identified health information. These rigorous protections would also serve to build confidence in those who wish to contribute their data and, in turn, facilitate a higher response rate in participation.

- Is identity verification required for participants who agree to share their electronic health record? If so, by whom and to what standards

One of the most common methods for identity proofing in healthcare occurs by way of remote identity proofing when issuing credentials for use in electronic prescribing of controlled substances. While identity proofing of healthcare providers and individuals should take place, the onus would be on the healthcare provider to take reasonable steps to ensure that both the provider and the patient have reasonably proven that they are who they claim to be.

In addition to providing the standard proof of identification, such as a state identification card, driver's license, passport, and the like (showing the current address, date of birth, and photo), healthcare providers may also confirm that the person is who they claim to be (e.g., liveness detection). This should be done at the time that the credentials are generated for the individual. Multi-factor authentication should also be set up for that individual as well – preferably passwordless multi-factor authentication (e.g., with the use of an authentication application or otherwise) with the use of the Fast Identity Online (FIDO) standard.

Continuous authentication may also be used where a user's behavior and activity are tracked to help distinguish between what is normal versus what is unusual for that user. Based upon this analysis, additional steps may be required to verify a user's identity to confirm that the individual is who he or she claims to be.

- What restrictions do HINs or HIEs place on the use of these data that might restrict *All of Us* from making the sourced data available on the *All of Us* Researcher Workbench

HIEs cannot share data that is not for a permitted purpose or required by law. This is usually a compliance issue with respective stakeholders, rather than a technical issue. HIE's that are entered into use cases must get their governance bodies to authorize the use of sharable data for a specific purpose in that agreement. Circumstances for sharing/releasing data must also match State HIE regulations and privacy/security laws.

5. **Other Considerations**

- What other considerations beyond those covered in the previous questions should *All of Us* be aware of when considering HINs and HIEs?

HIMSS is a global advisor and thought leader supporting the reform of the global health ecosystem through the power of information and technology. As a mission-driven non-profit, HIMSS offers a unique depth and breadth of expertise from our members, many of which oversee the exchange of health information, and will be submitting on behalf of their respective organizations. HIMSS and Civitas are partnering on this response to provide an overarching overview to help the All of Us team understand the importance of HIE contributions to data collection and research. HIMSS works closely with Civitas, the trade association for HIE's and for Regional Health Improvement Collaboratives (RHICs), with a specific focus on information exchange at the state, local and regional level. Our organizations want to explicitly emphasize consideration for the Health Data Utility (HDU) model of HIEs.

HDUs present a unique and achievable opportunity to enhance and exchange health data for health equity and improvement, and HIMSS and Civitas believe that the All of Us program should take the model

into consideration as it relates to improving research and approaches to health data exchange with and between HINs and HIEs across the country.

As a general theme, public utilities are designed for use by the public for the common good, and incorporate many different use cases and stakeholders, including individual people and families, government entities, and private businesses. In the United States, we have created and sustained the essential infrastructure to support access to many critical life-improving utilities. Health data fits the definition of a public-private utility, or critical shared infrastructure. As we envision thriving communities of tomorrow, ones that foster whole-person health and equitable outcomes, we must ensure the necessary infrastructure which will enable data-informed, multi-stakeholder and cross-sector approaches to making such advancements.

State to state the HDU model for shared health data infrastructure is has moved from theory into practice, and likely precipitated by the urgency of the COVID-19 pandemic and disparate and siloed data systems. Statewide entities combine, enhance, and exchange electronic health data across care and services settings for treatment, care coordination, quality improvement, and public and community health purposes. HDUs enable specific, defined use cases, with extra protections to ensure patient privacy and appropriate data use.

HDUs represent both the evolution of community health information exchange as well as a new paradigm—a multistakeholder, cross-sector data resource for multiple use cases and services. Whole-person and public health today is reflected in clinical and non-clinical data across multiple settings and sources. HDUs emphasize multistakeholder organizational and use case-specific data governance with an emphasis on public health. Most organizations at the center of an HDU will be designated non-profit organizations or independent state agencies. In all cases, state and multistakeholder governance, oversight, and accountability is paramount. HDUs are flexible and uniquely capable of meeting state-specific health data needs.

States have existing infrastructure in place for clinical data exchange, including regional and statewide HIEs. However, this existing technical and relationship infrastructure needs to be strengthened and developed further, especially where services and organizations are not capable of meeting HDU requirements. There needs to be a pathway and a funding stream to support both the planning and development needed to build capacity. HDUs leverage existing infrastructure, displaying the critical application and responsible use of federal funds.

Civitas Networks for Health represents more than one hundred regional and statewide health information exchanges (HIEs), regional health improvement collaboratives (RHICs), quality improvement organizations (QIOs), and all-payer claims databases (APCDs) as well as more than 50 affiliated organizations as members and reaches approximately 95 percent of the United States population. With this extensive geographic footprint and network of implementers, co-creating a roadmap for HDUs is possible.

Civitas has expertise in convening and designing communities of practice where learning and problem-solving across regions and states is a reality. We have work to realize the full potential of HDUs and propose launching such an effort as an important next step to having a newly recognized utility in our country which not only will assist in essential health improvement efforts but also expand collective efforts to advance health equity.

Another one of HIMSS's key priorities is health data interoperability as well as standardization. HIMSS can be a resource for NIH on these issues. HIMSS leads [Integrating the Healthcare Enterprise \(IHE\) USA](#), which works with colleagues from across the globe to deploy IHE integration profiles in real-world care settings across the US and abroad. IHE Profiles provide the backbone to much of the health data exchange occurring across the health ecosystem today. One profile of relevance, that IHE developed for the All of Us Research Project, was the Assessment Curation and Data Collection Profile (ACDC). This

profile enables assessment developers and curators a means by which they can distribute assessment instruments to healthcare providers, supporting exchange of assessment data in a standardized form using the HL7 FHIR Questionnaire resource. It provides the opportunity for provider organizations to choose from a variety of instruments yet integrate them using a common interface. We are committed to ensuring our work in the standards domain continues to support research and broader data sharing for the purpose of advancing the All of Us research project. The health community increasingly incorporates emerging and long-standing data sources into new methods of health data exchange and analytics (e.g., social determinants of health gathered from public health registries, social services agencies, as well as genomic information, immunization information, quality reporting, environmental science, payer and billing components and other non-traditional stakeholders). As a result, standards-focused education is pivotal to ensuring that these data are based on known and adopted standards—standards that will continue to drive semantic interoperability and value for the broader healthcare community.

Additionally, IHE USA is working to advance and broaden HIE connectivity is working with National EMS Information System (NEMSIS) to advance EMS interoperability to get eHealth outcomes data. To get that data, EMS systems must be able to connect HIE's and lack the resources (funding, training, technology) to do so.

Finally, All of Us should lay out a clear explanation of the safety & security of the data when engaging with HIE/HINs. We cannot underestimate the need to ensure that researchers are as forthcoming as possible and ensure that the patient controls the data under every future use or scenario. We would reinforce that the key here is specific permissions and consents.

We welcome the opportunity further to discuss these recommendations with the All of Us leadership team. Thank you for your consideration.